RadioGraphics

Quality Initiatives

Guidelines for Use of Medical Imaging during Pregnancy and Lactation[1]

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ONLINE-ONLY CME

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LEARNING OBJECTIVES

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

- Describe an approach for contrast-enhanced imaging in pregnant or lactating women.
- Discuss the risks associated with administration of iodinated contrast agents during pregnancy, and how to monitor or avoid them.
- Counsel breast-feeding women about the exposure of their babies to contrast media through breast milk.

TEACHING POINTS

See last page

The use of computed tomography (CT) and magnetic resonance (MR) imaging has increased tremendously in the past 2 decades. Hence, pregnant and breast-feeding women, although generally healthier than the population at large, are also more likely to require contrast material–enhanced imaging. When a contrast-enhanced CT or MR imaging study is being considered for a pregnant or lactating patient, the potential risks to the fetus related to exposure to radiation, high magnetic fields, or contrast agents must be considered and weighed carefully against the risks of potential misdiagnosis due to withholding contrast agents and imaging studies. Fetal radiation doses up to 1 mGy are considered acceptable; with larger doses, the risk of carcinogenesis approximately doubles, although it remains low in absolute terms. No damage to a developing human fetus caused by MR imaging exposure has been documented. However, caution is advised, and risks and benefits must always be considered before evaluating a pregnant patient with MR imaging. The use of iodinated contrast agents is generally safe during pregnancy; nevertheless, these agents should be used with caution due to the risk of fetal hypothyroidism and should be administered only when the clinical situation clearly requires doing so. The use of gadolinium-based contrast agents during pregnancy remains controversial due to lack of human clinical data and potential toxicity. Use of all contrast agents is considered safe during lactation. It is hoped that this knowledge will help radiologists develop a consensus with their clinical colleagues regarding case management of pregnant and lactating patients.

Abbreviations: ACR = American College of Radiology, TSH = thyroid-stimulating hormone

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Introduction

In the past 10 years, the use of radiologic examinations in pregnant women has increased by 107% (1), with the greatest increase occurring in the use of contrast material–enhanced computed tomography (CT). Although ultrasonography (US) is the first-line examination of choice in pregnant women, CT and magnetic resonance (MR) imaging are sometimes required to answer a clinical question, and these examinations often require the intravenous injection of contrast material. Parallel to the increased use of radiologic examinations in pregnant women, CT and MR imaging are also increasingly being used in the evaluation of women during the breast-feeding period.

However, information about the use of diagnostic contrast agents in pregnant and breast-feeding women is limited, and the guidelines are sometimes contradictory. Thus, it is not surprising that many radiologists are uncomfortable in these situations. When in doubt, many err on the side of caution and limit the use of contrast media or cancel a CT or MR imaging examination altogether, potentially leading to delays or errors in diagnosis and subsequent patient management. Because of misconceptions about fetal risk of radiation exposure, some women have even been incorrectly counseled that pregnancy termination should be considered (2–4). The American College of Obstetricians and Gynecologists clearly states that abortion should not be recommended solely on the basis of exposure to diagnostic radiation (5). When used appropriately during pregnancy and lactation (taking into account the risks and potential benefits), contrast-enhanced CT and MR imaging can be of significant value in patient management.

We performed a comprehensive review of the radiology literature regarding potential risks to the fetus or infant related to maternal exposure to radiation, high magnetic fields, or iodinated or gadolinium-based contrast agents at imaging performed during pregnancy or lactation. In this article, we present our conclusions and provide an easy-to-follow reference chart to assist physicians and technicians in the appropriate use of contrast media for CT and MR imaging of pregnant and lactating patients.

Risks to an Unborn Child from Radiation Exposure

The first concern when a pregnant woman undergoes radiologic examination is the risk related to radiation exposure. This risk can be considered in terms of deterministic and stochastic effects of radiation.

Deterministic Effects

Deterministic effects of radiation result from damage to a number of cells, with a dose threshold before damage occurs; such effects of radiation exposure include malformations, growth retardation, mental retardation, and death (3,6). The most vulnerable stage of the embryo in terms of teratogenesis is between the 2nd and 20th weeks of gestation, particularly the period between the 8th and 15th weeks (7). In its 2007 recommendations, the International Committee on Radiological Protection concluded that no deterministic effects of practical significance would be expected to occur below a dose of 100 mGy (8,9).

Normal radiation exposure at diagnostic radiology or nuclear medicine studies should never result in cumulative fetal doses greater than 100 mGy (6); the exact radiation dose transmitted to the fetus depends on *(a)* the precise gestational age at the time of exposure and *(b)* examination parameters, and exposure levels can be roughly categorized into low, moderate, and higher levels (Table 1) (2,6,10). For example, even if a woman who presented with clinical suspicion for pulmonary embolism—a common condition in pregnant women—were to undergo chest radiography, lung scintigraphy, CT pulmonary angiography, and traditional pulmonary angiography, the fetus would be exposed to only about 1.5 mGy of radiation (11). Thus, the radiation dose to the embryo or fetus that is likely to result from any diagnostic procedure in current use should present no risk of fetal death, malformation, growth retardation, or impairment of mental development (3,6).

Teaching Point

Table 1
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

Note.—Annual average background radiation = 1.1–2.5 mGy, ^{18}F = 2-[fluorine-18]fluoro-2-deoxy-D-glucose, PET = positron emission tomography.
*Fetal exposure varies with gestational age, maternal body habitus, and exact acquisition parameters (2,5,6,10–12).

Stochastic Effects

Stochastic effects of ionizing radiation originate from damage to a single cell and can lead to carcinogenesis. There is no absolute dose threshold, but the risk of damage increases with radiation dose. The latest estimate of the risk of developing childhood cancer is approximately one in 500 in the general population (6), increased from the former reference value of one in 1000 (2,12). Fetal radiation doses of up to 1 mGy are considered acceptable, being associated with an incremental risk of carcinogenesis of less than one in 10,000 (6). Most radiologic examinations of anatomic structures below the knees or above the diaphragm fall into this category and thus need not be withheld in pregnant women if the examination is indicated and dose is kept to a minimum consistent with the diagnostic requirements (Figure). Most radiologic procedures increase the risk of childhood cancer by less than one in 1000 (6). With larger doses (eg, a fetal dose of 20–50 mGy received during pelvic CT), the risk of carcinogenesis increases approximately by a factor of 2 (2), although it remains low in absolute terms (less than one in 250).

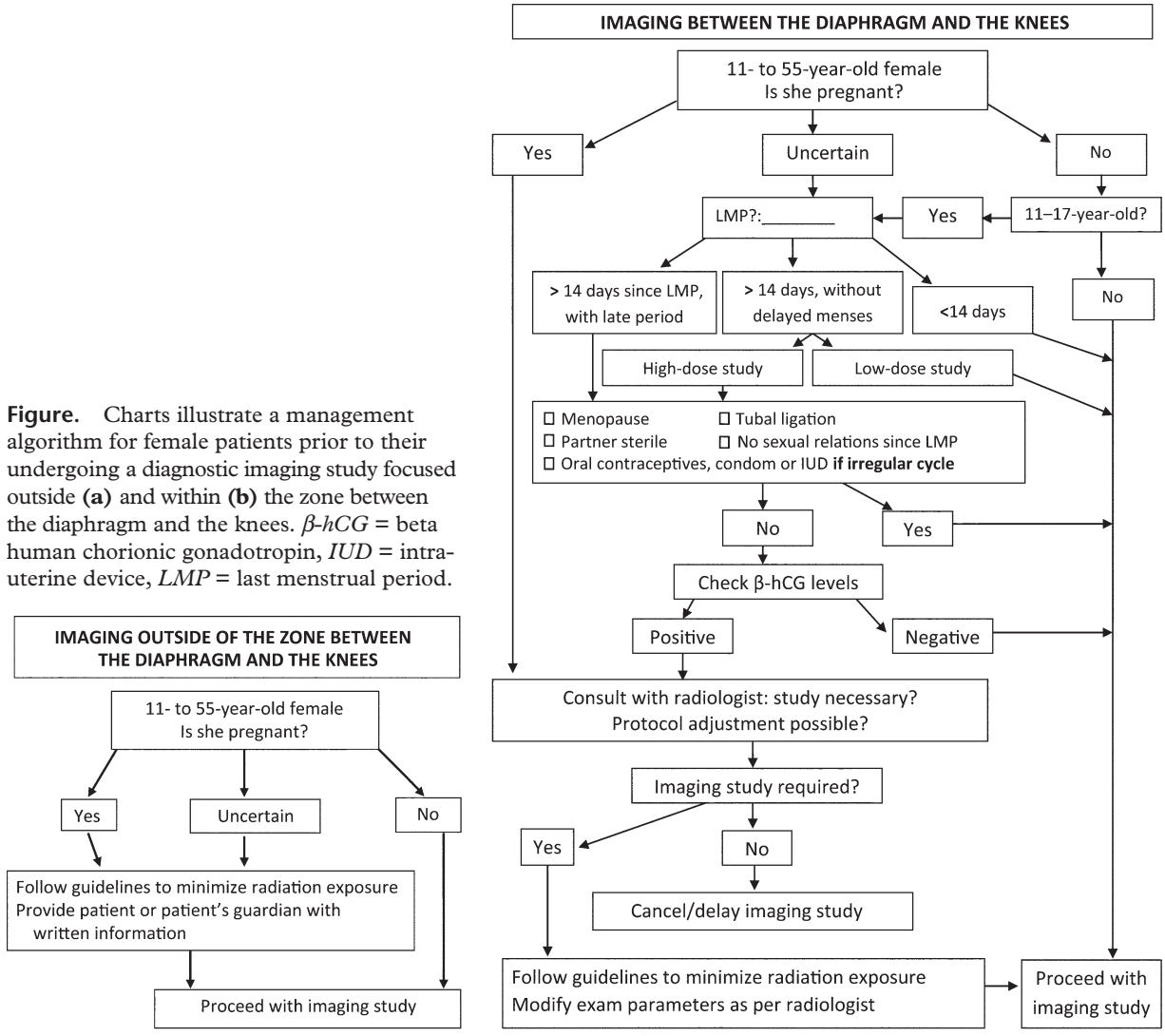

Figure. Charts illustrate a management algorithm for female patients prior to their undergoing a diagnostic imaging study focused outside **(a)** and within **(b)** the zone between the diaphragm and the knees. *β-hCG* = beta human chorionic gonadotropin, *IUD* = intrauterine device, *LMP* = last menstrual period.

When a pregnant woman requires exposure to radiation for a medical condition, consultation with a medical physicist should be expedited to evaluate the fetal dose that would be required and the risks associated with it. These risks can then be discussed with the parents so that they can make an informed decision. If the patient agrees to undergo the examination, the medical physicist will then calculate the dose delivered to the fetus. Generally, termination of pregnancy will not be appropriate based solely on the radiation risk.

On the other hand, some women may be unaware that they are pregnant at the time of their undergoing radiologic examination. All radiology facilities should have a written policy for screening and management in pregnant women. The Figure illustrates the algorithm that we use at our medical center for management in all females of childbearing age. The confirmation of pregnancy allows adjustments in management, including consideration of alternative tests, modifications to the radiologic protocol, or delay of the examination.

Case Example 1

Clinical Setting.—A 26-year-old woman who was 30 weeks pregnant presented with fever and lower abdominal pain. Laboratory tests revealed an elevated white blood cell count. US was performed, revealing a small amount of free fluid in the right lower quadrant, with tenderness. Because the differential diagnosis includes inflammatory bowel disease, appendicitis, or infectious colitis, with the possibility of an underlying abscess, further imaging was required. What imaging options should be considered?

Considerations and Recommendations.—After US, contrast-enhanced CT is the imaging study of choice for narrowing the differential diagnosis and optimizing management of the clinical condition. The risks and benefits of the test must initially be discussed with the patient, including exposure to radiation and iodinated contrast agents. When the benefits outweigh the risks, with the patient's consent, a well-planned contrast-enhanced CT examination can be performed. It is suggested that the medical physicist be involved for precise quantification of the radiation dose to the fetus. The fetal dose from such an examination would typically be about 10–50 mGy (Table 1), which results in a roughly twofold increase in the risk of cancer for the child, although the risk remains low in absolute terms (one in 250). The risk of mismanagement in a mother and child who do not undergo adequate imaging is much higher.

Risks to an Unborn Child from Exposure to High Magnetic Fields

MR imaging is not associated with any radiation exposure but does expose the fetus to a magnetic field more than 10,000 times greater than that of Earth (50 μT). Potential hazards linked to MR imaging exposure fall into three categories.

1. Risks related to exposure to the static magnetic field, with theoretic biologic damage related to cell migration, proliferation, and differentiation, up to and including miscarriage.

2. Risks related to the pulsed radiofrequency fields, with tissue heating potential and secondary damage, particularly with regard to organogenesis. Some authors have suggested decreasing the room temperature in the MR imaging suite to less than 24°C to diminish potential heating effects on the developing fetus (13).

3. Risks related to the varying-gradient electromagnetic fields, which are particularly high with the fast-acquisition sequences required for good fetal imaging, with potential damage to the fetal ear (especially after 24 weeks gestation) due to the high acoustic noise level (14,15).

A review published in 2005 by De Wilde et al (14) did not highlight any documented damage to a developing human fetus due to MR imaging exposure; however, the authors cautioned that further research was necessary. In their guidance document for safe MR imaging practices, the American College of Radiology (ACR) did not distinguish the first trimester of pregnancy from the second and third trimesters in terms of risks of MR imaging exposure (16), advising that risks versus benefits should be considered before performing MR imaging in a pregnant patient.

Kok et al (17) evaluated 35 women who underwent 1.5-T MR imaging during the third trimester of pregnancy and reported no noticeable harmful effects in the months after birth that could be related to MR imaging exposure, nor any longer-term effects of MR imaging exposure in utero in nine children who were followed up for 9 years after exposure. A 3-year follow-up study of 20 children imaged with echoplanar MR imaging at 0.5 T did not show any demonstrable increase in the occurrence of disease or disability (18), nor did a study of 74 women who underwent MR imaging compared with 148 controls (19). Attempts at numeric quantification of local temperature changes and increases in specific absorption rates have been published based on a 26-week-pregnant woman model that was subjected to MR imaging at 1.5- and 3.0-T field strengths (20). Results suggest that, when safety standards for human adult exposure are respected, the fetal effects of MR imaging remain within international safety limits.

Exposure of the fetus to acoustic noise is also a concern. Noise levels in the range of 80–120 dB have been measured from clinical MR imaging systems (14). Sound attenuation occurs as the

sound passes through the mother's abdomen to the fetus, making it difficult to quantify the exact noise levels to which the fetus is exposed. Glover et al (21) estimated sound attenuation within the gravid uterus to be approximately 30 dB. The American Academy of Pediatrics suggested 90 dB as an upper limit above which hearing damage can occur (22). Although noise exposure during MR imaging is short lived, caution is advised due to unclear risks to the fetus.

In summary, the use of MR imaging is considered safe during pregnancy, although caution is necessary. Most authors suggest that evaluation be limited to the second and third trimesters of pregnancy (2,14,15,23,24). On the other hand, because of the lack of documented deleterious effects of MR imaging on the developing fetus, the ACR eliminated restrictions related to gestational age in its 2007 update, simply stating that the potential benefits for the mother and fetus must always outweigh the risks (16).

Transfer of Intravenous Contrast Material to the Fetal Circulation

The maternal and fetal circulations are distinct yet closely interconnected systems, with the placenta acting as a dynamic barrier and interface between the two circulations that evolves over the course of the pregnancy. Maternal blood seeps into the intervillous spaces in the placenta, allowing nutrients to pass into the fetal circulation by crossing a single layer of chorionic epithelium (25,26).

Most drugs that are dissolved in maternal blood reach the fetus by means of simple diffusion across this layer of chorionic epithelium. Lipid-soluble and low-molecular-weight (<100 Da) nonionized water-soluble molecules cross the placental barrier fairly easily (25). Nonionic iodinated and gadolinium-based agents are water soluble and weigh between 500 and 850 Da; they can cross the placental barrier, but this movement is somewhat restricted due to their high molecular weight (25). Once in the fetal systemic circulation, molecules of iodinated and gadolinium-based contrast material are filtered through the kidneys and make their way into the amniotic fluid via the urine. When the fetus swallows amniotic fluid, a small amount of contrast material enters the fetal gastrointestinal tract. A small amount of additional contrast medium may pass directly from the maternal blood into the amniotic fluid, be swallowed by the fetus, and reach the fetal gastrointestinal tract (25). Women with impaired renal function have longer circulation times for contrast medium, and doses in fetuses may reach higher levels due to longer circulation times in the placenta. On the other hand, experimental studies suggest that a small quantity of iodinated and gadolinium-based contrast medium may return to the placenta and be excreted by the mother, effectively lowering the contrast material dose in the fetus (25,27,28).

Use of Iodinated Contrast Material during Pregnancy

No mutagenic or teratogenic effects have been described after the administration of iodinated contrast material during pregnancy, and neither in vitro nor in vivo tests performed in animals revealed any deleterious effects from exposure to iodinated contrast material (25). The principal deleterious effect of iodine-based compounds is their potential impact on the neonatal thyroid gland.

Development of the Neonatal Thyroid

The fetal thyroid develops early in pregnancy, about 3 weeks after conception (29), and plays an important role in the development of the central nervous system. Synthesis of thyrotropin-releasing hormone begins around the 4th week of gestation, and the hormone is first released between the 6th and 8th weeks of gestation. The hypothalamic-pituitary-thyroid axis begins to develop between the 8th and 10th weeks of gestation and is usually mature by 12 weeks, resulting in the release of thyroid-stimulating hormone (TSH) (30). Thus, by the 11th week of gestation, colloid appears in the thyroid, and thyroxine can be noted in amniotic fluid by the 12th week

of gestation, although secretion is minimal until 18–20 weeks gestation (30). In comparison, triiodothyronine synthesis begins around 20 weeks gestation. The neonatal hypothalamic-pituitary axis is independent of the maternal hypothalamic-pituitary axis and continues to mature during the second and third trimesters. There is a normal upsurge of TSH at delivery, with normalization of thyroid hormone levels by 2 weeks of age (25). Premature infants may have a different response, depending on gestational age and maturity of the pituitary-thyroid axis: TSH and thyroxine levels measured in premature newborns show a reduced hormone surge compared with full-term babies (25).

Congenital hypothyroidism is seen in one of every 4000 births and is associated with few clinical symptoms at birth. If left untreated, hypothyroidism leads to failure to thrive and is the leading cause of treatable mental and developmental impairment (29). Thus, every newborn in North America and Europe is systematically screened for hypothyroidism in the 1st week of life, most often on the basis of serum TSH levels, with some centers also measuring thyroxine levels. Treatment is straightforward and eliminates the dramatic occurrence of mental impairment and developmental delays.

The thyroid makes use of iodine to synthesize thyroid hormones; thus, iodine-containing drugs are generally considered to be contraindicated during pregnancy because of the risk of fetal thyroid uptake of iodine with secondary hypothyroidism. When exposure to excess iodine occurs, a protective autoregulatory process known as the Wolff-Chaikoff process results in a reduction in thyroid hormone production, but this mechanism is not mature until 36 weeks gestation (29). Although the Wolff-Chaikoff process is beneficial over the short term, when prolonged extrinsic exposure to iodine occurs (days to weeks), physiologic "escape" from this protective process allows the baby to resume normal thyroid hormone production. However, this escape does not occur as rapidly in newborns as in older children or adults (31), further increasing the risk of hypothyroidism after exposure to iodine in *(a)* fetuses during their last weeks in utero, or *(b)* very young infants.

Clinical Research

Cases describing hypothyroidism after the administration of iodinated contrast medium in pregnant women are relatively rare, and the majority were described decades ago, when amniofetography was performed to detect congenital malformations. This technique has been replaced by sonography (32). Lipid-soluble iodinated contrast agents such as iodized oil (Lipiodol; Guerbet, Roissy, France) were used for amniofetography, with high rates of occurrence of hypothyroidism, likely because of the easy passage of this lipid-soluble agent into the fetal circulation, with subsequent poor excretion by the kidneys (30,32). In the past 30 years, there have been no documented cases of hypothyroidism or other adverse effects due to the injection of water-soluble iodinated contrast agents for pyelography, angiography, or CT (2,30).

In a retrospective study of 343 newborns whose mothers had received a single dose of intravenous contrast medium during pregnancy for clinical suspicion of pulmonary embolism, Bourjeily et al (29) recorded normal thyroxine levels in all children at birth, except in one infant whose mother had been exposed to many drugs during pregnancy (and in whom transient high TSH levels self-corrected at day 6). The authors concluded that "a single, high-dose in utero exposure to water-soluble, low-osmolar, iodinated intravenous products, such as iohexol, is unlikely to have a clinically important effect on thyroid function at birth" (29). Atwell et al (30) reported normal TSH levels at birth in 23 babies whose mothers (n = 21) had received water-soluble nonionic iodinated contrast medium at a mean gestational age of 23 weeks. Despite the evidence that iodinated contrast medium received in utero has no effect on the neonatal thyroid at birth, a transient effect on the neonatal thyroid at the time of injection of the mother cannot be excluded on the basis of these

retrospective studies. Nevertheless, it would seem that this exposure is likely to have minimal to no effect on the developing child.

The World Health Organization has set 500 μg as the upper limit for maternal daily iodine intake during pregnancy (29). For example, the one-time administration of 150 mL of iohexol 300 (300 mg of iodine per milliliter) in a pregnant woman results in a received dose of 45,000 mg of bound iodine. However, it is not so much the bound iodine as the free iodide found in intravenous contrast medium that can damage the neonatal thyroid because of its easy absorption across the placental barrier. The allowable amount of free iodide in iodinated contrast media is also regulated, with a permitted upper level of less than 50 μg/mL in contrast medium of 300 mg of iodine per milliliter; usually, however, the free iodide concentration is one-tenth this limit (25,33). If 150 mL of iohexol 300 is administered to a pregnant woman, the received dose of free iodide is at most 7500 μg. Although there are no data about its pharmacodynamics, free iodide is likely to traverse the placenta readily in both directions, so that the fetal thyroid is exposed to the iodide for only a short period of time (33).

When iodine exposure is the suspected cause of hypothyroidism, iodine concentration in the baby's urine should be measured and, if found to be abnormal, can be confirmed with serum iodine tests (31).

Use of Topical Iodine

Iodine-based disinfectants, such as Proviodine or Betadine (both common products with several local distributors), contain large amounts of free iodide, which is readily absorbed and may cause the most damage to the fetal thyroid. Consequently, special care should be taken to avoid the use of these disinfectants during pregnancy (34,35). The hypothyroidism that may result from exposure to iodine-based disinfectants is transitory and is reversed with cessation of iodine exposure (35).

Current Recommendations

On the basis of in vivo tests in animals, the ACR stated in their 2010 Manual of Contrast Media that no evidence of either mutagenic or teratogenic effects secondary to iodine exposure in utero has been encountered (36). However, because no direct evidence is available from human studies, the Committee stated, "While it is not possible to conclude that iodinated contrast media present a definite risk to the foetus, there is insufficient evidence to conclude that they pose no risk" (36). Thus, the Committee recommended that iodinated contrast media be used in pregnant women only when *(a)* no alternative test is available, *(b)* information to be obtained from the study is useful to both mother and fetus during the pregnancy, and *(c)* the referring physician considers it imprudent to delay the imaging study until after delivery. If these conditions are met, written informed consent from the parents as to the risks and benefits of the procedure, as well as alternative diagnostic options (when available), are recommended (36). The U.S. Food and Drug Administration considers iodinated contrast agents to be category B drugs; that is, reproductive studies in animals demonstrate no risk, but there have been no controlled studies in pregnant women (37). The Contrast Media Safety Committee of the European Society of Urogenital Radiology released revised guidelines in 2005, in which they recommended that iodinated contrast media be given to the mother only in exceptional circumstances, and that when this occurs, neonatal thyroid function should be checked in the 1st week of life (25).

Teaching Point

Use of Gadolinium-based Contrast Material during Pregnancy

There have been no documented mutagenic or teratogenic effects after the inadvertent administration of MR imaging contrast agents in pregnant women in the 1st month of pregnancy or (in some instances) during the second or third trimester (16,25,28). Experimental in vitro and in vivo animal studies involving the administration of elevated nonclinical doses of gadolinium-based agents reported effects including postimplantation fetal loss in rats, retarded development in rats and rabbits, and skeletal and visceral abnormalities in rabbits (38–41). There have been no adequate well-controlled studies in pregnant women, and responses in humans cannot be inferred from studies in animals. Neither a series of 26 women who received gadopentetate dimeglumine in the first trimester of pregnancy (42), nor two series of six and 11 women, respectively, who were evaluated during the second and third trimesters of pregnancy (43,44),

reported any maternal or fetal effects related to gadolinium exposure.

Gadolinium chelate traverses the placenta and may accumulate in the amniotic cavity and theoretically remain there for an indefinite period of time, with contrast medium cycling through the fetal gastrointestinal and genitourinary tracts. Studies show that only 0.01% of the gadolinium dose is present in the fetus 4 hours after contrast medium injection, with only traces remaining after 24 hours (25). Recently, in a study of pregnant mice, Mühler et al (45) reported that gadoterate meglumine passed through the placenta but was subsequently redistributed to the mother, resulting in undetectable fetal concentrations after 48 hours.

It is the free gadolinium ion that is neurotoxic, and in vivo protection is obtained through binding of the gadolinium molecule to a chelating agent, forming a stable complex. However, no studies have established the in vivo stability of this chelate, although in patients with severely reduced renal function, no free gadolinium was measured in the blood on 5 consecutive days following the administration of contrast medium (46).

Current Recommendations

Teaching Point

Although the available literature suggests that it is unlikely that gadolinium would have an adverse effect on the developing fetus, even the least strict authors recommend that caution be exercised and that contrast-enhanced MR imaging be performed only when essential to the diagnosis (eg, in the absence of alternative imaging studies or when it is not possible to delay the MR imaging examination until after delivery) (25,28,44).

In their product monographs, the commercial vendors of many contrast agents, including gadobutrol (Gadovist; Bayer Healthcare Pharmaceuticals, Wayne, NJ) (47), gadopentetate dimeglumine (Magnevist, Bayer) (40), gadobenate dimeglumine (MultiHance; Bracco Diagnostics, Princeton, NJ) (48), and gadodiamide (Omniscan; GE Healthcare, Waukesha, Wis) (41), recommend that gadolinium-based contrast agents not be used in pregnant women unless the benefits clearly outweigh the risks. Other sources are even more restrictive and state that gadolinium is contraindicated during pregnancy because its long-term effects are unknown (2,28). The U.S. Food and Drug Administration has classified gadolinium-based agents as category C drugs (37), meaning that animal studies have revealed adverse effects on the fetus (at supraclinical doses) and there have been no controlled studies in women. Therefore, such agents should be administered only if the potential benefit justifies the potential risk to the fetus. In its 2010 Manual of Contrast Media, the ACR states that gadolinium-based agents should be used with extreme caution, taking into consideration the potential risks and benefits, and that the situation should be discussed with the patient to obtain informed consent before performing the contrast-enhanced study (36). This being said, counseling of patients is difficult considering the paucity of scientific facts available regarding fetal exposure to gadolinium-based agents.

Case Example 2

Clinical Setting.—A 30-year-old woman, 22 weeks pregnant ($G_4P_2A_1$), presented with vague upper abdominal pain of a few weeks duration. Prior to this pregnancy, the patient had been diagnosed with multiple hepatic hemangiomas. Laboratory tests revealed normal liver function and normal hemoglobin levels. US was performed first and displayed two of five known liver hemangiomas, both of which were stable in size. There was no free fluid, and no other cause for the patient's pain was identified. Pelvic US findings confirmed fetal well-being, with no placental abruption. What additional tests can be offered?

Considerations and Recommendations.—In a pregnant woman with hepatic hemangioma and abdominal pain, the concern is for an increase in size and risk of bleeding of the hemangioma. Although the two hemangiomas seen at US were well evaluated with prepregnancy MR imaging, gadolinium-based contrast medium is contraindicated during pregnancy, unless the benefits clearly outweigh the risks, so that contrast-enhanced MR imaging is the last option and must be essential. Thus, options include observation or iodinated contrast-enhanced CT (after discussion with the patient regarding the risks and benefits of this test). Given that there was no free peritoneal or perihepatic fluid, watchful observation was selected as the best option in this case.

Use of Contrast Media during Lactation

Benefits of Breast-feeding

Breast-feeding is recommended as the only source of feeding for full-term, healthy infants during the first 6 months of life, and the World Health Organization suggests that breast-feeding be continued during the first 2 years of life, and longer if the mother and child desire (49). Many mothers are likely to require contrast-enhanced imaging during this period. Breast-feeding has many benefits, and even temporary cessation can lead to complete weaning (50,51).

Pharmacology of Drug Excretion into Breast Milk

Drugs are excreted into breast milk either by passive diffusion through intercellular clefts if they are of low molecular weight, or, in cases of lipid-soluble or larger water-soluble products, through cell membranes into alveolar cells by binding to a cation transport system (25,52). Because iodinated and gadolinium-based contrast media are of high molecular weight and are nonionized and water soluble, there is minimal binding to milk and plasma proteins (25).

The milk-to-plasma drug concentration ratio is the ratio of contrast medium in breast milk compared to that in maternal plasma and is affected by the inherent characteristics of the product and its distribution characteristics, as well as by the mother's physiologic makeup. The product of the drug concentration ratio and the baby's rate of clearance of the drug yields a global "exposure index" that is indicative of the amount of the drug in the breast milk that the infant ingests, and that is expressed as a percentage of the therapeutic dose for the infant (52). As a general rule, a product can be considered safe if the dose that ultimately reaches the infant is less than 10% of the therapeutic dose (52).

Only small amounts of contrast medium reach the breast milk, on the order of 0.01% of the dose received by the mother for gadopentetate (53,54) and 0.5% for iohexol (55). The concentration of contrast agent in breast milk peaks at approximately 5 hours after injection (53,55), and falls to less than one-fifth of this level by 22 hours after injection (16,53). The half-life of iodinated contrast medium in women with normal renal function is less than 60 minutes, so that the amount of contrast medium remaining in the mother after 12 hours is essentially undetectable (56).

The 2010 Manual of Contrast Media from the ACR states that potential additional risks to the infant include direct toxicity from and allergic sensitization or reaction to contrast media, although these are theoretic concerns that have not been reported (36).

Transfer of Iodinated Contrast Agent Dose to a Breast-fed Baby

Consider the administration of iohexol—one of the contrast agents most commonly used in multidetector CT (29)—to a breast-feeding woman. Given a concentration of 350 mg of iodine per milliliter for iohexol (Omnipaque 350, GE Healthcare) and an average daily ingestion of 150 mL/kg of maternal milk, Nielsen et al (55) calculated that a nursing baby would receive 1.7 mg of iodine per kilogram of body weight, or 0.5% of the maternal dose. If one then compares this value with the recommended pediatric dose for urography—900 mg of iodine per kilogram of body weight for babies weighing less than 6.5 kg and 600 mg for babies over 7.0 kg—the dose received through ingestion of maternal milk is 0.2% of the maximum dose allowed for urography (25) and can, therefore, be considered safe.

Contrast agents that are more lipophilic (eg, iopanoic acid used for oral cholecystography) may become more concentrated in breast milk, yet do not reach the 10% threshold (52). Consequently, the use of iodinated contrast agents in nursing mothers is considered safe (51,52). However, special consideration should be given to mothers nursing preterm infants because, in the absence of a mature autoregulatory thyroid axis, these infants are more sensitive to variations in TSH and thyroxine levels, and are therefore more at risk for transient hypothyroidism (29,51).

Use of Topical Iodine in Breast-feeding Women

Teaching Point

As in pregnant women, topical iodine disinfectants are contraindicated in nursing mothers, owing to the risk of hypothyroidism developing in the breast-feeding infant (31,35). Indeed, cases

of hypothyroidism in breast-fed infants, although rare, have been reported following the topical application of iodine in their mothers (eg, iodine swabs for treatment of an abdominal wall abscess, iodine vaginal douches) (34,35). If exposure inadvertently occurs, TSH levels should be measured in the child. Treatment with oral thyroxine (if necessary) leads to rapid reversal and normalization of thyroid function.

Case Example 3

Clinical Setting.—Three weeks after giving birth, a 35-year-old woman noticed a 3-cm palpable mass associated with pain, redness, and heat in her right breast. Clinical examination revealed associated fever (39.2°C). The patient was breast-feeding her child on demand, day and night. Breast US findings confirmed a 3.4-cm abscess in the right breast.

Considerations and Recommendations.—Drainage of such an abscess is required and can be performed under US guidance. Initial cutaneous disinfection must not be performed with topical iodinated products; chlorexidine or alcohol are alternative options. Oral antibiotics should also be administered, with clinical follow-up and repeat US in case of incomplete response. The mother should be instructed to continue breast-feeding normally.

Transfer of a Dose of Gadolinium-based Contrast Agent to a Breast-fed Baby

Gadolinium-based agents are acceptable for MR imaging in children, with a recommended maximum pediatric dose of 0.2 mmol/kg. Kubik-Huch et al (27) measured gadolinium concentrations in breast milk in the first 24 hours after the intravenous injection of contrast medium and found that, on average, 0.04% of the gadolinium dose administered to the mother is excreted in breast milk, only 0.8% of which is absorbed by the infant (53). In a heavy (100-kg) nursing woman who receives an injection of 0.3 mmol/kg of gadopentetate dimeglumine, a 10-kg infant would ingest 0.012 mmol of gadolinium, or 0.6% of the recommended pediatric dose (27), so that contrast medium injection can be considered safe.

Current Recommendations for Use of Iodinated and Gadolinium-based Contrast Agents in Breast-feeding Mothers

Many manufacturers recommend that breast-feeding be interrupted for 24–48 hours following the injection of iodinated (Omnipaque, Visipaque [GE Healthcare]) or gadolinium-based (Gadovist, Magnevist, MultiHance) contrast agents (40,47,48,57,58). However, in light of the benefits of breast-feeding and mother-child bonding, the recommendation to interrupt breast-feeding seems unnecessarily harsh to many authors (2,25,27,29,51,52,59). In their 2010 Manual on Contrast Media, the ACR stated that the available data suggest that it is safe for both mother and infant to continue breast-feeding after contrast agent administration.

Teaching Point

Cautious practitioners may nevertheless wish to inform the mother about the small exposure to contrast medium that is possible through breast-feeding and to allow her to make the decision regarding temporary cessation of breast-feeding (60). If the mother remains concerned, she may be instructed to discard breast milk for 24 hours after contrast material injection (36).

Like all drugs and foodstuffs, contrast material may slightly alter the taste of milk for a short period of time (25,29,33).

Case Example 4

Clinical Setting.—Two days after delivering a healthy baby at 36 weeks gestation, a 32-year-old woman complained of headaches associated with visual and behavioral disturbances. She was breast-feeding her newborn on demand, at intervals of less than 2 hours. What imaging test would you recommend?

Considerations and Recommendations.—Initially, unenhanced CT can be performed to rule out intracranial bleeding or mass effect. If CT findings are normal, considering that the differential diagnosis for this patient's clinical symptoms includes multiple sclerosis, contrast-enhanced MR imaging is recommended to evaluate for active lesions. Whichever contrast-enhanced imaging modality is performed (with either iodinated or

Table 2
Considerations and Recommendations for Use of Iodinated and Gadolinium-based Contrast Agents during Pregnancy and Lactation

Guideline	Iodinated Contrast Agents	Gadolinium-based Contrast Agents
	Pregnancy	
Considerations	Data on fetal exposure to iodinated contrast agents are scarce	Few studies have evaluated fetal exposure to gadolinium
	No malformations or side effects have been reported in newborns	There have been no studies on long-term risks in humans
	Iodinated products given during pregnancy may induce neonatal hypothyroidism	Free gadolinium could potentially lead to neurotoxicity
Recommendations	Screening newborns for hypothyroidism during the 1st week of life is standard pediatric practice	Consensus is that gadolinium should not be used during pregnancy unless the benefits outweigh the risks
	Iodinated contrast agents must be essential for making the diagnosis	
	Informed consent as to the risks and benefits of the procedure is recommended	
	Use of topical iodine is contraindicated	
	Lactation	
Considerations	Dose of iodinated contrast agent in breast milk absorbed by the infant is 0.5% of the maternal dose	About 0.01% of the maternal gadolinium dose is excreted into breast milk
	Breast-feeding after the injection of iodinated contrast agent is safe	Breast-feeding after the injection of gadolinium-based contrast agent is safe
Recommendations	Concerned mothers may be instructed to discard breast milk for 24 hours after injection to eliminate fetal exposure to contrast agent	Concerned mothers may be instructed to discard breast milk for 24 hours after injection to eliminate fetal exposure to contrast agent
	Use of topical iodine is contraindicated because free iodine excretion may induce neonatal hypothyroidism	

gadolinium-based intravenous contrast material), it is safe for the mother to continue breast-feeding after contrast material administration.

Risk Management

Radiology facilities should have a procedure for evaluating pregnant patients, and radiologists should be knowledgeable about the effects of radiation and contrast media during pregnancy and lactation. Because of medicolegal considerations, all discussions with patients and their physicians should be documented (61). To allow an informed decision regarding the use of contrast material during pregnancy, the following three questions should be carefully considered and discussed with the parents, with written documentation.

1. Can the information sought from the contrast-enhanced study be obtained some other way?
2. Will the information sought affect the care of the mother or fetus during the pregnancy?
3. Can imaging be safely deferred until after pregnancy?

If the answer to any one of these questions suggests an alternative to contrast-enhanced imaging, such an alternative should be considered. We recommend that radiology facilities have a

written policy for management in pregnant and lactating women that radiologists, technologists, and residents can refer to when faced with such a situation. Table 2 provides a summary chart for quick reference.

Summary

Deterministic effects of radiation result from damage to a number of cells, with a dose threshold before damage occurs. No deterministic effect of practical significance is expected to occur below a dose of 100 mGy. Stochastic effects of ionizing radiation originate from damage to a single cell and can lead to carcinogenesis. Fetal radiation doses up to 1 mGy—used in most radiologic examinations below the knees and above the diaphragm—are considered acceptable, with an additional risk of carcinogenesis of less than one in 10,000. With larger doses (eg, a fetal dose of 20–50 mGy received during pelvic CT), the risk of carcinogenesis increases approximately by a factor of 2, although it remains low in absolute terms (less than one in 250). All radiology facilities should have a written policy for screening and management in pregnant women (Figure).

There has been no documented damage to a developing human fetus caused by MR imaging exposure. However, caution is advised, and risks and benefits must always be weighed before evaluating a pregnant patient with MR imaging.

Because the fetal thyroid develops throughout pregnancy, any iodine-containing product is contraindicated in pregnant women, given the risk of depression of fetal thyroid function. If iodinated compounds are used in the course of pregnancy, either inadvertently or due to exceptional circumstances, neonatal thyroid function should be checked during the 1st week of life. This testing is already performed routinely for all newborns in North America and Europe.

Because of limited scientific evidence regarding their safe use during pregnancy in humans, gadolinium-based contrast agents are contraindicated in the course of pregnancy unless the benefits outweigh the risks. If gadolinium-based contrast agents are administered, either inadvertently or due to exceptional circumstances, no neonatal tests are necessary.

The dose of iodinated or gadolinium-based contrast medium that reaches the infant through ingestion of breast milk is very small, and only a minute proportion of that which reaches the infant's gastrointestinal tract is subsequently absorbed. There is insufficient evidence to recommend even a temporary cessation of breast-feeding following the administration of either iodinated or gadolinium-based contrast agents. Because of their higher concentration of free iodide, topical iodine-based disinfectants should be avoided in pregnant and breast-feeding women due to the risk of hypothyroidism in the infant.

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Quality Initiatives
Guidelines for Use of Medical Imaging during Pregnancy and Lactation

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Thus, the radiation dose to the embryo or fetus that is likely to result from any diagnostic procedure in current use should present no risk of fetal death, malformation, growth retardation, or impairment of mental development (3,6).

Page 904
Thus, the Committee recommended that iodinated contrast media be used in pregnant women only when *(a)* no alternative test is available, *(b)* information to be obtained from the study is useful to both mother and fetus during the pregnancy, and *(c)* the referring physician considers it imprudent to delay the imaging study until after delivery.

Page 905
Although the available literature suggests that it is unlikely that gadolinium would have an adverse effect on the developing fetus, even the least strict authors recommend that caution be exercised and that contrast-enhanced MR imaging be performed only when essential to the diagnosis (eg, in the absence of alternative imaging studies or when it is not possible to delay the MR imaging examination until after delivery) (25,28,44).

Page 906
As in pregnant women, topical iodine disinfectants are contraindicated in nursing mothers, owing to the risk of hypothyroidism developing in the breast-feeding infant (31,35).

Page 907
In their 2010 Manual on Contrast Media, the ACR stated that the available data suggest that it is safe for both mother and infant to continue breast-feeding after contrast agent administration.