

Malpractice Issues in Radiology

Radiation-Induced Skin Injuries and Fluoroscopy

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The Case

A 57-year-old, 6-foot-2-inch (188 cm) tall man weighing 220 lb (99 kg) developed angina pectoris and exertional dyspnea. After his exercise stress test and radionuclide scan of the heart were interpreted as indicating myocardial ischemia, the patient underwent cardiac catheterization. On finding three separate areas of marked stenosis in the left circumflex artery, a cardiologist proceeded to perform balloon dilation and adjunctive rotational atherectomy. Although the procedure was lengthy, involving 173 min of fluoroscopy time and a multitude of cinefluorographic images, the cardiologist was successful in dilating and stenting the three arterial lesions and in reestablishing good arterial flow.

Five months later, the patient experienced a recurrence of chest discomfort. Diagnostic cardiac catheterization revealed excellent flow in the left circumflex artery, but now a marked degree of stenosis was noted in the left anterior descending artery. In another rather lengthy procedure that involved 74 min of fluoroscopy time and more than 2700 cine images, the cardiologist performed balloon dilation and adjunctive rotational atherectomy to reestablish arterial flow. At the conclusion of the procedure, the cardiologist felt satisfied that he had achieved a superb angiographic result.

Although the patient did well from a cardiologic point of view and remained free of

chest pain, within 24 hr after the second procedure he, nonetheless, developed a painful and erythematous area involving the skin below his right scapula. Over the next 5 months the affected skin went on to ulcerate and then necrose. Eventually, the patient underwent extensive skin grafting.

One year later the patient filed a medical malpractice lawsuit against the cardiologist, alleging that the cardiologist had been negligent in using an inordinate amount of fluoroscopy during the angioplasty procedures, and that the radiation resulting from this excessive fluoroscopy not only caused severe skin burns, but also increased the patient's likelihood of later developing lung cancer. The patient also charged that he had not been informed by the cardiologist before the angioplasties that the procedures might cause skin burns and eventual lung cancer. Efforts to achieve an out-of-court settlement of the lawsuit were unsuccessful, and the case proceeded to a jury trial.

The Trial

At trial, the patient testified that he had visited five doctors over a several-month period after the second angioplasty before he found one who correctly diagnosed his skin condition. Finally, testified the patient, he visited a dermatologist "who looked at it and said, 'Heck, you've got a radiation burn. Did you have chemo or something?'" "No,"

the patient said he responded, "just angioplasty" [2]. The patient also testified that after the first angioplasty he had developed a "rash" on his upper back that, according to the dermatologist, represented an "undiagnosed radiation burn."

A radiation physicist retained by the attorney for the plaintiff testified as to the amount of radiation received by the patient. The physicist explained that the actual radiation dose to which the skin of the patient is exposed during a radiologic interventional procedure depends on many factors, including patient dimensions, orientation and proximity of the fluoroscope tube relative to the skin, dose-rate settings for fluoroscopy and fluorography, kilovoltage, and tube current. The expert in physics estimated that during the first procedure the patient received a total combined skin dose from fluoroscopy and cinefluorography of 27–43 Gy (2700–4300 rad). The physicist estimated that the total dose received from both fluoroscopy and cinefluorography during the patient's second procedure was 8–13 Gy (800–1300 rad). The physicist pointed out that the generally accepted single-dose threshold for erythema is 6 Gy (600 rad) and, in fact, the threshold is even lower if a patient has undergone previous exposure to radiation in the same area. The physicist concluded that the total skin dose clearly exceeded the thresholds known to result in the type of injury sustained by the patient, particularly because there was undoubtedly overlap

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of the areas of skin exposed during the two angioplast procedures.

A radiobiologist retained by the attorney for the plaintiff testified that as a result of the radiation dose received by the patient, the patient would not only be at increased risk for developing additional radiation-induced coronary atherosclerosis, but for developing cancer of the lung as well. Lung cancer would constitute the major concern for the patient's future health, concluded the radiobiologist, and because the fact that the patient was a smoker would further increase this risk "since it is known that radiation and smoking act synergistically to induce lung cancer."

A cardiologist testifying on behalf of the patient charged that the defendant cardiologist had breached the standard of care in multiple ways. According to the cardiology expert, the defendant cardiologist should not have undertaken the second angioplasty until he had examined the area of the patient's back that had been exposed during the first angioplasty and warned the patient about the possibility of incurring additional radiation injury to the skin. The expert also criticized the defendant cardiologist for ignoring the dose-monitoring equipment that was attached to the fluoroscopic unit, for overutilizing fluoroscopy and cinefluorography far beyond that which is acceptable, and for failing to call in another interventional cardiologist for assistance once he encountered technical problems that necessitated using excessive amounts of fluoroscopy.

When called to the witness stand, the defendant cardiologist denied that he had been negligent in performing the cardiac catheterizations and angioplasties. The patient had extensive coronary artery disease—three separate lesions within the left circumflex artery on the first occasion and a densely calcified lesion in the left anterior descending artery on the second occasion—asserted the defendant cardiologist. The cardiologist acknowledged that both procedures were lengthy and involved a considerable amount of fluoroscopy and cinefluorography, but argued that because of the extent of the patient's coronary artery disease, there would have been no way to shorten the procedure times. On the issue of informed consent and preprocedure examination of the patient's skin, the defendant cardiologist stated that he saw no need to look at the patient's back or discuss the possibility of radiation dermatitis with the patient, inasmuch as this type of complication was extremely rare.

The defendant cardiologist's testimony was supported by a cardiology expert retained by the defense. The expert contended that his re-

view of the cineangiograms obtained during the two angioplasties made it clear that the degree and the extent of the atheromatous disease were extensive, indeed quite remarkable for an individual of the patient's age, and that the diseased areas were laden with calcific deposits. The calcium in turn rendered the arteries less amenable to balloon angioplasty, thereby necessitating rotation atherectomy and prolonged fluoroscopic times, explained the cardiology expert for the defense. The expert also agreed with the defendant cardiologist that examining the patient's back and including within informed consent the possibility of radiation injury to the skin were not necessary. The defense expert concluded that both procedures were clearly indicated and well executed, the lesions were successfully revascularized, a near-ideal angiographic result was achieved, and the skin reaction sustained by the patient was unavoidable and clearly not the result of a violation of the standard of care.

A radiation physicist retained by the attorney for the defendant cardiologist acknowledged that the amount of fluoroscopy and cinefluorography used in the procedures was high, but contended that this was unavoidable because of the technical difficulties encountered while performing the angioplasties. Although the physicist further acknowledged that the skin reaction was undoubtedly related to the radiation exposure, he flatly denied that there was credible scientific evidence to indicate that the patient would have any increased risk for worsening of his coronary atherosclerosis or for developing lung cancer in the future.

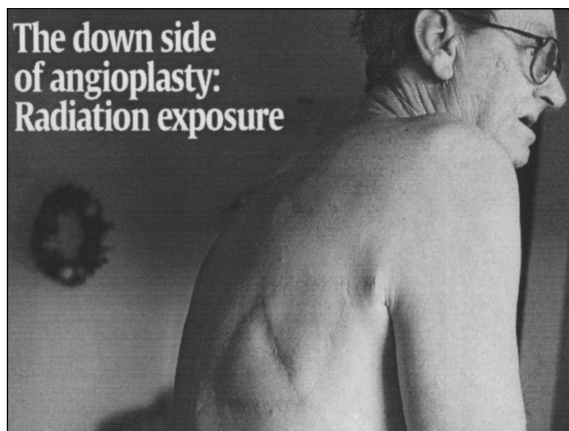
At the conclusion of the trial and after due deliberation, the jury found that the defendant cardiologist had indeed been negligent and was liable for the damages sustained by the patient. The jury awarded the patient \$1 million in com-

pensation [1]. The verdict was reported by the news media, including *USA Today* [2] (Fig. 1).

Discussion

Almost immediately after the announcement in 1895 of Wilhelm Roentgen's discovery of the X-ray beam, a number of manufacturers began producing X-ray apparatuses designed to diagnose medical conditions. Because the potential dangers of X-radiation were not well understood at that time and equipment used low-energy X-ray tubes without shielding, beam filtration, and coning, many patients sustained skin injuries as a result of undergoing diagnostic radiography. Where there was medically induced injury, there was malpractice litigation. In 1896, in what was apparently the first malpractice lawsuit in the United States to be brought for damages sustained by exposure to X rays, a Chicago laborer sued a physician who specialized in using this new diagnostic modality, claiming that an ulcerating burn of the skin on his ankle had developed as a result of radiologic studies. The patient had fractured his ankle, and radiographs that were obtained had necessitated exposure times of 35–40 min each. The skin injury eventually led to amputation, and the jury awarded the patient \$10,000 in damages [3].

It was not long thereafter that a medical malpractice lawsuit dealing with another case of complications of diagnostic radiography reached the United States Supreme Court. In 1905 in Washington, DC, a woman who had undergone seven radiologic examinations to diagnose a rib fracture sustained injury to her skin and sued the physician who had operated the radiography unit. At trial a jury exonerated the physician because the attorney for the plaintiff had been unable to find an expert who



**The down side
of angioplasty:
Radiation exposure**

Fig. 1.—Headline and photograph accompanying article published in *USA Today* [2] reporting jury award of \$1 million to 57-year-old man who sustained serious skin injury after two coronary artery angioplasties that occurred 5 months apart. Patient filed medical malpractice lawsuit alleging use of excessive fluoroscopy. (Reprinted with permission from Cohn J, Pittsburgh, PA)

Malpractice Issues in Radiology

would testify that the defendant physician had been negligent in the operation of the equipment. The patient appealed, and the case finally reached the nation's Supreme Court. In its ruling, the court acknowledged that as a result of the radiologic examination, the woman "felt bad effects," and the portion of her body that had been "exposed to the X-ray...was red and irritated...and burned...and caused and continues to cause much suffering" [4]. The court took note of and was persuaded by experts testifying on behalf of the defendant physician, a "specialist in the use of the X ray for diagnostic purposes," who stated that it was "impossible, by the use of any degree of care, to prevent...or guard absolutely against...occasional X-ray burns from use of the apparatus" [4]. The Supreme Court affirmed the jury's finding that the defendant physician was not liable for malpractice.

For the next 80 years there was a dearth of reported cases of radiographically or fluoroscopically induced skin injuries. Indeed, as has been pointed out by Koenig et al. [5] in their comprehensive review of the literature published elsewhere in this issue of the *AJR*, of 73 cases of skin injuries resulting from fluoroscopically guided procedures, only two occurred before 1990. The infrequency of fluoroscopic complications perhaps can be explained by the fact that radiation dose rates for screen fluoroscopy in common use until the late 1960s were in the range of 0.03 to 0.05 Gy (3–5 rad) per minute [6]. Inasmuch as fluoroscopy use was limited mainly to gastrointestinal examinations that rarely exceeded 15 min in length and the means of reducing radiation exposure through appropriate filtration and coning were well understood, the likelihood of skin injury was remote. The introduction into the radiology community in the 1960s and 1970s of the X-ray image intensifier lowered the dose rate even further.

The birth of interventional radiology, with its requisite higher dose radiographic equipment and procedures that often necessitate long fluoroscopic times, drastically increased the radiation exposure to which patients are subjected. In 1991, Cagnon et al. [7] warned radiologists that high-level fluoroscopic boost options would allow equipment to reach dose rates of 0.93 Gy (93 rad) per minute. In an article published in the *ACR* (American College of Radiology) *Bulletin* in 1992, the chairman of the ACR Commission on Physics and Radiation Safety admonished the radiology community that newly manufactured fluoroscopy equipment using a high-level control mode could generate radiation exposure rates of as high as 1.2 Gy

(120 rad) per minute and that its use in interventional procedures that often involve prolonged fluoroscopy times could result in patient exposures exceeding 20 Gy (2000 rad), more than enough to cause serious radiation skin burns [8].

Not long thereafter, radiation injuries drew the attention of the federal government. In September 1994, the United States Food and Drug Administration (FDA) issued public health advisories that dealt with serious skin injuries as a result of radiation received during fluoroscopy [9, 10]. The FDA voiced its concern that an increasing number of invasive procedures using fluoroscopic guidance were inducing skin injuries as a result of exposure to radiation because of prolonged fluoroscopy times. These procedures included angioplasties of coronary and other vessels, cardiac ablations, vascular embolizations, stent and filter placements, thrombolyses, transhepatic cholangiographies, endoscopic retrograde cholangiopancreatographies, nephrostomies, biliary drainages, urinary or biliary stone removals, and transjugular intrahepatic portosystemic shunts. The FDA advisory warned physicians performing these procedures to be aware of the potential for causing serious injury and advised them to observe certain safety principals. Safety principles enumerated included recommendations that physicians establish standard operating procedures and clinical protocols, know the radiation dose rates for specific fluoroscopic procedures, assess each procedure's protocol for the potential for radiation injury to the patient, modify the protocol as appropriate to limit radiation exposure, and enlist a qualified medical physicist for consultation. One year later the FDA issued another advisory that addressed the issues of which patients should have information recorded regarding radiation exposure and what kind of information should be included in that recording [11].

As might be anticipated, the ACR has remained inextricably linked to radiation safety issues. In the past decade the ACR has addressed in four different Standards the fact that excessive fluoroscopy used during interventional radiologic procedures can cause severe skin injury. Radiation dose to patients is directly addressed in the ACR Standard for Diagnostic Medical Physics Performance Monitoring of Radiographic and Fluoroscopic Equipment [12], originally passed in 1992 and most recently amended in 1997:

Patient radiation dose shall be evaluated for radiographic and fluoroscopic equipment at least annually. Tables of pa-

tient radiation exposure for representative examinations shall be prepared and supplied to the facility. These tables shall be prepared using measured radiation output data and imaging techniques provided by the facility. These results shall be compared with appropriate guidelines or recommendations when they are available. The medical physicist should assist facilities in developing policies and procedures to evaluate patient risk from studies and interventions requiring prolonged fluoroscopy.

Three ACR standards formulated between 1990 and 1995 and revised between 1995 and 2000—ACR Standard for the Performance of Percutaneous Nephrostomy [13], ACR Standard for the Performance of Image-Guided Percutaneous Needle Biopsy (PNB) in Adults [14], and ACR Standard for Specifications and Performance of Image-Guided Percutaneous Drainage/Aspiration of Abscesses and Fluid Collections (PDAFC) in Adults [15]—contain similar language with respect to patient radiation exposure. They all mandate that the physician performing the specific procedure should have a thorough understanding of radiation safety considerations, including the principles of radiation protection, the hazards of radiation exposure to both patients and radiology personnel, and the monitoring requirements of the imaging methods. These standards go on to include statements that a medical physicist should have the responsibility for overseeing the equipment quality control and for monitoring fluoroscopy studies. The two standards that became effective in 2000 also add that when fluoroscopy is used, fluoroscopic time should be kept to a minimum and that "the operator will use only as much fluoroscopy as is necessary to complete" [14, 15] the procedure.

In addition to these standards, the ACR in 1996 also published a booklet entitled "Radiation Risk: A Primer" [16]. In it, the ACR urges all radiologists to accomplish fluoroscopically guided interventional studies in a way that minimizes patient radiation dose. The ACR again admonishes radiologists to be familiar with dose-reducing features available on fluoroscopy equipment and with the radiation safety issues identified by the FDA that carry the risk of radiation-induced skin injury. Specific suggestions are given as to how to reduce radiation exposure.

Although the case described in this article involved a patient injury that resulted from radiation received during a coronary angioplasty performed by a cardiologist, similar injuries have occurred with all kinds of inter-

ventional procedures performed by radiologists. For example, in 1994 in Virginia, a patient who had undergone an 8-hr thyroid arteriogram in the radiology department of a university hospital and had developed, shortly thereafter, a radiation burn on her back that required skin grafts sued the interventional radiologist for using "excessive" fluoroscopy. During a trial in federal court, the plaintiff retained an expert in radiation physics who testified that the amount of radiation received by the patient was indeed excessive and sufficient to cause severe skin injury. The court ruled in favor of the defendant radiologist because the plaintiff did not provide any expert testimony that the defendant radiologist had been negligent [17].

In 1999, Wagner et al. [18] described a case in which a patient sustained a 10 × 7 cm severe skin ulceration as a result of a transjugular intrahepatic portosystemic shunt (TIPS) procedure. To determine the level of radiation to which these patients were being exposed, the researchers reviewed 50 TIPS procedures; although the researchers found that the procedures averaged 5 hr, the actual fluoroscopy times ranged from 60 to 90 min and the estimated skin doses ranged from 5 to 8 Gy (500–800 rad). However, maximum radiation dose in certain patients reached 12 Gy (1200 rad). Wagner et al. discovered that skin injuries were more common in patients who underwent multiple interventional procedures and in patients with collagen diseases such as rheumatoid arthritis, systemic lupus erythematosus, scleroderma, or mixed connective tissue disease. Exaggerated and intense reactions after high-dose interventional procedures were also more frequent in patients with diabetes and in patients receiving certain chemotherapeutic drugs.

As techniques in interventional radiology continue to advance and radiology equipment becomes even more sophisticated, patients are likely to be exposed to higher doses of radiation, which in turn may well lead to more frequent and more severe injuries. An example of this is technology that is currently being introduced into the radiology community—CT fluoroscopy. It generates dose rates to the skin of patients of up to 0.01 Gy (1 rad) per second, rates that can easily achieve dose levels that are far in excess of those required to produce erythema [19].

In an article appearing elsewhere in this issue of the *AJR*, Koenig et al. [20] discuss in detail the natural history of skin reactions to radiation, including threshold doses and times of onset. These researchers also enumerate the multiple technical factors that contribute to radiation injury to patients from fluoroscopy and fluorogra-

phy. These factors include long fluoroscopy times through thick body parts, lack of radiation dose monitoring, incomplete training of physicians, reticence of interventional physicians to seek more experienced help when faced with a difficult procedure, unnecessary direct radiation of certain body parts such as arms and breasts, overuse of high-dose-rate modes of operation, and failure to use heavy beam filtration and remove the grid when appropriate.

A discussion of one of the allegations made in the lawsuit presented here—that the radiation to which the patient was exposed increased his risk of developing lung cancer in the future—is beyond the scope of this article. Suffice it to say, however, that excessive fluoroscopy has been implicated as a cause of breast cancer but thus far there is no evidence to link fluoroscopy to lung cancer. Lung cancer has been found to be more common in miners who have worked with uranium or ore from which radium has been extracted, but a definite cause-and-effect relationship between occupational exposure to radiation and lung cancer remains nebulous [21].

One final point should be made regarding whether education can modify behavior of fluoroscopists. In 1994 Swayne et al. [22] described the implementation of an instructional program covering basic principles of radiation physics, radiobiology, radiation safety, and fluoroscopic techniques for 73 nonradiologist physicians (28 surgeons, 23 cardiologists, eight orthopedists, eight gastroenterologists, and six pulmonologists) whose medical practices involved using fluoroscopy. The educational program consisted of an introductory 1-hr lecture that emphasized practical aspects of radiation protection and precautions, particularly related to fluoroscopy. In addition, these researchers provided the nonradiology physicians with a 10-page booklet that presented additional basic information on radiation physics. As a result of this project, mean fluoroscopy times in procedures performed by these nonradiology physicians were reduced from 7 to 4.4 min, a decrease of 37%.

Summary and Risk Management

Although radiation-induced adverse effects in the skin became apparent almost immediately after discovery of the X ray, it was not until the 1990s, when interventional radiology reached maturity, that radiation injuries to the skin resulting from diagnostic radiologic procedures became recognized as a real rather than a theoretic hazard to patients. Federal and local governmental agencies, professional organizations such as the ACR, and a multitude of researchers writing in professional journals

have all drawn a great deal of attention to the issue of skin injury resulting from fluoroscopy. In the midst of this attention, radiologists should remind themselves of the truism that any radiologic procedure that places a patient at risk for sustaining a complication more than likely will also subject the radiologist to the threat of malpractice litigation.

Risk management can minimize the likelihood of incurring medical malpractice lawsuits involving injuries due to fluoroscopy, maximize the chances of a successful defense if such a suit is filed, and enhance patient care. The following risk management pointers will help radiologists meet these objectives:

- Radiologists should ensure that all equipment used in interventional or other fluoroscopic procedures is maintained in optimal working condition so that acceptable image quality is achieved with the lowest possible radiation dose, and that appropriate individuals conduct and document periodic inspections.
- Radiologists performing interventional procedures should be familiar with, and make use of, any available dose-reducing features such as low-dose fluoroscopy mode, collimators, and image-hold capabilities. Fluoroscopy times should be kept to a minimum and, if possible, the beam entry site should be changed periodically during prolonged procedures.
- Consideration should be given to including radiation injury as part of the discussion of risks and benefits of the procedure during the consent process in patients who are at high risk for developing skin complications, such as patients with connective tissue collagen disease and diabetes. Radiologists should also consider examining the skin of patients on whom a fluoroscopically guided interventional procedure is being repeated.
- Dosimeters allowing dose measurement during interventional procedures should be used if possible. If a procedure has been prolonged and the radiation dose to the skin is known to have been high, the patient should be advised to undergo an examination of the skin 2–4 weeks after completion of the procedure.
- Radiologists whose practices involve fluoroscopy, especially those performing interventional procedures, should be familiar with the FDA advisories of 1994 and 1995 and appropriate standards of the ACR that address skin injuries to patients during fluoroscopically guided procedures.

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Malpractice Issues in Radiology

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