Malpractice Issues in Radiology

Iodine-131 and the Pregnant Patient

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The Case

A 29-year-old woman was referred to the radiology department of a hospital for a whole-body radionuclide scan using iodine-131. The patient had undergone a total thyroidectomy for papillary carcinoma 4 years earlier and was being examined for metastases. Images obtained 48 hr after oral administration of 2 μCi (74 MBq) of iodine-131 disclosed no evidence of functioning thyroid tissue or metastatic disease.

Three weeks later, the patient discovered that she was pregnant. The patient’s obstetrician consulted with the radiologist, who suggested that the patient consider terminating the pregnancy because of potential damage to the fetal thyroid gland. The patient rejected this course of action, however, and elected to continue the pregnancy. At term, the patient delivered a baby afflicted with severe hypothyroidism. Six months later, the mother filed a medical malpractice lawsuit on behalf of her infant child and herself against the radiologist and the hospital, alleging that the defendants’ failure to ascertain whether the patient had been pregnant at the time of iodine-131 administration constituted negligence.

Medical–Legal Issues

Defense attorneys representing the hospital and the radiologist immediately reviewed the pertinent medical records. They found that the patient indeed had been unknowingly 15 weeks pregnant at the time of iodine-131 administration. The attorneys discovered that the routine practice in the department was for nuclear medicine technologists to ask each patient undergoing a radionuclide procedure specific questions, including one about the possibility of pregnancy, and to record the response on a form. On the questionnaire filled out for this patient, a nuclear medicine technologist had checked off “no” next to the question, “Is patient pregnant?” When questioned, the technologist told the attorneys that he specifically remembered asking the patient whether she was pregnant and that the patient had appeared reliable and had answered, “No.” The form was later reviewed and countersigned by the radiologist.

The defense attorneys then reviewed the radiology department policy that covered procedures for examinations using radionuclides. The policy stated, in part, that “[d]etermination should be made prior to administration of iodine-131 that female patients in the childbearing age are not pregnant.” Furthermore, the policy also stated that signs containing the language, “If you are pregnant or think you are pregnant, please notify technologist or radiologist” should be posted in plain view throughout the nuclear medicine department.

Before formal legal discovery proceedings began, the attorney for the plaintiff produced an affidavit signed by the patient stating that she had no recollection of ever having been asked by the technologist at the time of the iodine-131 administration whether she was pregnant. The patient also claimed that she may have been “vaguely aware” of signs posted in the department that advised patients to notify a technologist if they were pregnant but that she “did not pay attention to them” because none of the department personnel “called her attention to the signs.” In the meantime, the defense attorneys reinterviewed the nuclear medicine technologist who had filled out the original questionnaire. The technologist reaffirmed that he had a definite independent recollection of having asked the patient if she were pregnant and of hearing her respond, “No.”

Soon thereafter, the attorney for the plaintiff obtained an affidavit signed by an expert radiology witness who was extremely critical of both the radiologist and radiology department personnel. The plaintiff’s radiology expert wrote that iodine-131 was “absolutely contraindicated” in pregnant women and that the defendants were “derelict in performance of this duty, and thus were grossly negligent.”
The attorney representing the radiologist retained a radiology expert who wrote in an affidavit that although it is true that iodine-131 administration is contraindicated in pregnant women, nonetheless the radiologist had sufficiently conformed to the standard of radiologic care by simply inquiring of the patient whether there had been a possibility that she was pregnant. The defense expert added that there was no local or national standard that required radiologists or hospitals to perform a pregnancy test on a patient before administering iodine-131, providing the patient seemed to be able to understand questions and to answer them credibly.

At this point the defense attorneys met with the radiologist, the claims manager of the radiologist’s insurance company, and hospital officials to discuss the future course of action. The attorneys thought that there would be little chance of obtaining a verdict favorable to the defense at a jury trial. They pointed out that the patient had indeed been given iodine-131 when she had been 15 weeks pregnant, physicians on both sides of the lawsuit agreed that iodine-131 is contraindicated during pregnancy, the patient denied having been asked whether she was pregnant, no pregnancy test had been offered before administration of the iodine-131, and the patient’s infant had severe and permanent hypothyroidism. The attorneys strongly recommended that the lawsuit be settled.

Eventually the parties did agree to a settlement that resulted in a “substantial payment” to the mother and child. The court ordered that the exact terms of the settlement not be disclosed publicly.

Discussion

It is well established that oral administration of radioactive iodine to a mother will have deleterious effects on the thyroid gland of the fetus. The placental transfer of radioactive iodine occurs as early as 8 weeks after conception [1]. According to Harbert [2], the fetal thyroid gland is developed sufficiently to concentrate iodine and synthesize hormones by 11–12 weeks’ gestation. Some researchers have placed the onset of fetal thyroid function as early as 8 weeks’ gestation [1], and others as late as 14 weeks’ [3]. In any event, the capacity of the fetal thyroid gland to concentrate iodine and to store both iodine and thyroid hormones increases progressively until birth [2]. The fetal thyroid has a much greater relative affinity for radioactive material than does the maternal thyroid. Some researchers have shown that concentration of radioactive iodine in the fetal thyroid gland is at least 10 times greater than that in the maternal thyroid [4], but others claim that the fetal thyroid gland can concentrate as much as 50 times more than can the mother’s [5].

The radiation dose delivered by 2 μCi (74 MBq) of iodine-131 to the fetal thyroid gland at 15 weeks’ gestation cannot be calculated with certainty. With the use of various references as guidelines, however, the radiation dose can be estimated to range from 10,000 to 40,000 rad (100,000–400,000 mGy) [2, 6, 7]. The likelihood that radiation from iodine-131 in this dosage range and delivered during this period of gestation will cause hypothyroidism in the newborn is not actually known because literature on this subject is sparse. Nonetheless, a large study on the incidence of hypothyroidism among infants born to mothers who inadvertently had been given radioactive iodine-131 during pregnancy was conducted by Stoffer and Hamburger in 1975 [8]. These researchers reported on 237 such cases. The doses of iodine-131, when known, ranged from 10 μCi (370 MBq) to 150 μCi (5550 MBq), and gestational age at time of administration ranged from mid first trimester to mid second trimester. In 55 patients, therapeutic abortion was advised and carried out. Among the outcomes of the 182 remaining pregnancies, there were two spontaneous abortions, two stillborn infants, and two infants born with abdominal or chest anomalies, a complication rate that was not greater than what might be expected in a similar number of random pregnancies. However, there were six infants with hypothyroidism, four of whom exhibited mental deficiencies. Thus, hypothyroidism occurred in just over 3% of infants whose mothers had been given iodine-131 and whose pregnancies resulted in birth of a live baby. It is not possible to extrapolate from this data about women who were given 10–150 μCi (370–5550 MBq) of iodine-131 the likelihood of newborn hypothyroidism occurring in the infant of a woman who had been administered 2 μCi (74 MBq) of iodine-131. Notwithstanding scientific uncertainty about a cause-and-effect relationship between newborn hypothyroidism and a 2-μCi (74 MBq) dose of iodine-131, it is quite reasonable to presume, as did the defense attorneys in the case described in this article, that a jury of lay people would undoubtedly determine that a causal relationship did exist.

Both the radiology literature and Standards published by the American College of Radiology (ACR) explicitly state that iodine-131 is contraindicated during pregnancy. A booklet entitled “Radiation Risk: A Primer” [9], published in 1996 by the ACR, admonishes that “radiation exposure of a pregnant female should be avoided unless the patient has an acute medical problem.” Other publications put the prohibition about administering iodine-131 to pregnant women in stronger terms. Russell et al. [5] state that the use of iodine-131 as a diagnostic or therapeutic agent during pregnancy is generally considered to be contraindicated; Green et al. [4] state that it is “amply clear” that radioactive iodine is contraindicated in pregnant women. In his book Radiobiology for the Radiologist, Hall [10] writes that it is “prudent to avoid” using even small amounts of radioactive iodine in pregnant patients “except in extreme cases when there is no alternative.” Hall cautions that in regard to treatment of a patient’s hypothyroidism with iodine-131, “pregnancy is, of course, an absolute contraindication.”

The ACR is quite direct in its prohibition against the use of iodine-131 during pregnancy. Its Standard for the Performance of Therapy with Unsealed Radionuclide Sources [11] specifically names iodine-131 as well as phosphorus-32 and strontium-89 and admonishes, “Female patients must not be pregnant...at the time of orally, intravenously or intraperitoneally administered therapy.” This standard does not address diagnostic use of these radionuclides, but one can presume that the prohibition would be similar. A standard that does deal with diagnostic use of radioactive iodine is the ACR’s Standard for the Performance of Thyroid Scintigraphy and Uptake Measurements [12]. This standard points out that the radiopharmaceutical of choice for thyroid scintigraphy is iodine-123 because the radiation dose it delivers to the thyroid gland is considerably less than that delivered by iodine-131. However, this standard does recognize that use of iodine-131 is acceptable to detect thyroid remnants after surgery or functioning thyroid metastases.

Do radiologists have a duty to assure themselves that women are not pregnant before administering iodine-131, and if so, what is the extent of that duty? Are oral statements made by patients that they are not pregnant sufficient to satisfy the radiologist’s duty? Must radiologists mandate that every woman of childbearing age undergo a pregnancy test before administration of iodine-131? Neither the radiology literature nor any ACR standard provides clear-cut answers to these questions, but some guidance is given.
The ACR Standard for the Performance of Therapy with Unsealed Radionuclide Sources [11] does not call for mandatory pregnancy tests but points out that “pregnancy may be ruled out by a negative beta human chorionic gonadotropin (hCG) test obtained within 48 hours prior to administration of the radiopharmaceutical.” As was reported earlier, this standard does not address the use of iodine-131 in the diagnostic dose range, but the ACR Standard for Diagnostic Procedures Using Radioisotopes in the Nuclear Medicine Department [13] does, stating that imaging facilities should “reasonably attempt” to identify pregnant patients before performing any diagnostic examination involving ionizing radiation. The standard then adds, “There shall be posting of radiation precaution signs in areas where radioactive agents are used or stored [and posting of] warnings to patients to inform the staff if they are or could be pregnant.” Saenger and Kerieakes [14] concur that the posting of signs in the nuclear medicine department is good practice. They suggest language such as, “If there is any possibility that you could be pregnant, notify the technologist or physician before your exam.”

“Radiation Risk: A Primer” [9] suggests that the radiologist’s duty to ascertain whether a patient is pregnant is satisfied by oral communication. It states, “All women of childbearing potential should be questioned as to whether pregnancy could be present at the time of a radiological examination.” A Health and Human Services publication published in 1986 [15] is broader, recommending that “[a] woman who is or thinks she is pregnant should be encouraged to give this information to the physician… Radiologic technologists should be encouraged to ask each patient whether she is pregnant.” This publication also adds that radiology questionnaire forms ordinarily filled out by referring physicians should include a section dealing with the possibility of pregnancy.

No governmental regulation or formal professional standard absolutely requires that radiologists determine before a radiologic procedure, by means of a pregnancy test or otherwise, whether a patient of childbearing age is pregnant [16], although Habert [17] has written that “[t] is prudent policy to require a negative pregnancy test before administering therapeutic doses of iodine-131.” Is it common practice among radiologists to mandate a pregnancy test before administering a diagnostic dose of iodine-131? This question was posed from the podium at the 21st International Congress of Radiology held in September 2000 in Buenos Aires, Argentina. The speaker asked those radiologists who required mandatory pregnancy tests to raise their hand. Of the approximately 700 radiologists seated in the auditorium, six raised their hand.

**Summary and Conclusion**

Malpractice lawsuits alleging that a fetal anomaly or thyroid malfunction was caused by radiation exposure due to administration of a radionuclide are rare [18]. Nonetheless, as this article illustrates, administering a radionuclide such as iodine-131 to a woman who may unknowingly be pregnant represents a clinical hazard to the mother and her fetus as well as a medical–legal hazard to the radiologist.

Risk management in radiology practice can lessen the likelihood of incurring a medical malpractice lawsuit and maximize chances for a successful defense if a suit is filed by enhancing good patient care.

The following risk management pointers will help radiologists meet all three of these objectives:

- Although no governmental regulation or professional standard absolutely requires that radiologists definitively determine the pregnancy status of women of childbearing age for whom administration of iodine-131 or other radionuclides is being considered, it is nonetheless prudent for all radiology facilities to have a policy in place that assists radiologists in making that determination. Commonly used methods for this purpose include having radiology questionnaire forms contain an inquiry about a patient’s possible pregnancy, posting signs throughout the waiting and examining areas of the nuclear medicine department that alert patients to the importance of informing a technologist or physician if they think they are or could be pregnant, having patients fill out a form that includes a question about possible pregnancy, and authorizing nuclear medicine technologists to ask patients whether they are or could be pregnant.

- If patients are asked to complete a questionnaire that includes a question regarding the possibility of pregnancy, the patient should be asked to affix her signature to the form after completion. Documentation of this kind would preclude the situation that arose in the case described in this article—namely, the finger-pointing between the patient and the nuclear medicine technologist in which the technologist says, “I asked the patient about possible pregnancy,” but the patient says, “You did not.” If patients are asked orally whether they are or could be pregnant, the name of the questioner and the patient’s specific response should be documented in writing.

  - Whenever possible, iodine-123, a radionuclide that generates 1% of the radiation exposure of a comparable dose of iodine-131 [7], should be used in diagnostic examinations.

**References**