ADMINISTRATION OF CONTRAST MEDIUM TO PREGNANT OR POTENTIALLY PREGNANT PATIENTS

Studies of low molecular weight water-soluble extracellular substances such as iodinated diagnostic and gadolinium-based magnetic resonance (MR) contrast agents in pregnancy have been limited, and effects on the human embryo or fetus are unknown. Iodinated diagnostic contrast media have been shown to cross the human placenta and enter the fetus in measurable quantities (1,2). A standard gadolinium-based MR contrast agent has been shown to cross the placenta in primates and appear within the fetal bladder within 11 minutes after intravenous administration (3). It must be assumed that all iodinated and gadolinium-based contrast media behave in a similar fashion and cross the blood-placental barrier into the fetus.

After entering the fetal blood stream, these agents will be excreted via the urine into the amniotic fluid and be subsequently swallowed by the fetus (4). It is then possible that a small amount will be absorbed from the gut of the fetus and the rest eliminated back into the amniotic fluid, the entire cycle being repeated innumerable times.

In the study in primates, placental enhancement could be detected up to 2 hours following the intravenous administration of gadopentetate dimeglumine. When gadopentetate dimeglumine was injected directly into the amniotic cavity, it was still conspicuous at 1 hour after administration (3). There are no data available to assess the rate of clearance of contrast agents from the amniotic fluid.

The ACR Committee on Drugs and Contrast Media has reviewed this issue extensively and has prepared the following summary of information and recommendations.

Iodinated X-Ray Contrast Media (ionic and nonionic)

Diagnostic iodinated contrast agents have been shown to cross the human placenta and enter the fetus when given in usual clinical doses. No adequate and well-controlled teratogenic studies of the effects of these agents in pregnant women have been performed.

In conjunction with the existing ACR policy for the use of ionizing radiation in pregnant women, we recommend that all imaging facilities should have policies and procedures to reasonably attempt to identify pregnant patients prior to the performance of any diagnostic examination involving ionizing radiation to determine the medical necessity for the administration of iodinated contrast media. If a patient is known to be pregnant, both the potential radiation risk and the potential added risks of contrast media should be considered before proceeding with the study (Res. 24, 1995, ACR Policy).

While it is not possible to conclude that contrast agents present a definite risk to the fetus, there is insufficient evidence to conclude that they pose no risk. Consequently, the Committee recommends the following:

A. The radiologist should confer with the referring physician and document in the radiology report or the patient’s medical record the following:

1. That the information requested and the necessity for contrast material administration cannot be acquired via other means (e.g., ultrasonography).
2. That the information needed affects the care of the patient and fetus during the pregnancy.
3. That the referring physician is of the opinion that it is not prudent to wait to obtain this information until after the patient is no longer pregnant.

B. It is recommended that pregnant patients undergoing a diagnostic imaging examination with ionizing radiation and iodinated contrast material provide informed consent to document that they understand the risk/benefits of the procedure to be performed and the alternative diagnostic options available to them (if any), and that they wish to proceed.

Gadolinium-Based Contrast Agents

It is known that gadolinium-based MR contrast media cross the human placenta and into the fetus when given in clinical dose ranges. No adequate and well-controlled teratogenic studies of the effects of these agents in pregnant women have been performed. We recommend that all imaging facilities should have policies and procedures to reasonably attempt to identify pregnant patients prior to the performance of the MR exam, and before the use of MR contrast media in these patients. The ACR has issued a White Paper on MR safety in pregnancy and related issues (4) that is also consistent with the ACR Committee on Drugs and Contrast Media’s recommendation for MR contrast media.

While there is no compelling evidence of teratogenicity or other adverse effect on the fetus of MR imaging or of gadolinium-based contrast agents, neither the safety of the MR environment nor the safety of the MR contrast agents in pregnant patients has been established. It is therefore prudent for pregnant patients at any stage of pregnancy to be informed of the risk-benefit ratio that may warrant the performance of an MR scan with or without contrast media. The radiologist should confer with the referring physician and document the following in the radiology report or the patient’s medical record:

1. The information requested from the MR study cannot be acquired using other nonionizing radiation imaging modalities (e.g., ultrasonography).
2. That the information needed affects the care of the patient and fetus during the pregnancy.
3. That the referring physician is of the opinion that it is not prudent to wait to obtain this information until after the patient is no longer pregnant.

It is recommended that the pregnant patient undergoing an MR examination with contrast material provide informed consent to document that she understands the risk/benefits of the MR procedure to be performed, and the alternative diagnostic options available to her (if any), and that she wishes to proceed.

REFERENCES