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WOMEN'S HEALTH CARE PHYSICIANS

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Committee on Obstetric Practice

This document is endorsed by the American College of Radiology and the American Institute of Ultrasound in Medicine. This Committee Opinion was developed by the American College of Obstetricians and Gynecologists' Committee on Obstetric Practice. Member contributors included Joshua Copel, MD; Yasser El-Sayed, MD; R. Phillips Heine, MD; and Kurt R. Wharton, MD. This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

INTERIM UPDATE: This Committee Opinion is updated as highlighted to reflect a limited, focused change in the language and supporting evidence regarding exposure to magnetic resonance imaging and gadolinium during pregnancy.

PDF Format

Guidelines for Diagnostic Imaging During Pregnancy and Lactation

ABSTRACT: Imaging studies are important adjuncts in the diagnostic evaluation of acute and chronic conditions. However, confusion about the safety of these modalities for pregnant and lactating women and their infants often results in unnecessary avoidance of useful diagnostic tests or the unnecessary interruption of breastfeeding. Ultrasonography and magnetic resonance imaging are not associated with risk and are the imaging techniques of choice for the pregnant patient, but they should be used prudently and only when use is expected to answer a relevant clinical question or otherwise provide medical benefit to the patient. With few exceptions, radiation exposure through radiography, computed tomography scan, or nuclear medicine imaging techniques is at a dose much lower than the exposure associated with fetal harm. If these techniques are necessary in addition to ultrasonography or magnetic resonance imaging or are more readily available for the diagnosis in question, they should not be withheld from a pregnant patient. Breastfeeding should not be interrupted after gadolinium administration.

Recommendations

The American College of Obstetricians and Gynecologists' Committee on Obstetric Practice makes the following recommendations regarding diagnostic imaging procedures during pregnancy and lactation:

- Ultrasonography and magnetic resonance imaging (MRI) are not associated with risk and are the imaging techniques of choice for the pregnant patient, but they should be used prudently and only when use is expected to answer a relevant clinical question or otherwise provide medical benefit to the patient.
- With few exceptions, radiation exposure through radiography, computed tomography (CT) scan, or nuclear medicine imaging techniques is at a dose much lower than the exposure associated with fetal harm. If these techniques are necessary in addition to ultrasonography or MRI or are more readily available for the diagnosis in question, they should not be withheld from a pregnant patient.
- The use of gadolinium contrast with MRI should be limited; it may be used as a contrast agent in a pregnant woman only if it significantly improves diagnostic performance and is expected to improve fetal or maternal outcome.
- Breastfeeding should not be interrupted after gadolinium administration.

Introduction

Imaging studies are important adjuncts in the diagnostic evaluation of acute and chronic conditions. The use of X-ray, ultrasonography, CT, nuclear medicine, and MRI has become so ingrained in the culture of medicine, and their applications are so diverse, that women with recognized or unrecognized pregnancy are likely to be evaluated with any one of these modalities (1). However, confusion about the safety of these modalities for pregnant and lactating women and their infants often results in unnecessary avoidance of useful diagnostic tests or the unnecessary interruption of breastfeeding. This document reviews the available literature on diagnostic imaging in pregnancy and lactation. Obstetrician-gynecologists and other health care providers caring for pregnant and breastfeeding women in need of diagnostic imaging should weigh the risks of exposure to radiation and contrast agents with the risk of

nondiagnosis and worsening of disease. Planning and coordination with a radiologist often is helpful in modifying technique so as to decrease total radiation dose when ionizing radiation studies are indicated (Table 1).

Ultrasonography

Ultrasound imaging should be performed efficiently and only when clinically indicated to minimize fetal exposure risk using the keeping acoustic output levels As Low As Reasonably Achievable (commonly known as ALARA) principle. Ultrasonography involves the use of sound waves and is not a form of ionizing radiation. There have been no reports of documented adverse fetal effects for diagnostic ultrasonography procedures, including duplex Doppler imaging. The U.S. Food and Drug Administration limits the spatial-peak temporal average intensity of ultrasound transducers to 720 mW/cm2. At this intensity, the theoretical increase in temperature elevation for the fetus may be as high as 2°C (35.6°F) (2, 3). However, it is highly unlikely that any sustained temperature elevation will occur at any single fetal anatomic site (3). The risk of temperature elevation is lowest with B-mode imaging and is higher with color Doppler and spectral Doppler applications (4).

Table 1. Some Measures of Ionizing Radiation ⇦

Measure	Definition	Legacy Unit	SI* Unit
Exposure	Number of ions produced by X-ray or gamma radiation per kilogram of air	Roentgen (R)	2.58×10^{-4} C/kg
Dose	Amount of energy deposited per kilogram of tissue	Rad (rad)†	Gray (Gy)† 1,000 mGy = 1 Gy 1 Gy = 100 rad
Relative effective dose	Amount of energy deposited per kilogram of tissue normalized for biological effectiveness	Roentgen equivalent man (rem)	sievert (Sv) 1,000 mSv = 1 Sv 1 Sv = 100 rem

*International System of Units (SI) – these are preferred.

†For diagnostic X-rays, 1 rad = 1 rem, 1 Gy = 1 Sv.

Modified from Cunningham FG, Leveno KJ, Bloom SL, Spong CY, Dashe JS, Hoffman BL, et al. General considerations and maternal evaluation. In: Williams obstetrics. 24th ed. New York (NY): McGraw Hill Medical; 2014. p. 926–39.

Ultrasound machines are configured differently for different indications. Those configured for use in obstetrics do not produce the higher temperatures delivered by machines using nonobstetric transducers and settings. Similarly, although color Doppler in particular has the highest potential to raise tissue temperature, when used appropriately for obstetric indications, it does not produce changes that would risk the health of the pregnancy. However, the potential for risk shows that ultrasonography should be used prudently and only when its use is expected to answer a relevant clinical question or otherwise provide medical benefit to the patient (5). When used in this manner and with machines that are configured correctly, ultrasonography does not pose a risk to the fetus or the pregnancy.

Magnetic Resonance Imaging

The principal advantage of MRI over ultrasonography and computed tomography is the ability to image deep soft tissue structures in a manner that is not operator dependent and does not use ionizing radiation. There are no precautions or contraindications specific to the pregnant woman. Magnetic resonance imaging is similar to ultrasonography in the diagnosis of appendicitis, but when MRI is readily available, it is preferred because of its lower rates of nonvisualization (6). Although there are theoretical concerns for the fetus, including teratogenesis, tissue heating, and acoustic damage, there exists no evidence of actual harm. With regard to teratogenesis, there are no published human studies documenting harm, and the preponderance of animal studies do not demonstrate risk (1). Tissue heating is proportional to the tissue's proximity to the scanner and, therefore, is negligible near the uterus (1, 7). Finally, available studies in humans have documented no acoustic injuries to fetuses during prenatal MRI (1). In considering available data and risk of teratogenicity, the American College of Radiology concludes that no special consideration is recommended for the first (versus any other) trimester in pregnancy (8).

Unlike CT, MRI adequately images most soft tissue structures without the use of contrast. However, there are diagnostic situations in which contrast enhancement is of benefit. Two types of MRI contrast are available: 1) gadolinium-based agents and 2) superparamagnetic iron oxide particles. Gadolinium-based agents are useful in imaging of the nervous system because they cross the blood-brain barrier when this barrier has been disrupted, such as in the presence of a tumor, abscess, or demyelination (9). Although gadolinium-based contrast can help define tissue margins and invasion in the setting of placental implantation abnormalities, noncontrast MRI still can provide useful diagnostic information regarding placental implantation and is sufficient in most cases (7).

Even though it can increase the specificity of MRI, the use of gadolinium-based contrast enhancement during pregnancy is controversial. Uncertainty surrounds the risk of possible fetal effects because gadolinium is water soluble and can cross the placenta into the fetal circulation and amniotic fluid. Free gadolinium is toxic and, therefore, is only administered in a chelated (bound) form. In animal studies, gadolinium agents have been found to be teratogenic at high and repeated doses (1), presumably because this allows for gadolinium to dissociate from the chelation agent. In humans, the principal concern with gadolinium-based agents is that the duration of fetal exposure is not known because the contrast present in the amniotic fluid is swallowed by the fetus and reenters the fetal circulation. The longer gadolinium-based products remain in the amniotic fluid, the greater the potential for dissociation from the chelate and, thus, the risk of causing harm to the fetus (8). The only prospective study evaluating the effect of antepartum gadolinium administration reported no adverse perinatal or neonatal outcomes among 26 pregnant women who received gadolinium in the first trimester (10). More recently, a large retrospective study evaluated the long-term safety after exposure to MRI in the first trimester of pregnancy or to gadolinium at any time during pregnancy (11). This study interrogated a universal health care database in the province of Ontario, Canada to identify all births of more than 20 weeks of gestation, from 2003 to 2015. Comparing first-trimester MRI (n=1,737) to no MRI (n=1,418,451), there were 19 stillbirths or deaths versus 9,844 in the unexposed cohort (adjusted relative risk [RR], 1.68; 95% CI, 0.97–2.90). The risk also was not significantly higher for congenital anomalies, neoplasm, or vision or hearing loss. However, comparing gadolinium MRI (n=397) with no MRI (n=1,418,451), the outcome of any rheumatologic, inflammatory, or infiltrative skin condition occurred in 123 versus 384,180 births (adjusted hazard ratio, 1.36; 95% CI, 1.09–1.69). Stillbirths and neonatal deaths also occurred more frequently among 7 gadolinium MRI–exposed versus 9,844 MRI unexposed pregnancies (adjusted RR,

3.70; 95% CI, 1.55–8.85). Limitations of the study assessing the effect of gadolinium during pregnancy include using a control group who did not undergo MRI (rather than patients who underwent MRI without gadolinium) and the rarity of detecting rheumatologic, inflammatory, or infiltrative skin conditions (12). Given these findings, as well as ongoing theoretical concerns and animal data, gadolinium use should be limited to situations in which the benefits clearly outweigh the possible risks (8, 12).

To date, there have been no animal or human fetal studies to evaluate the safety of superparamagnetic iron oxide contrast, and there is no information on its use during pregnancy or lactation. Therefore, if contrast is to be used, gadolinium is recommended.

The water solubility of gadolinium-based agents limits their excretion into breast milk. Less than 0.04% of an intravascular dose of gadolinium contrast is excreted into the breast milk within the first 24 hours. Of this amount, the infant will absorb less than 1% from his or her gastrointestinal tract. Although theoretically any unchelated gadolinium excreted into breast milk could reach the infant, there have been no reports of harm. Therefore, breastfeeding should not be interrupted after gadolinium administration (13, 14).

Ionizing Radiation Including X-rays

Commonly used for the evaluation of significant medical problems or trauma, X-ray procedures are indicated during pregnancy or may occur inadvertently before the diagnosis of pregnancy. In addition, it is estimated that a fetus will be exposed to 1 mGy of background radiation during pregnancy (2). Various units used to measure X-ray radiation are summarized in Table 1.

Concerns about the use of X-ray procedures during pregnancy stem from the risks associated with fetal exposure to ionizing radiation. The risk to a fetus from ionizing radiation is dependent on the gestational age at the time of exposure and the dose of radiation (15). If extremely high-dose exposure (in excess of 1 Gy) occurs during early embryogenesis, it most likely will be lethal to the embryo (Table 2) (15, 16). However, these dose levels are not used in diagnostic imaging.

Table 2. Effects of Gestational Age and Radiation Dose on Radiation-Induced Teratogenesis

Gestational Period	Effects	Estimated Threshold Dose*
Before implantation (0–2 weeks after fertilization)	Death of embryo or no consequence (all or none)	50–100 mGy
Organogenesis (2–8 weeks after fertilization)	Congenital anomalies (skeleton, eyes, genitals)	200 mGy
	Growth restriction	200–250 mGy
Fetal period	**Effects**	**Estimated Threshold Dose***
8–15 weeks	Severe intellectual disability (high risk)†	60–310 mGy
	Intellectual deficit	25 IQ-point loss per 1,000 mGy
	Microcephaly	200 mGy
16–25 weeks	Severe intellectual disability (low risk)	250–280 mGy*

*Data based on results of animal studies, epidemiologic studies of survivors of the atomic bombings in Japan, and studies of groups exposed to radiation for medical reasons (eg, radiation therapy for carcinoma of the uterus).

†Because this is a period of rapid neuronal development and migration.

Modified from Patel SJ, Reede DL, Katz DS, Subramaniam R, Amorosa JK. Imaging the pregnant patient for nonobstetric conditions: algorithms and radiation dose considerations. Radiographics 2007;27:1705–22.

In humans, growth restriction, microcephaly, and intellectual disability are the most common adverse effects from high-dose radiation exposure (Table 2) (2, 17). With regard to intellectual disability, based on data from atomic bomb survivors, it appears that the risk of central nervous system effects is greatest with exposure at 8–15 weeks of gestation. It has been suggested that a minimal threshold for this adverse effect may be in the range of 60–310 mGy (2, 18); however, the lowest clinically documented dose to produce severe intellectual disability is 610 mGy (14, 19). Even multiple diagnostic X-ray procedures rarely result in ionizing radiation exposure to this degree. Fetal risk of anomalies, growth restriction, or abortion have not been reported with radiation exposure of less than 50 mGy, a level above the range of exposure for diagnostic procedures (20). In rare cases in which there are exposures above this level, patients should be counseled about associated concerns and individualized prenatal diagnostic imaging for structural anomalies and fetal growth restriction (Table 3) (16).

Table 3. Fetal Radiation Doses Associated With Common Radiologic Examinations ⇦

Type of Examination	Fetal Dose* (mGy)
Very low-dose examinations (<0.1 mGy)	
Cervical spine radiography (anteroposterior and lateral views)	<0.001
Radiography of any extremity	<0.001
Mammography (two views)	0.001–0.01
Chest radiography (two views)	0.0005–0.01
Low- to moderate-dose examinations (0.1–10 mGy)	
Radiography	
Abdominal radiography	0.1–3.0
Lumbar spine radiography	1.0–10
Intravenous pyelography	5–10
Double-contrast barium enema	1.0–20
CT	
Head or neck CT	1.0–10
Chest CT or CT pulmonary angiography	0.01–0.66
Limited CT pelvimetry (single axial section through the femoral heads)	<1
Nuclear medicine	
Low-dose perfusion scintigraphy	0.1–0.5
Technetium-99m bone scintigraphy	4–5
Pulmonary digital subtraction angiography	0.5
Higher-dose examinations (10–50 mGy)	
Abdominal CT	1.3–35
Pelvic CT	10–50
^{18}F PET/CT whole-body scintigraphy	10–50

Abbreviations: CT, computed tomography; PET, positron emission tomography.

*Fetal exposure varies with gestational age, maternal body habitus, and exact acquisition parameters.

Note: Annual average background radiation = 1.1–2.5 mGy, ^{18}F = 2-[fluorine-18]fluoro-2-deoxy-D-glucose.

Reprinted from Tremblay E, Therasse E, Thomassin-Naggara I, Trop I. Quality initiatives: guidelines for use of medical imaging during pregnancy and lactation. Radiographics 2012;32:897–911.

The risk of carcinogenesis as a result of in-utero exposure to ionizing radiation is unclear but is probably very small. A 10–20 mGy fetal exposure may increase the risk of leukemia by a factor of 1.5–2.0 over a

background rate of approximately 1 in 3,000 (7, 20). Thus, pregnancy termination should not be recommended solely on the basis of exposure to diagnostic radiation. Should a pregnant woman undergo multiple imaging studies using ionizing radiation, it is prudent to consult with a radiation physicist to calculate the total dose received by the fetus. The Health Physics Society maintains a website with an ask-the-expert feature: www.hps.org/publicinformation/ate/cat4.html. There is no risk to lactation from external sources of ionizing radiation (diagnostic X-rays) (21).

Computed Tomography

Computed tomography is a specific use of ionizing radiation that plays an important diagnostic role in pregnancy, and its use increased by 25% per year from 1997 to 2006 (1). Use of CT and associated contrast material should not be withheld if clinically indicated, but a thorough discussion of risks and benefits should take place (8). In the evaluation for acute processes such as appendicitis or small-bowel obstruction, the maternal benefit from early and accurate diagnosis may outweigh the theoretical fetal risks. If accessible in a timely manner, MRI should be considered as a safer alternative to CT imaging during pregnancy in cases in which they are equivalent for the diagnosis in question. Radiation exposure from CT procedures varies depending on the number and spacing of adjacent image sections (Table 2). For example, CT pelvimetry exposure can be as high as 50 mGy but can be reduced to approximately 2.5 mGy (including fetal gonad exposure) by using a low-exposure technique that is adequate for diagnosis. In the case of suspected pulmonary embolism, CT evaluation of the chest results in a lower dose of fetal exposure to radiation compared with ventilation-perfusion scanning (2). With typical use, the radiation exposure to the fetus from spiral CT is comparable with conventional CT.

Oral contrast agents are not absorbed by the patient and do not cause real or theoretical harm. The use of intravenous contrast media aids in CT diagnosis by providing for enhancement of soft tissues and vascular structures. The contrast most commonly used for CT is iodinated media, which carries a low risk of adverse effects (eg, nausea, vomiting, flushing, pain at injection site) and anaphylactoid reactions (9). Although iodinated contrast media can cross the placenta and either enter the fetal circulation or pass directly into the amniotic fluid (22), animal studies have reported no teratogenic or mutagenic effects from its use (8, 22). Additionally, theoretical concerns about the potential adverse effects of free iodide on the fetal thyroid gland have not been borne out in human studies (17). Despite this lack of known harm, it generally is recommended that contrast only be used if absolutely required to obtain additional diagnostic information that will affect the care of the fetus or woman during the pregnancy.

Traditionally, lactating women who receive intravascular iodinated contrast have been advised to discontinue breastfeeding for 24 hours. However, because of its water solubility, less than 1% of iodinated contrast administered to a lactating woman is excreted into the breast milk, and less than 1% of this amount of contrast will be absorbed through the infant's gastrointestinal tract. Therefore, breastfeeding can be continued without interruption after the use of iodinated contrast (1, 9, 13, 16, 23).

Nuclear Medicine Imaging

Nuclear studies such as pulmonary ventilation-perfusion, thyroid, bone, and renal scans are performed by "tagging" a chemical agent with a radioisotope. This type of imaging is used to determine physiologic organ function or dysfunction rather than to delineate anatomy. Hybrid systems, which combine the

function of nuclear imaging devices with computed tomography, improve the quality of information acquired and can help to correct artifacts produced by nuclear medicine imaging alone (9).

In pregnancy, fetal exposure during nuclear medicine studies depends on the physical and biochemical properties of the radioisotope. Technetium 99m is one of the most commonly used isotopes and is used for brain, bone, renal, and cardiovascular scans. Its most common use in pregnancy is in ventilation–perfusion lung scanning for detection of pulmonary embolism. In general, these procedures result in an embryonic or fetal exposure of less than 5 mGy, which is considered a safe dose in pregnancy. The half-life of this radioisotope is 6 hours, and it is a pure gamma ray emitter, which minimizes the dose of radiation without compromising the image (9). All these facts support the safety of technetium 99m at 5 mGy when indicated during pregnancy.

Not all radioisotopes can be used safely during pregnancy. Radioactive iodine (iodine 131) readily crosses the placenta, has a half-life of 8 days, and can adversely affect the fetal thyroid, especially if used after 10–12 weeks of gestation (9). Whether for diagnostic or therapeutic treatment purposes, iodine 131 should not be used during pregnancy. If a diagnostic scan of the thyroid is essential, technetium 99m is the isotope of choice.

Radionuclide compounds are excreted into breast milk in varying concentrations and for varying periods of time. In addition, rates of excretion of the same compound can vary between patients. Because some specific nuclear materials excreted into breast milk can have deleterious effects, consultation with experts on breastfeeding and nuclear medicine are recommended when these compounds are used in lactating women.

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