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Radiation management and credentialing of fluoroscopy users

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Abstract During the last 15 years, developments in X-ray technologies have substantially improved the ability of practitioners to treat patients using fluoroscopically guided interventional techniques. Many of these procedures require a greater use of fluoroscopy and more recording of images. This increases the potential for radiation-induced dermatitis and epilation, as well as severe radiation-induced burns to patients. Many fluoroscope operators are untrained in radiation management and do not realize that these procedures increase the risk of radiation injury and radiation-induced cancer in personnel as well as patients. The hands of long-time fluoroscope operators in some cases exhibit radiation damage—especially when sound radiation protection practices have not been followed. In response, the Center for Devices and Radiological Health of the United States Food and Drug Administration has issued an Advisory calling for proper training of operators. Hospitals and administrators need to support and enforce the need for this training by requiring documentation of credentials in radiation management as a prerequisite for obtaining fluoroscopy privileges. A concerted effort on the part of professional medical organizations and regulatory agencies will be required to train fluoroscopy users to prevent physicians from unwittingly imparting serious radiation injuries to their patients.

Keywords Credentialing fluoroscopist · Fluoroscopist radiation dose

Introduction

During the last 15 years, developments in X-ray technologies have substantially improved the ability of practitioners

to treat patients using fluoroscopically guided interventional techniques. Many of these procedures require a greater use of fluoroscopy and serial imaging (cine). This has increased the potential for radiation-induced dermatitis and epilation, as well as severe radiation-induced burns to patients. In fact, several multimillion-dollar judgments have recently been awarded to plaintiffs following such injuries, and many more cases are in litigation.

In response, the Center for Devices and Radiological Health of the United States Food and Drug Administration issued an Advisory [1] warning health-care facilities of the potential for radiation-induced burns to patients from fluoroscopic procedures. A separate article cites the growing number of cases of severe injury [2]. To date, the FDA has documented about 100 cases of radiation-induced burns. European investigations have confirmed at least 15 cases of radiation dermatitis that resulted from cardiological procedures [3–6]. Additional case histories of injuries to both patients and physicians have appeared in the literature [7–9]. Some of the radiation-induced injuries discussed in these studies have required skin grafts resulting in permanent disfigurement. Cataracts and serious radiation injuries to hands have also been observed in physicians who have recently (as late as 1994) started using fluoroscopy in their practice [10].

Fluoroscopy users must realize that these high-dose procedures increase the risk of radiation injury and radiation-induced cancer in personnel as well as patients. We describe here positive, proactive steps that can be taken to credential fluoroscopists in radiation management and thereby help to prevent such injuries.

Discussion

Government alert

The FDA Advisory alerted facilities to assure proper training of fluoroscopy personnel in light of “occasional

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but severe” radiation injuries from invasive procedures. Specific recommendations of this Advisory include the following:

- That all operators be trained and understand system operation, including the implications for radiation exposure from each mode of operation
- That facilities ensure that physicians performing fluoroscopic procedures have education so they can, on a case-by-case basis, assess risks and benefits for individual patients, considering variables such as age, beam location and direction, tissues in the beam and previous fluoroscopic procedures or radiation therapy
- That patients be counseled regarding the symptoms and risks when radiation exposures are expected to be high
- That physicians justify and limit the use of high dose rate modes of operation
- *That facilities assure appropriate credentials and training for physicians performing fluoroscopy*

Unfortunately, with the general exception of radiologists and a few other specialists, a large proportion of physicians who use fluoroscopy have no training or credentials in management of radiation or the biological effects associated with its use. The FDA warning points out that training of physicians for modern-day use of the fluoroscope is for the most part insufficient and needs to be expanded. Many prominent medical organizations such as the American College of Cardiology [11] and the American Heart Association [12] have published strongly worded position papers agreeing that there is an exigent need for such training. The consensus is that “rubber-stamp” privileges [13, 14] to perform fluoroscopic procedures should no longer be granted.

Potential JCAHO involvement

According to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), there are currently no JCAHO standards addressing training and credentialing in radiation management for fluoroscopy practitioners. Rather, JCAHO requires that practitioners be privileged for all activities they perform and that each organization defines its criteria for receiving each privilege. There are several regulatory agencies and task groups affiliated with national organizations that are in the process of preparing recommendations for the delineation of privileges for practitioners to use fluoroscopic X-ray equipment. Based on previous publications and discussions by a number of interested groups, their recommendations will likely include statements similar to the following:

1. All physicians who use or operate fluoroscopic X-ray systems should have this clinical privilege specifically delineated based on evidence of completion of specific training in radiation safety, the management of fluoroscopic radiation and operation of the specific fluoroscopic X-ray system(s) used in the facility.

2. Such training in radiation safety and fluoroscopic radiation management shall be in addition to any clinical training or qualifications to perform the specific clinical diagnostic or therapeutic procedure (s) for which the fluoroscopic systems are used.
3. The facility requires specific documentation of appropriate training prior to granting fluoroscopic privileges and evidence of appropriate training with respect to the operation of the specific fluoroscopic systems utilized in the facility. Training in the operation of the specific fluoroscopic equipment to be utilized in the facility is described and documented in the records of the facility prior to the granting of such privilege.
4. The facility requires periodic (annual) in-service training or evidence of continuing medical education in radiation safety and management for all physicians granted privileges to use fluoroscopic X-ray equipment.

The enactment of such measures could help to eliminate radiation burns that lead to statements such as that of a cardiologist in a recent deposition for a patient’s severe burn he had unwittingly caused: “If I had only known that I could have done that to my patient”. The patient was subsequently awarded a substantial monetary judgment.

Focused training needed

Whether or not the JCAHO becomes involved, it is becoming increasingly clear that all practitioners who use fluoroscopic radiation should be required to complete focused training in radiation physics, radiation biology and radiation safety. Training should include the pertinent aspects of radiation management in the clinical setting so that these physicians will be able to acceptably control risks to patients and personnel. The American Association of Physicists in Medicine (AAPM) has issued a comprehensive report primarily designed to assist medical physicists in managing the use of radiation from fluoroscopic equipment [15]. The report suggests several possible formats for training:

- Self-study using videotape, slides, books and self-tests [16]
- Lectures to provide interaction between experts and physicians
- Hands-on demonstrations

The task of securing these materials and lecturers and documenting everything will no doubt ultimately fall on the shoulders of the Radiology Administrator. Completion of an approved educational program (with appropriate testing) provides the evidence needed by the facility to approve the practitioner’s qualifications. A physician can be credentialed simply by completing an appropriate course(s) in radiation management. The JCAHO audit would ensure that program goals are being achieved.

What fluoroscopists should know: unit-specific training

The configuration of the system control panel and other factors differ from machine to machine. Many units have special controls that are used for specific applications to control dose rate and image quality. The very high dose rate modes needed to produce high-quality images are rarely required for fluoroscopic purposes. Therefore, it is imperative that operators understand how to activate the controls that will provide acceptable image quality with the lowest dose levels. Instruction of staff by manufacturer's application specialists should occur before new equipment is placed into service. Many medical physicists are board-certified in diagnostic imaging physics and can also assist with information about equipment function.

Conclusion

Many fluoroscopists enter their practices without the appropriate knowledge base to safely manage the radiation that they deliver to their patients and staff. Therefore, training of every fluoroscopist, at minimum on the topics and concepts presented above, must be the foundation of any program to manage patient dose during fluoroscopy. It is likely that many of the fluoroscopic radiation burns that have occurred could have been avoided or reduced in severity if the physicians had been appropriately trained in radiation management.

Hospitals and administrators can proactively enforce such training by requiring documentation of credentials in radiation management as a prerequisite for obtaining fluoroscopy privileges. Concern about malpractice litigation should provide convincing motivation for facilities to proactively seek credentialing and to welcome external audits. But the major motivation should result from the innate ethical realization that we should always do the "right thing" for our patients and staff.

It will take a concerted effort on the part of professional medical organizations and regulatory agencies to ensure that the wealth of preventative information now available is disseminated to and digested by these physicians who can potentially although unwittingly seriously injure their patients. All would agree that even one radiation injury caused by lack of education on the part of a fluoroscopist is unacceptable. Thus, training in radiation management must become a required component in the educational experience of every physician who uses fluoroscopy in his or her practice.

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