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Deterministic Effects of Interventional Radiology Procedures

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Abstract

The purpose of this paper is to describe deterministic radiation injuries reported to the Food and Drug Administration (FDA) that resulted from therapeutic, interventional procedures performed under fluoroscopic guidance, and to investigate the procedure or equipment-related factors that may have contributed to the injury Reports submitted to the FDA under both mandatory and voluntary reporting requirements which described radiation-induced skin injuries from fluoroscopy were investigated. Serious skin injuries, including moist desquamation and tissue necrosis, have occurred since 1992 These injuries have resulted from a variety of interventional procedures which have required extended periods of fluoroscopy compared to typical diagnostic procedures. Facilities conducting therapeutic interventional procedures need to be aware of the potential for patient radiation injury and take appropriate steps to limit the potential for injury.

KEYWORDS - radiation injury, radiation protection, fluoroscopy, interventional radiology

Introduction

Serious, radiation-induced skin injuries to patients which resulted from fluoroscopically-guided, therapeutic, interventional procedures have recently been reported (1,2,3,4,5). The purpose of this paper is to describe the nature and circumstances of a number of these injuries, to alert staff involved in these procedures of this potential complication, to indicate the types of procedures which have resulted in such injuries, and to suggest steps which can taken to reduce the potential for such injuries.

Background

During 1992 and 1993, the staff of the Center for Devices and Radiological Health of the Food and Drug Administration (FDA) received a number of anecdotal, unverifiable reports of possible radiation injury to patients resulting from the use of fluoroscopic x-ray systems.

In early 1994, information became available which permitted verification of the nature and circumstances of some of these injuries This information came primarily through the mandatory reporting requirements imposed on manufacturers and users of medical devices under the Safe Medical Devices Act of 1990 (6,7) As a result of these requirements, FDA began to receive reports of radiation-induced injuries during fluoroscopy.

Fluoroscopically-guided, therapeutic, interventional procedures are being performed with increasing frequency (8). These procedures are often the only available treatment, or the treatment of choice, to address serious, life-threatening conditions Many of these procedures also have the characteristic of requiring extended periods of fluoroscopic exposure compared to the exposure times typically associated with diagnostic procedures The introduction of an array of new devices to facilitate the interventional treatment of a variety of vascular and other conditions is contributing to increased numbers of interventional procedures The risk which arises from these procedures is due to the extended fluoroscopic exposure times required and the often stationary x-ray beam position during a significant portion of this time. Table 1 illustrates the types of injuries which result from absorbed dose to the skin and the periods of fluoroscopic exposure required to produce these effects under typical dose rates.

Methods

Reports of radiation injury resulting from fluoroscopy which come to the attention of the FDA are investigated to the extent possible to determine the nature and circumstances of the injury. The reports are usually received through the manufacturer of the x-ray system and contain minimal information regarding the circumstances of the injury. The investigations are often conducted by telephone calls, letters and personal visits to the facilities or individuals involved Provision of additional information to the FDA has been voluntary to date and a majority of the facilities contacted declined to provide additional information due to concerns regarding liability or confidentiality

Results

Table 2 is a summary of the types of interventional procedures which have resulted in reports of skin injuries and the number of each type which had come to the attention of the FDA by October 1995. The severity of the injuries reported range from erythema in a few cases, through moist desquamation, to skin necrosis requiring skin grafting for treatment in the most serious cases. It is very probable that the injuries which have come to the attention of the FDA represent an unknown fraction of the total number of radiation-induced injuries resulting from fluoroscopically-guided procedures Since October 1995, reports of additional injuries continue to be received, however comprehensive follow-up has not been undertaken to date for some of these In addition, reports of injuries have appeared in the literature from other countries (3,4).

A sample of the injuries reported to the FDA is presented in Table 3. These are selected to illustrate the range of procedures and the severity of the injuries reported The attempted investigation of the majority of the incidents was unsuccessful in obtaining information which would permit estimation of the absorbed doses to the skin which occurred. Either no records were maintained of the extent of the fluoroscopic exposure time and other technique factors or the facility was unwilling to share additional information because of ongoing legal actions or concerns regarding liability or adverse publicity.

Table 4 presents an example of the magnitude of the skin exposures which can result from a complex case involving multiple diagnostic and therapeutic procedures. The patient required multiple hepatic and biliary procedures, including percutaneous cholangiography, mesenteric angiography and multiple embolization procedures during a four-week period The patient received an unknown amount of exposure from procedures performed prior to arrival at the tertiary care facility The estimates of skin exposure were made by staff of the facility from data on system technique factors, total fluoroscopic exposure times, number of digital subtraction angiography frames, exposure rates during fluoroscopy and exposure per frame during DSA, patient thickness and system geometry which were recorded by the facility under a program instituted to monitor patient exposures.

The total absorbed dose given in Table 4 of approximately 22 Gy is not localized to a specific area of skin; the location and size of the irradiated area varied with procedure and projection. The x-ray field sizes and entrance field locations were not monitored during the procedures. However, most of the irradiation would have been to the area of the lower right back with a significant probability of overlapping of fields Thus, the total exposure from Table 4 is an upper limit on the exposure to any specific area of skin and provides an indication that the potential for skin injury was significant in this case. In addition, the effect of dose fractionation due to the dose being delivered over a four-week period further complicates the estimation of the expected severity of the injury. Whether skin injury resulted from this series of procedures is unknown because the patient died two days after the last procedure

Example of Injury

An example of a skin injury attributable to x-rays from fluoroscopy was given in Figure 2 of Reference 10. That example, described herein as patient A in Table 3, is a 40-year-old male who underwent coronary angiography, coronary angioplasty and a second angiography procedure due to complications, followed by a coronary-artery by-pass graft, all on March 29, 1990. Figures given in the reference demonstrate the progression of the injury. The injury was described as "turning red about one month after the procedure and peeling a week later." In mid-May 1990, it had the appearance of a second-degree burn. In late summer 1990, it had the appearance of a healed burn, except for a small ulcerated area present near the center. Skin breakdown continued over the following months with progressive necrosis. The injury eventually required a skin graft. The magnitude of the skin dose received by this patient is not known. However, from the nature of the injury, it is probable that the dose exceeded 20 Gy (9).

FDA Recommendations to Reduce Radiation-Induced Skin Injuries

Review of the circumstances of many of the injuries revealed a lack of appreciation by the physicians performing these procedures, prior to observing the injury, of the magnitude of the skin doses which can result from the long exposure times which may be required by complex interventional procedures. This observation led the FDA to issue a Public Health Advisory on September 30, 1994, to alert the radiological community to this concern and to suggest actions which should be taken to reduce the potential for radiation-induced skin injuries (1). These actions included:

* Establishing standard procedures and protocols for each procedure, including consideration of fluoroscopy exposure time,
* Determining the radiation dose rates for specific fluoroscopy systems and for all operating modes,
* Assessing each protocol for the potential for radiation injury to the patient,
* Modifying protocols, when appropriate, to minimize cumulative absorbed dose to any specific skin area and using equipment which aids in minimizing absorbed dose. An international standard currently is being developed by a working group of the International Electrotechnical Commission which will provide particular requirements for the safety of x-ray equipment for interventional procedures. This standard will provide for equipment features which will aid in minimizing absorbed dose. The U.S. FDA is beginning efforts to incorporate similar requirements in the U.S.

performance standard for diagnostic x-ray systems

Recording of the Absorbed Dose to the Patient's Skin

FDA also suggested that information be recorded in the patient's record which would permit estimation of absorbed dose to the skin from interventional procedures.

In a September 15, 1995, follow-up to this suggestion, FDA recommended that the facility record in the patient's medical record information regarding absorbed dose to the skin for any procedure with the potential for a skin dose approaching or exceeding some threshold dose for injury (11). This threshold dose for the recording of data should be established by the facility FDA suggests a threshold absorbed dose in skin of 1 Gy. The following procedures are likely to meet this criterion due to their potential for long exposure times

Radio frequency cardiac catheter ablation
Vascular embolization
Transjugular interhepatic portosystemic shunt
Percutaneous endovascular reconstruction

The information suggested for recording in the patient's medical record includes

* An identification of those areas of the patient's skin that received an absorbed dose that may approach or exceed the selected threshold, and
* An estimate of the cumulative absorbed dose to each irradiated area noted in the patient record or sufficient data to permit estimation of the absorbed dose to those areas of skin.

A key requirement for the prevention or minimization of these types of injuries is to assure that all physicians performing interventional procedures are adequately trained in radiation safety and proper operation of the complex x-ray systems typically used This is especially important for non-radiologists users of fluoroscopic systems whose formal training in the subjects is often lacking or minimal at best. Health care facilities or government agencies should implement programs to credential or accredit physicians for the use of fluoroscopy to insure that a minimal level of knowledge of radiation safety procedures is demonstrated before they are permitted to perform these procedures and that periodic updates are obtained

Conclusions

Serious skin injuries have recently occurred as a result of interventional procedures involving extended fluoroscopic exposure times.

Facilities and physicians performing interventional procedures should monitor patient doses delivered during these procedures and implement measures to reduce the potential for radiation-induced skin injuries.

References

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Table 1: Radiation-induced skin injuries

Effect	Typical Threshold Absorbed Dose (Gy)*	Hours of Fluoroscopic "On Time" to Reach Threshold+ at: Usual Fluoro Dose Rate of 0.02 Gy/min (2 rad/min)	High-Level Dose Rate of 0.2 Gy/min (20 rad/min)	Time to Onset of Effect++
Early transient erythema	2	1 7	0.17	hours
Temporary epilation	3	2.5	0 25	3 wk
Main erythema	6	5.0	0 50	10 d
Permanent epilation	7	5.8	0.58	3 wk
Dry desquamation	10	8.3	0 83	4 wk
Invasive fibrosis	10	8.3	0.83	
Dermal atrophy	11	9 2	0.92	>14 wk
Telangiectasis	12	10.0	1 00	>52 wk
Moist desquamation	15	12.5	1.25	4 wk
Late erythema	15	12.5	1.25	6-10 wk
Dermal necrosis	18	15.0	1.50	>10 wk
Secondary ulceration	20	16.7	1.67	>6 wk

* The unit for absorbed dose is the gray (Gy) in the International System of units One Gy is equivalent to 100 rad in the traditional system of radiation units.

+ Time required to deliver the typical threshold dose at the specified dose rate.

++ Time after single irradiation to observation of effect.

(Table adapted from Ref. 9.)

Table 2: Reports received by FDA of skin injury from fluoroscopy*

Procedure with Report of Injury	Number of Injuries Reported from Procedure
RF cardiac catheter ablation	12
Catheter placement for chemotherapy	1
Transjugular interhepatic portosystemic shunt	3
Coronary angioplasty	4
Renal angioplasty	2
Multiple hepatic/biliary procedures (angioplasty, stent placement, biopsy, etc)	3
Percutaneous cholangiogram followed by multiple embolizations	1

*Reports received by FDA between January 1992 and October 1995.

Some injuries occurred prior to 1992.

Table 3: Examples of skin injuries from fluoroscopy

Patient	Sex / Age	Procedure	Nature of Injury	Fluoroscopic Exposure Time
A	M / 40	Coronary angiography and PTCA followed by second coronary angiography	Skin Necrosis requiring 12 cm x 10 cm skin graft	Unknown - Estimated to exceed 120 min.
B	F / ?	RF Cardiac Catheter Ablation	7.5 cm x 12.5 cm second degree skin burn	Unknown
C	F/ 25	RF Cardiac Catheter Ablation	Skin breakdown 3 weeks post procedure	Unknown - Procedure time of 325 min
D	F / 34	RF Cardiac Catheter Ablation	Draining skin lesion on back 5 weeks post procedure	Unknown - Procedure time of 190 min.
E	F / 62	Balloon dilation of bile duct anastomosis	Burn-like injury on back requiring skin graft	Unknown
F	F / 61	Renal angioplasty	Skin necrosis requiring skin graft	Unknown - Procedure time of 165 min

Table 4 : Example of estimated total skin exposure to one patient from a series of biliary procedures*

Procedure	Fluoroscopy exposure time (min)	Estimated skin exposure from fluoroscopy		Total Number of DSA frames	Estimated skin exposure from DSA frames	
		(10^{-3}C/kg)	(R)		(10^{-3}C/kg)	(R)
Percutaneous cholangiogram	21	47 7	184	16	0.5	2
Mesenteric angiogram and multiple embolizations+	187	396	1536	325	66.6	258
Hepatic embolizations	58	108	419	149	23.2	90
Total skin exposure from model++		560	2170		90.2	350

* Procedures performed during four-week period. Estimates are of entrance skin exposure and do not include backscatter.

+Two different fluoroscopy systems were used, due to equipment failure, and multiple dose rates (magnification modes) were used

++Total exposure may not have been delivered to a single area of skin due to movement of x-ray beam. Location of beam not monitored during various procedures