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Imaging of Pregnant and Lactating Patients

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Imaging of Pregnant and Lactating Patients: Part 1, Evidence-Based Review and Recommendations

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OBJECTIVE. The objectives of this article are to discuss the current evidence-based recommendations regarding radiation dose concerns, the use of iodinated and gadolinium-based contrast agents, and the comparative advantages of multimodality imaging (ultrasound, CT, and MRI) during pregnancy and lactation. We also discuss the use of imaging to evaluate pregnant trauma patients.

CONCLUSION. Maternal and fetal radiation exposure and dose are affected by gestational age, anatomic site, modality, and technique. The use of iodinated and gadolinium-based contrast agents during pregnancy and lactation has not been well studied in human subjects. Imaging should be used to evaluate pregnant trauma patients only when the benefits outweigh the risks.

Keywords: emergency radiology, evidence-based radiology, lactation, pregnancy, radiation protection

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The imaging issues of pregnant and lactating women can be confusing and controversial. With wide-ranging issues including maternal and fetal radiation dose concerns, the safety and appropriateness of iodinated and gadolinium-based contrast agents, and the most appropriate imaging studies for common acute processes, it is understandable that many radiologists regard this topic with some hesitation, if not trepidation. Our objective in this article is to review the current, evidence-based recommendations regarding radiology topics unique and common to pregnant and lactating patients.

Basic Concepts of Ionizing Radiation

X-rays and gamma rays are short-wavelength electromagnetic waves that can ionize tissues and change normal cellular structure through two types of effects: deterministic and stochastic. Deterministic effects involve the loss of tissue function, which in turn can stimulate inherent cellular repair mechanisms. If the radiation dose is distributed over time, the cellular repair mechanisms permit the tissue to recover from the damage, allowing it to show a greater tolerance to the radiation dose than if the dose had been administered all at once. This implies a threshold dose after which the tissue will exhibit damage because the radiation dose exceeds the capabilities of innate cellular repair mechanisms. In contrast, stochastic effects have no threshold dose; these effects refer to random modifications in a cell's components, such as a DNA mutation, that can occur at any radiation dose [1].

Understanding the measures of radiation dose can be simplified in the following way. Exposure is the total amount of ionization that a certain amount of radiation produces per unit of mass of air and is expressed in roentgens. Absorbed dose is the energy that is absorbed per unit of mass by the body from a radiation exposure and is expressed in rads. Equivalent dose and effective dose are expressed in rem (roentgen equivalents human). Equivalent dose accounts for the relative biologic effects of different types of ionizing radiation (e.g., α particles and x-rays). Effective dose is used to compare stochastic risks of radiation; it takes into account how much of the body was exposed and the relative radiosensitivities of the organs that were exposed. For practical purposes in diagnostic radiology, for x-rays and soft tissues, roentgen, rad, and rem are considered equivalent. In International System (SI) units, exposure is expressed as coulombs/kg (C/kg), absorbed dose as gray (Gy), and equivalent and effective dose as sievert (Sv). These are metric units, and 1 Gy is equal to 1 Joule/kg or 100 rad. Similarly, 1 Sv is equal to 100 rem. In radiologic imaging, where the absorbed dose for a single study is well below 1

Gy, it makes more sense to use mGy or mSv (1 Gy = 1000 mGy and 1 Sv = 1000 mSv). One rad is equal to 10 mGy. To summarize, when referring to diagnostic imaging, 1 rad, 1 rem, 10 mGy, and 10 mSv can be considered equivalent.

The average naturally occurring background radiation to a person is 3 mSv per year. For a fetus, the average dose from naturally occurring background radiation over the course of a normal gestation is 0.5–1.0 mSv [2], which is less than the annual dose to the mother from background radiation because of the attenuation of the mother's tissues and the gestation term of about 9 months. According to the National Council on Radiation Protection and Measurements (NCRP), the maximum permissible radiation dose to the fetus of a pregnant radiation worker from occupational exposure (e.g., scatter radiation from a patient) is 5 mSv [3].

Ionizing Radiation, Teratogenesis, and Carcinogenesis

Exposure to ionizing radiation from diagnostic imaging during pregnancy can cause high levels of anxiety in pregnant women. Whether exposed to ionizing radiation because of an imaging test necessary for a diagnostic workup or unknowingly before realizing they were pregnant, pregnant patients often question the potential effects of the radiation exposure and may perceive the teratogenic risk of the test as high [4]. This may be further exacerbated by the patients' physicians who may have unrealistically high misperceptions of the harmful effects of the radiation exposure and overestimate the teratogenic risks associated with diagnostic radiation [1]. In a Canadian study, 1% of surveyed family practitioners would recommend an abortion if the patient received a radiograph and 6% would recommend an abortion after CT on the basis of their perception of the teratogenic risk associated with the tests [1]. The relative radiation levels with their corresponding estimated effective dose ranges for different imaging tests are detailed by the American College of Radiology (ACR) [5] (Table 1).

The effects of ionizing radiation on the developing fetus include both teratogenic and carcinogenic risks. The teratogenic risk of ionizing radiation is well established, particularly at high doses [6]. The teratogenicity of radiation is dose-dependent, with the risk of fetal malformation significantly increasing at fetal doses above 150–200 mGy and fetal damage occurring at exposures greater than 500 mGy [7–10]. During the first or second postconceptus week, in the preimplantation and preorganogenesis stages, a fetal radiation dose of 50–100 mGy may cause the failure of blastocyst implantation and result in spontaneous abortion [7] (Table 2). However, if the embryo were to survive, the radiation dose would likely not result in deterministic or stochastic effects in the liveborn child because the cells of the blastocyst are omnipotent and can replace damaged cells in what is designated the "all-or-none period" [6, 11, 12]. The developing fetus is most vulnerable to radiation effects between 8–15 weeks of gestational age, with exposure to fetal radiation doses above 100–200 mGy associated with intrauterine growth retardation and CNS defects, such as microcephaly and mental retardation [7, 8]. According to Table 3, from the ACR Practice Guideline for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation [10], the preceding description pertains to radiation effects after exposures between the fifth and 17th weeks of gestational age or third and 15th weeks postconception [10]. After the 15th gestational week, the fetus is less sensitive to radiation effects on the CNS [6].

According to the consensus statements from the relevant major national organizations (NCRP, International Commission on Radiological Protection [ICRP], Biologic Effects of Ionizing Radiation VII [BEIR VII], Centers for Disease Control and Prevention, ACR, and American Congress of Obstetricians and Gynecologists [ACOG]), the risk of malignancy, miscarriage, or major malformations is negligible in fetuses exposed to 50 mGy or less [10, 12–16]. Nearly all diagnostic imaging studies confer an ionizing radiation dose well below 50 mGy (Tables 3 and 4). Exposure to ionizing radiation doses less than 50 mGy has not been shown to be associated with different pregnancy outcomes compared with fetuses exposed to background radiation alone [17]. It is important to note that the spontaneous pregnancy risks unrelated to ionizing radiation in a patient include a 15% risk of spontaneous abortion, 3% risk of major malformation, 4% risk of prematurity and growth retardation, and 1% risk of mental retardation [8, 18, 19].

The carcinogenic risk of ionizing radiation is less well established. The linear-no-threshold risk model has statistical limitations that make it difficult to predict cancer risk at radiation doses less than 100 mSv. This model posits that carcinogenesis risk decreases linearly with decreasing radiation doses, with even the smallest dose having the potential to increase cancer risk [8, 15, 20]. A number of notable studies support an association between in utero irradiation and the increased risk of childhood cancer, although

TABLE 1: American College of Radiology (ACR) Relative Radiation Levels

Relative Radiation Level[a]	Adult Effective Dose Estimate Range (mSv)	Pediatric Effective Dose Estimate Range (mSv)	Example Examinations
0	0	0	Ultrasound, MRI
☢	< 0.1	< 0.03	Chest radiography, hand radiography
☢☢	0.1–1	0.03–0.3	Pelvis radiography, mammography
☢☢☢	> 1–10	> 0.3–3	Abdomen CT, nuclear medicine bone scan
☢☢☢☢	> 10–30	> 3–10	Abdomen CT with and without contrast administration, whole-body PET
☢☢☢☢☢	> 30–100	> 10–30	CT angiography chest, abdomen, and pelvis with contrast administration; transjugular intrahepatic portosystemic shunt placement

Note—Reprinted with permission from the ACR. Refer to the ACR Website at www.acr.org/ac for the most current and complete version of the ACR Appropriateness Criteria.

[a]The relative radiation level assignments for some of the examinations could not be made because the actual patient doses in these procedures varied as a function of a number of factors (e.g., the region of the body exposed to ionizing radiation, the imaging guidance that is used, etc.). The relative radiation levels for these examinations were designated as not specified.

TABLE 2: American College of Radiology Summary of the International Commission on Radiological Protection Suspected In-Utero Induced Deterministic Radiation Effects

Menstrual or Gestational Age	Conception Age	Radiation Dose		
		< 50 mGy (< 5 rad)	50–100 mGy (5–10 rad)	> 100 mGy (> 10 rad)
0–2 wk (0–14 d)	Before conception	None	None	None
3rd and 4th wk (15–28 d)	1st–2nd wk (1–14 d)	None	Probably none	Possible spontaneous abortion
5th–10th wk (29–70 d)	3rd–8th wk (15–56 d)	None	Potential effects are scientifically uncertain and probably too subtle to be clinically detectable	Possible malformations increasing in likelihood as dose increases
11th–17th wk (71–119 d)	9th–15th wk (57–105)	None	Potential effects are scientifically uncertain and probably too subtle to be clinically detectable	Increased risk of deficits in intelligence quotient or mental retardation that increase in frequency and severity with increasing dose
18th–27th wk (120–189 d)	16th–25th wk (106–175 d)	None	None	Intelligence quotient deficits not detectable at diagnostic doses
> 27 wk (> 189 d)	> 25 wk (> 175 d)	None	None	None applicable to diagnostic medicine

Note—Reprinted with permission from [10].

many aspects of the available data remain controversial [8, 14, 20]. According to the ICRP, the best quantitative estimate of risk is about one cancer per 500 fetuses exposed to 30 mGy of radiation, or 0.2%, which is at the high end of the radiation dose from CT of the abdomen and pelvis [14, 21]. The ACR Practice Guidelines state: "A dose of 20 mGy represents an additional projected lifetime risk of about 40 additional cancers or fewer per 5000 babies, or about 0.8%" [10]. It remains uncertain whether in utero radiation exposure increases the risk similarly for leukemia and solid tumors or favors an increased risk for leukemia [20]. The impact of radiation exposure on the development of fatal childhood cancer may be greater if the fetus is exposed earlier in pregnancy. One study found that the relative risk of developing fatal childhood cancer was higher after a first-trimester radiation exposure (relative risk [RR] = 3.19) compared with a second- or third-trimester exposure (RR = 1.3) [22].

TABLE 3: Estimated Conceptus Doses from Radiographic and Fluoroscopic Examinations

Examination	Typical Conceptus Dose (mGy)
Cervical spine (anteroposterior, lateral)	< 0.001
Extremities	< 0.001
Chest (posteroanterior, lateral)	0.002
Thoracic spine (anteroposterior, lateral)	0.003
Abdomen (anteroposterior)	
21-cm patient thickness	1
33-cm patient thickness	3
Lumbar spine (anteroposterior, lateral)	1
Limited IV pyleogram[a]	6
Small-bowel study[b]	7
Double-contrast barium enema study[c]	7

Note—Reprinted with permission from [7].
[a]Limited IV pyelogram is assumed to include four abdominopelvic images. A patient thickness of 21 cm is assumed.
[b]A small-bowel study is assumed to include a 6-minute fluoroscopic examination with the acquisition of 20 digital spot images.
[c]A double-contrast barium enema study is assumed to include a 4-minute fluoroscopic examination with the acquisition of 12 digital spot images.

For postnatal radiation exposure, it has been shown that cancer risk and mortality from cancer are increased after exposure to low doses of radiation, ranging from 50 to 150 mSv [23]. According to BEIR VII, the degree of risk varies with the patient age (increased risk at a younger age) and sex (increased risk for females) [15]. Even in the 30- to 90-mSv range, which corresponds to two abdomen and pelvis CT examinations (30 mSV) and up to 45 head CT examinations (90 mSv), there is direct evidence to suggest an increased risk of cancer [23, 24]. This association is even more convincingly seen in children, who are more radiosensitive than adults for the same radiation dose and have a longer remaining lifespan in which to develop radiation-induced cancers.

The BEIR VII lifetime risk model predicts that approximately one person would be expected to develop cancer out of 100 people after a single exposure to 100 mSv, whereas 42 of the 100 people would be expected to develop cancer from nonradiation causes, which shows that the risk of developing cancer from a radiation exposure is far less than developing cancer from other causes. However, it should be noted that these values represent averages and are not sex or age specific. For example at an age of 5 years old, the risk for developing cancer after a 100-mSv dose would be about 3.4% for girls and 1.8% for boys, with an average of 2.6% or about three per 100 instead of the quoted one per 100 [15]. At an age of 30 years, the risk of developing cancer after a 100-mSv dose would be 1.1% for women and 0.7% for men, with an average of about 0.9% or about one per 100 [15].

In light of these considerations and remaining uncertainties and controversies on the topic, it is best for radiologists to proceed with caution when imaging patients, pregnant or otherwise, taking care to minimize the radiation exposure and dose when possible, in accordance with the as low as reasonably achievable (ALARA) principle.

IV Contrast Agent Use During Pregnancy and Lactation

The available literature on the excretion of gadolinium and iodinated contrast agents into breast milk is limited, however, it is known that both are excreted in very small quantities into the breast milk and even smaller quantities are absorbed by the infant gastrointestinal tract [25, 26]. Studies have shown that less than 1% of the IV-administered maternal dose of gadolinium and iodinated contrast agents is excreted into the breast milk and less than 1% of the contrast agent in the breast milk is absorbed by the infant [25–27]. The expected absorbed dose by the infant from the ingestion of the breast milk ends up being less than 0.05% of the recommended dose of contrast agent if the infant were to undergo a contrast-enhanced imaging study [28]. The theoretic risks from both types of contrast agents include direct toxicity or allergic sensitivity or reaction, neither of which has been reported. According to the ACR Manual on Contrast Media, it should be safe for the mother and infant to continue breastfeeding after receiving iodinated or gadolinium-based contrast agents, but if the mother desires, she may choose to pump and discard the breast milk for 24 hours before resuming breastfeeding [28].

As with the literature on the excretion of gadolinium and iodinated contrast agents into breast milk, the literature on the effect of these substances on the human embryo or fetus is limited. Iodinated contrast material is known to cross the human placenta and enter the fetus [29]. Gadolinium has been shown to cross the placenta and appear in the fetal bladder in animal studies only but should be assumed to cross the human placenta [30–32].

No teratogenic effects have been reported with iodinated contrast agents. Although iodinated contrast agents can cause neonatal hypothyroidism if directly instilled into the amniotic sac, there are no reports of clinical sequelae induced by iodinated contrast agents administered IV [33]. A recent study evaluated the effect of in utero exposure to a single high dose of water-soluble iodinated contrast material on neonatal thyroid function and concluded that such an exposure is unlikely to be clinically important [34]. Given the insufficient literature to conclude that iodinated contrast material poses no risk to the fetus and in light of the small potential risk to the fetal or neonatal thyroid gland, the ACR Manual on Contrast Media recommends that iodinated contrast agents be administered IV only as needed in pregnant patients [28].

Gadolinium has been shown in animal studies to have teratogenic effects when administered at high and repeated doses [35]. Although no well-controlled human studies have been performed (and likely will never be performed) to assess the teratogenic effect of gadolinium in pregnant women, no harmful effects have been reported in human fetuses exposed to gadolinium in utero. Studies have shown that the fetus can excrete, swallow, and reabsorb gadolinium into the GI tract with gadolinium remaining in the amniotic fluid indefinitely because the half-life of gadolinium in the fetus is unknown [23]. According to the ACR white paper for safe MR practices, gadolinium should be used during pregnancy with extreme caution and only if the benefit to the mother overwhelmingly outweighs the theoretic risks to the fetus [36].

TABLE 4: Estimated CT Conceptus Doses From Single Acquisition

Examination	Dose Level	Typical Conceptus Dose (mGy)
Extraabdominal		
Head CT	Standard	0
Chest CT	Standard	0
Routine	Standard	0.2
Pulmonary embolus	Standard	0.2
CT angiography of coronary arteries	Standard	0.1
Abdominal		
Abdomen, routine	Standard	4
Abdomen/pelvis, routine	Standard	25
CT angiography of aorta (chest through pelvis)	Standard	34
Abdomen-pelvis, stone protocol[a]	Reduced	10

Note—Reprinted with permission from [7].

[a]Anatomic coverage is the same as for routine abdominopelvic CT, but the tube current is decreased and the pitch is increased because standard image quality is not necessary for detection of high-contrast stones.

CT and MRI Safety in Pregnancy

CT use has increased dramatically in the past decade [37]. In pregnant patients, medical imaging using ionizing radiation also has increased significantly—similar in rate to the general population—with the rate of increased use highest for CT [24, 38, 39]. Because fetal tissue is more radiosensitive than maternal tissue and both fetal and maternal tissue are exposed to radiation, often directly in the radiation beam, radiation dose concerns and consequent cancer risks are relevant and radiation dose concerns have understandably increased [8, 15, 40]. Despite these concerns, CT remains an essential imaging modality, particularly in the acute setting where it can serve as a critical triaging tool and prevent delays in diagnoses that could result in increased morbidity and mortality to the fetus or mother. In any clinical setting, emergent or otherwise, CT should be used in the pregnant patient only after the physician performs a risk-benefit assessment. If CT is to be used, radiation dose reduction methods should be implemented, including decreasing the voltage and current, increasing the pitch, widening the beam collimation, or limiting the scanned areas [21].

Although use of MRI has not been shown to have any deleterious effects on the fetus, the safety of MRI during pregnancy has yet to be definitely established [30, 41]. The potential risk of heating effects from radiofrequency pulses and effects of acoustic noise on the fetus have not been validated [22, 42–44]. The concern that MRI could cause harmful fetal tissue heating stems from the concept of specific absorption rate (SAR), which quantifies the amount of radiofrequency and the rate at which it is deposited on the fetus during pulse sequences [45]. Increased static magnetic field strength, increased flip angle, increased number of radiofrequency pulses, and decreased spacing between radiofrequency pulses all increase the SAR. Radiofrequency refocusing pulses tend to generate more magnetization and thus more heat because they have flip angles close to 180° [46]. Because single-shot echo-train spin-echo sequences (such as single-shot fast spin-echo [SSFSE]) use 180° refocusing pulses, these sequences have relatively high SAR whereas gradient-recalled echo sequences, which do not depend on radiofrequency refocusing pulses,

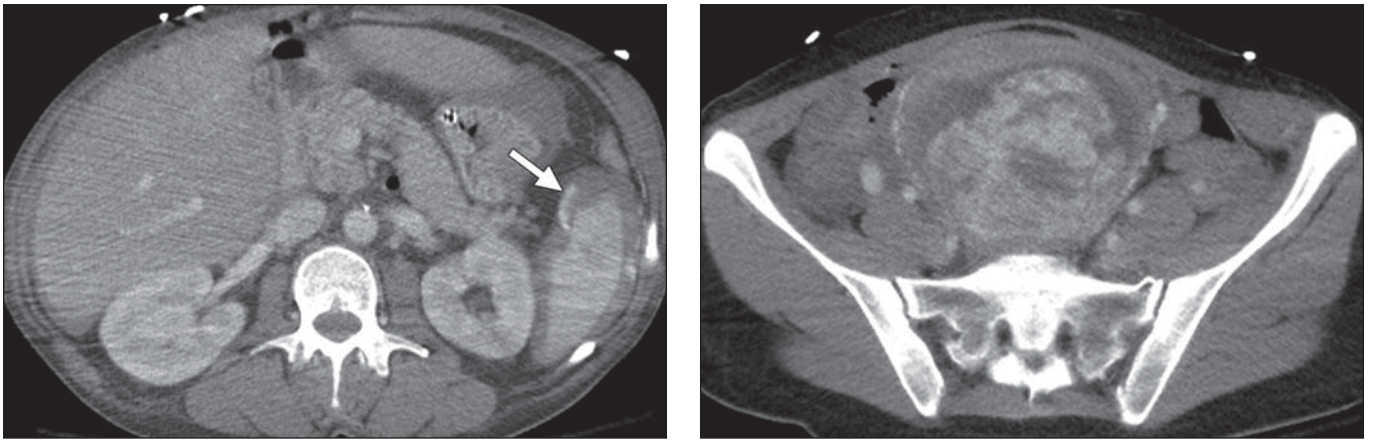

Fig. 1—22-year-old pregnant woman who was involved in motor vehicle accident.
A, CT image shows perisplenic hemorrhage with evidence of active arterial bleeding from splenic laceration (*arrow*).
B, CT image shows heterogeneous areas of enhancement in gravid uterus that represent areas of hemorrhage secondary to placental abruption.

have a comparatively lower SAR [45, 47]. Sequences such as SSFSE operate at SAR limits imposed by the International Commission on Non-Ionizing Radiation Protection (ICNIRP) [48]. The ALARA principle should be used when determining the need for additional pulse sequences. To date, there is no data to indicate that single-shot echo-train spin-echo sequences commonly used in diagnostic MRI result in significant temperature changes when performed on 1.5-T magnets [49].

The ICNIRP recommends postponing elective MRI until after the first trimester because of the potential risks discussed previously [50]. ACOG suggests that MRI should be considered instead of radiography when appropriate and that MRI is not associated with known adverse fetal effects [16]. According to the 2007 ACR guidelines, MRI can be used in pregnant patients regardless of gestational age when the benefit outweighs the risks, as decided by a designated MRI attending radiologist [36]. In acute nonelective situations, if the potential benefit is believed to outweigh the risk, then MRI, even in the first trimester, should be considered an option. According to the ACR white paper on MR safety, it is important to answer and document the following [36]: Could the information be obtained by ultrasound? Will this study likely impact or change the care of the patient? Could this study be postponed until the patient is no longer pregnant?

Acute Trauma

Trauma complicates 6–7% of all pregnancies and is a leading cause of nonobstetric maternal death [51]. The pregnancy status may be unknown to the trauma team or the patient. In one study, the trauma team was unaware of the pregnancy status in 11.4% of the patients and of these patients, 7.8% were unaware of their gravid state [52].

Complications associated with obstetric trauma include internal hemorrhage, placental abruption, uterine rupture, direct fetal injury or demise, and maternal injury or demise [53]. The timely and efficient evaluation of the pregnant patient after traumatic injury is critical for the well being of both the mother and fetus.

In the hemodynamically stable obstetric patient, ultrasound should be performed as part of the initial assessment to evaluate for free intraperitoneal hemorrhage. Splenic rupture is the most common cause of free intraperitoneal hemorrhage in pregnant patients, occurring earlier in pregnancy compared with the nonpregnant state [54] (Fig. 1). Up to 25% of pregnant patients have hemodynamically significant hepatic or splenic injury after severe blunt trauma. Ultrasound is also used to document fetal viability and evaluate for placental abruption and uterine rupture [55]. In pregnant patients, ultrasound imaging for evidence of traumatic injury is approximately 61–83% sensitive and 94–100% specific [8]. If ultrasound shows the presence of free intraperitoneal hemorrhage, contrast-enhanced CT should be considered the next imaging test to evaluate for visceral injury. Because of its ease of use, rapidity, and high sensitivity and specificity, contrast-enhanced CT is the reference standard imaging test for the evaluation of solid organ injury in the setting of trauma (Fig. 1). If the trauma team has determined that the mother would benefit from CT, proceeding with CT should not be delayed by concerns over fetal radiation dose or iodinated contrast material [8]. The fetal radiation dose from a single CT of the abdomen and pelvis is approximately 25–30 mSv, well below the 50-mSv threshold noted by the NCRP as posing negligible risk to the fetus [13]. Iodinated contrast material is not teratogenic in pregnancy [28]. MRI is not an appropriate imaging modality for the assessment of severely injured and potentially unstable patients.

According to the ICRP, ACR, and ACOG, fetal radiation doses below 50–100 mGy should not be considered a reason for terminating a pregnancy [16, 56, 57]. Most diagnostic imaging tests are well below this dose. Radiation doses above 100 mGy may result in a 1% combined increased risk of organ malformation and the development of childhood cancer [7]. A fetal radiation exposure of at least 100 mGy is necessary before pregnancy termination should be considered [54]. The risk of malformations increases significantly above baseline at radiation doses above 150 mGy [7]. This radiation dose level can be reached or exceeded during the care of a trauma patient because multiple imaging studies using ionizing radiation could be necessary. In these instances, the pregnant patient may wish to consult a medical physicist to perform a risk assessment to enable an informed decision regarding the radiation risk to the fetus and the option of pregnancy termination [10].

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This article is part of a self-assessment module (SAM). Please also refer to "Imaging of Pregnant and Lactating Patients: Part 2, Evidence-Based Review and Recommendations" which can be found on page 785.

Each SAM is composed of two journal articles along with questions, solutions, and references, which can be found online. You can access the two articles at www.ajronline.org, and the questions and solutions that comprise the Self-Assessment Module via http://www.arrs.org/Publications/AJR/index.aspx.

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