Radiation-induced Skin Injuries from Fluoroscopy
Thomas B. Shope, Ph.D.
Office of Science and Technology
Center for Devices and Radiological Health
Food and Drug Administration
Rockville, Maryland 20857

Note
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Abstract
The purpose of this study was to investigate radiation injuries reported to the Food and Drug Administration (FDA) resulting 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 have recently been reported which have resulted from fluoroscopically-guided, therapeutic, interventional procedures (1,2). 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 (3,4). 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. 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.

An example of the increased frequency of interventional procedures of this growth is shown in Figure 1. It gives estimates of the number of radio-frequency (RF) cardiac catheter ablation procedures performed per year from a survey of 157 electrophysiology laboratories (5). The introduction of an array of new devices to facilitate the interventional treatment of a variety of vascular and other conditions is also contributing to increased numbers of interventional procedures.

Figure 1. Annual number of RF catheter ablation procedures from a survey of 157 electrophysiology laboratories.

Scheinmann MM. PACE Vol. 18:1474-1478, 1995

Methods

All reports of radiation injury resulting from fluoroscopy which have come to the attention of the FDA have been investigated 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 investigation was conducted by telephone calls, letters and personal visits to the facilities or individuals involved. Provision of additional information to the FDA was voluntary and a majority of the facilities contacted declined to provide additional information due to concerns regarding liability or confidentiality.

Results

Table 1 is a summary of the types of interventional procedures which have resulted in reports of skin injuries and the number of each type which have come to the attention of the FDA. 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.

Table 1. Reports Received by FDA of Skin Injury from Fluoroscopy (1)

<table>
<thead>
<tr>
<th>Procedure with Report of Injury</th>
<th>Number of Injuries Reported from Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF cardiac catheter ablation</td>
<td>12</td>
</tr>
<tr>
<td>Catheter placement for chemotherapy</td>
<td>1</td>
</tr>
<tr>
<td>Transjugular interhepatic portosystemic shunt</td>
<td>3</td>
</tr>
<tr>
<td>Coronary angioplasty</td>
<td>4</td>
</tr>
</tbody>
</table>

http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImagin... 1/4/2013
Renal angioplasty                      2
Multiple hepatic/biliary procedures  3
(angioplasty, stent placement,
biopsy, etc.)
Percutaneous cholangiogram followed
by multiple embolizations           1

(1) Reports received by FDA between January 1992 and October 1995.
Some injuries occurred prior to 1992.

A sample of the injuries reported to the FDA is presented in Table 2. 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 determining 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 2. Examples of Skin Injuries from Fluoroscopy

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

Table 3 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.

Table 3. Example of Estimated Total Skin Exposure to One Patient from a Series of Biliary Procedures (1)

http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImagin... 1/4/2013
### Procedure

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Fluoroscopy Exposure Time (min)</th>
<th>Estimated Skin Exposure from Fluoroscopy (R)</th>
<th>Total Number of DSA Frames</th>
<th>Estimated Skin Exposure from DSA Frames (R)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percutaneous cholangiogram</td>
<td>21</td>
<td>184</td>
<td>16</td>
<td>2</td>
</tr>
<tr>
<td>Mesenteric angiogram and multiple embolizations (2)</td>
<td>187</td>
<td>1536</td>
<td>325</td>
<td>258</td>
</tr>
<tr>
<td>Hepatic embolizations</td>
<td>58</td>
<td>419</td>
<td>149</td>
<td>90</td>
</tr>
</tbody>
</table>

**Total skin exposure from mode (3) 560 2170 350**

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

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

3. 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.

The total skin exposure given in Table 3 of 650 x 10^{-3} C/kg (2,522 R), 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 3 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 is shown in Figure 2. This case, patient A in Table 2, is that of 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. Figure 2(a) shows the area of injury six to eight weeks following the procedures. 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. Figure 2(b) shows the condition in late summer 1990, exact date unknown, with 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, Figure 2 (c and d). The injury eventually required a skin graft as shown in Figure 2(e). 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. (6)
Figure 2(a). Condition of patient's back six to eight weeks following multiple coronary angiography and angioplasty procedures.

Figure 2(b). Appearance of skin injury approximately 16 to 21 weeks following the procedures with small ulcerated area present.

Figure 2(c). Appearance of skin injury approximately 18 to 21 months following procedures, evidencing tissue necrosis.
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.

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 (7). 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.

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

Address for Reprints
Thomas B. Shope, Ph.D. (HFZ-140)
FDA/Center for Devices and Radiological Health
12720 Twinbrook Parkway
Rockville, Maryland 20857
(301) 443-3314, Extension 32
FAX: (301) 443-9101
Internet: tbs@cdrh.fda.gov

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