Medical Fluoroscopic Exposures and Incidents

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Use Of X-rays In The Healing Arts: Should It Be Regulated? An RSO Perspective

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May 8, 2012

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Disclaimer

Views and opinions expressed in this presentation do not necessarily reflect those of my employer, Mayo Clinic.
Overview

- Interventional Procedures
- Radiation Skin Effects
- Challenges To Regulatory Oversight
- Arguments For Regulatory Oversight
- Examples of Fluoroscopy Incidents
<table>
<thead>
<tr>
<th>Procedure</th>
<th>2006 # of Procedures (% of total)</th>
<th>2006 Effective Dose, Ave</th>
<th>1980/82 Effective Dose, Ave</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT</td>
<td>67,000,000 (17%)</td>
<td>1.47 mSv</td>
<td>0.016 mSv</td>
</tr>
<tr>
<td>Conventional radiography and fluoroscopy</td>
<td>293,000,000 (74%)</td>
<td>0.33 mSv</td>
<td>0.36 mSv</td>
</tr>
<tr>
<td>Interventional fluoroscopy</td>
<td>17,000,000 (4%)</td>
<td>0.43 mSv</td>
<td>0.018 mSv</td>
</tr>
<tr>
<td>Nuclear medicine</td>
<td>18,000,000 (5%)</td>
<td>0.77 mSv</td>
<td>0.53 mSv</td>
</tr>
</tbody>
</table>
Vertebroplasty – 16 mSv (mean)

Stent Placement
- Renal PTA with stent – 63 mSv (mean)
- Iliac PTA with stent – 64 mSv (mean)
- Carotid stent – 14 mSv (mean)
- Bile duct stenting – 14 mSv (mean)

Embolization
- Bronchial artery embolization – 17 mSv (mean)
- Hepatic chemoembolization – 70 mSv (mean)
- Pelvic arterial embolization – 78 mSv (mean)
- Pelvic vein embolization – 44 mSv (mean)
Fluoroscopically-Guided High Dose Interventional Procedures – NCRP 160

- Percutaneous Interventions
  - Angioplasty – 7 mSv
  - PTCA – 6 to 22 mSv
  - Cardiac embolization – 20 mSv
  - Cardiac Rf ablation – 15 mSv (mean)
  - TIPS – 112 mSv (mean)
FOOD AND DRUG ADMINISTRATION

IMPORTANT INFORMATION FOR PHYSICIANS AND OTHER HEALTH CARE PROFESSIONALS

September 9, 1994

AVOIDANCE OF SERIOUS X-RAY-INDUCED SKIN INJURIES TO PATIENTS DURING FLUOROSCOPICALLY-GUIDED PROCEDURES

WARNING - FDA has reports of occasional but at times severe radiation-induced burns to patients from fluoroscopically-guided, invasive procedures. This communication describes the nature of these injuries and provides recommendations for avoiding them.

PROCEDURES RESULTING IN INJURIES

An increasing number of invasive procedures, primarily therapeutic in nature and involving use of devices under fluoroscopic guidance, are becoming accepted medical practice. Examples of such procedures are listed in Table I. These procedures are performed by a variety of medical specialists and may provide significant advantages over alternative therapies in terms of improved clinical outcome and reduced overall patient risk. However, physicians performing these procedures should be aware of the potential for serious radiation-induced skin injury caused by long periods of fluoroscopy occurring with some of these procedures. Such injuries have recently been reported as a result of radiation exposure during some of these procedures (Ref. 1-3) due to long fluoroscopic exposure times, high dose rates or both.

TYPES OF INJURIES

The types of injuries to skin and adjacent tissues which result from x-ray radiation are summarized in Table II along with the typical absorbed dose in the skin and adjacent tissues.

Table I. Procedures typically involving extended fluoroscopic exposure time

<table>
<thead>
<tr>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiofrequency cardiac catheter ablation</td>
</tr>
<tr>
<td>Percutaneous transluminal angioplasty (Coronary and other vessels)</td>
</tr>
<tr>
<td>Vascular embolization</td>
</tr>
<tr>
<td>Stent and filter placement</td>
</tr>
<tr>
<td>Thrombolytic and fibrinolytic procedures</td>
</tr>
<tr>
<td>Percutaneous transhepatic cholangiography</td>
</tr>
<tr>
<td>Endoscopic retrograde cholangiopancreatography</td>
</tr>
<tr>
<td>Transjugular intrahepatic portosystemic shunt</td>
</tr>
</tbody>
</table>
Radiation Skin Effects

<table>
<thead>
<tr>
<th>Skin Effect</th>
<th>Approximate Threshold Dose (mGy)</th>
<th>Approximate Time to Onset</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early transient erythema</td>
<td>2,000</td>
<td>hours</td>
</tr>
<tr>
<td>Temporary epilation</td>
<td>3,000</td>
<td>3 weeks</td>
</tr>
<tr>
<td>Main erythema</td>
<td>6,000</td>
<td>10 days</td>
</tr>
<tr>
<td>Permanent epilation</td>
<td>7,000</td>
<td>3 weeks</td>
</tr>
<tr>
<td>Dry desquamation</td>
<td>10,000</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Invasive fibrosis</td>
<td>10,000</td>
<td></td>
</tr>
<tr>
<td>Dermal atrophy</td>
<td>11,000</td>
<td>&gt;14 weeks</td>
</tr>
<tr>
<td>Telangiectasis</td>
<td>12,000</td>
<td>&gt;52 weeks</td>
</tr>
<tr>
<td>Moist desquamation</td>
<td>15,000</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Late erythema</td>
<td>15,000</td>
<td>6-10 weeks</td>
</tr>
<tr>
<td>Dermal necrosis</td>
<td>18,000</td>
<td>&gt;10 weeks</td>
</tr>
<tr>
<td>Secondary ulceration</td>
<td>20,000</td>
<td>&gt;6 weeks</td>
</tr>
</tbody>
</table>

Reference: Avoidance of Serious X-Ray-Induced Skin Injuries to Patients During Fluoroscopically-guided Procedures; FDA, Sept 9, 1994
# Radiation Skin Effects


<table>
<thead>
<tr>
<th>Skin Effect</th>
<th>Approximate Threshold Dose (mGy)</th>
<th>Approximate Time to Onset</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early transient erythema</td>
<td>2,000</td>
<td>2-24 hours</td>
</tr>
<tr>
<td>Main erythema reaction</td>
<td>6,000</td>
<td>1.5 weeks</td>
</tr>
<tr>
<td>Temporary epilation</td>
<td>3,000</td>
<td>3 weeks</td>
</tr>
<tr>
<td>Permanent epilation</td>
<td>7,000</td>
<td>3 weeks</td>
</tr>
<tr>
<td>Dry desquamation</td>
<td>14,000</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Moist desquamation</td>
<td>18,000</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Secondary ulceration</td>
<td>24,000</td>
<td>&gt;6 weeks</td>
</tr>
<tr>
<td>Late erythema</td>
<td>15,000</td>
<td>8-10 weeks</td>
</tr>
<tr>
<td>Ischaemic dermal necrosis</td>
<td>18,000</td>
<td>&gt;10 weeks</td>
</tr>
<tr>
<td>Dermal atrophy</td>
<td>10,000</td>
<td>&gt;52 weeks</td>
</tr>
<tr>
<td>Telangiectasis</td>
<td>10,000</td>
<td>&gt;52 weeks</td>
</tr>
<tr>
<td>Dermal necrosis</td>
<td>&gt;12,000</td>
<td>&gt;52 weeks</td>
</tr>
<tr>
<td>Skin cancer</td>
<td>None known</td>
<td>&gt; 15 years</td>
</tr>
</tbody>
</table>

### Eye Effect

- Lens opacity (detectable): >1,000 - 2000
- Cataract (debilitating): >5,000

# Skin Injuries From Acute Radiation Exposure

Adapted from Balter, et al, Radiology, Volume 254: Number 2; February 2010

<table>
<thead>
<tr>
<th>Acute Skin Dose, Gy</th>
<th>Time Till Onset of Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-2</td>
<td>Prompt No effects No effects No effects</td>
</tr>
<tr>
<td>5-10</td>
<td>Transient erythema Erythema, epilation Recovery Recovery</td>
</tr>
<tr>
<td>10-15</td>
<td>Transient erythema Erythema, epilation Prolonged erythema Telangiectasia</td>
</tr>
<tr>
<td>&gt;15</td>
<td>Transient erythema Moist desquamation Necrosis Telangiectasia</td>
</tr>
</tbody>
</table>
Challenges To Regulatory Oversight

• Historical – Non-interference in the practice of medicine
• Moratorium on new state regulations
• Non-repairable skin damage relatively rare event
• Empirical data difficult to obtain
• Definitions
  • DAP readout vs peak skin dose
• Equipment limitations
  • DICOM dose structured reports
• Difficult to enforce
Arguments For Regulatory Oversight

• # of interventional fluoro procedures is increasing
• Many physicians lack comprehensive radiation safety training in residency programs
• Skin injuries underreported
• Regulations already exist in some states
• Increased concern from the public
• Increased concern from accreditation agencies
  • Joint Commission
  • ACR
Joint Commission Sentinel Event Definition (Partial)

- Suicide of any patient
- Unanticipated death of a full-term infant
- Discharge of an infant to the wrong family
- Rape
- Surgical and nonsurgical invasive procedure on the wrong patient, wrong site or wrong procedure
- Unintended retention of a foreign object in a patient after surgery or other procedure
- Prolonged fluoroscopy with cumulative dose > 1500 rads (15 Gy) to a single field
Radiation risks of diagnostic imaging

Correction: The American College of Radiology (ACR) launched its National Radiology Data Registry (NRDR) in 2008. Its Dose Index Registry (DIR), which is part of the NRDR, launched in May 2011 (see fourth paragraph).

Diagnostic radiation is an effective tool that can save lives. The higher the dose of radiation delivered at any one time, however, the greater the risk for long-term damage. If a patient receives repeated doses, harm can also occur as the cumulative effect of those multiple doses over time.\textsuperscript{1,2,3} Conversely, using insufficient radiation may increase the risk of misdiagnosis, delayed treatment, or, if the initial test is inadequate, repeat testing with the attendant exposure to even more radiation.\textsuperscript{4} The risks associated with the use of ionizing radiation in diagnostic imaging include cancer, burns and other injuries.\textsuperscript{1,5,6,7} X-rays are officially classified as a carcinogen by the World Health Organization’s International Agency for Research on Cancer, the Agency for Toxic Substances and Disease Registry of the Centers for Disease Control and Prevention, and the National Institute of Environmental Health Sciences.\textsuperscript{1}
9. Record the dosage or exposure as part of the study’s summary report of findings.

13. Ensure all physicians and technologists who prescribe diagnostic radiation or use diagnostic radiation equipment receive dosing education and are trained on the specific model of equipment being used. Institute a process for annual education, review and competency testing.
Joint Commission Diagnostic Imaging Standards

- Phased approach
- 1st Phase
  - Effective July 1, 2014
  - CT, Nuc Med, PET and MR
- 2nd Phase
  - Effective sometime in 2015
  - Fluoroscopy, minimum qualifications for clinicians and cone beam CT
Joint Commission Diagnostic Imaging Standards

Highlights of 2014 Changes:

- Minimum competency for radiology technologists, including registration and certification by July 1, 2015
- Annual performance evaluations of imaging equipment by a medical physicist
- Documentation of CT radiation dose in the patient’s clinical record
- Meeting the needs of the pediatric population through imaging protocols and by considering patient size or body habitus when establishing imaging protocols
- Management of safety risks in the MRI environment
- Collection of data on incidents during which identified radiation dose limits have been exceeded
<table>
<thead>
<tr>
<th>Procedure</th>
<th>1980/82 # of Procedures (NCRP 100)</th>
<th>2006 # of Procedures (NCRP 160)</th>
<th>% Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT</td>
<td>3,300,300</td>
<td>67,000,000</td>
<td>2030%</td>
</tr>
<tr>
<td>Conventional radiography and fluoroscopy</td>
<td>167,900,000</td>
<td>293,000,000</td>
<td>175%</td>
</tr>
<tr>
<td>Interventional fluoroscopy</td>
<td>8,400,000 (‘Other’)</td>
<td>17,000,000</td>
<td>202%</td>
</tr>
<tr>
<td>Nuclear medicine</td>
<td>7,279,000 (1982)</td>
<td>18,000,000</td>
<td>247%</td>
</tr>
</tbody>
</table>
## Examples Of FGI Procedures Performed

<table>
<thead>
<tr>
<th>Interventional Radiology</th>
<th>Interventional Cardiology</th>
<th>Vascular Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angioplasty</td>
<td>Angioplasty</td>
<td>Angioplasty</td>
</tr>
<tr>
<td>Catheter-delivered stents</td>
<td>Catheter-delivered stents</td>
<td>Catheter-delivered stents</td>
</tr>
<tr>
<td>Peripheral interventions</td>
<td>Peripheral interventions</td>
<td>Peripheral interventions</td>
</tr>
<tr>
<td>Embolization</td>
<td>Embolization</td>
<td>Embolization</td>
</tr>
<tr>
<td>Neuro interventions</td>
<td>Coronary angiography</td>
<td>Stent grafting for AAA repair</td>
</tr>
<tr>
<td>TIPS</td>
<td>Rf ablation for aortic aneurisms</td>
<td></td>
</tr>
</tbody>
</table>
“… shifting a portion of these procedures “in-house” could produce a significant positive impact on group revenue”

Ref: Peer-reviewed nephrology journal
Turf Wars

Treatment of Peripheral Artery Disease (PAD) or Peripheral Vascular Disease (PVD) By Department/Specialty

Source: Clearstate
ACGME Program Requirements Related To Radiation Safety

- **Interventional Cardiology**
  - Effective July 1, 2007
  - “The program must provide formal instruction for the fellows to acquire knowledge of the following content areas: Radiation physics, biology and safety related to the use of x-ray imaging equipment”
- **Vascular Surgery**
  - Effective July 1, 2007
  - “Residents should have education in the entire vascular system. Instruction in each area should be associated with relevant patient exposure”
  - Required hours not stated
ACGME Program Requirements Related To Radiation Safety

- **Vascular and Interventional Radiology**
  - Effective January 2005
  - “The fundamentals of radiation physics, radiation biology and radiation protection should all be reviewed during the vascular and interventional training experience”
  - Required hours not stated

- **Diagnostic Radiology**
  - Effective July 1, 2008
  - “There must be didactic components that address the following subjects: diagnostic radiologic physics and radiation biology; patient and medical personnel safety (i.e., radiation protection, MRI safety)”
  - Required hours not stated except of Nuclear Medicine NRC T&E requirements
Reports Received from FDA of Skin Injury from Fluoroscopy

Reports received between January 1992 and October 1995

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rf cardiac ablation</td>
<td>12</td>
</tr>
<tr>
<td>Coronary angioplasty</td>
<td>4</td>
</tr>
<tr>
<td>TIPS</td>
<td>3</td>
</tr>
<tr>
<td>Multiple hepatic/biliary procedures</td>
<td>3</td>
</tr>
<tr>
<td>Renal angiography</td>
<td>2</td>
</tr>
</tbody>
</table>
Regulations Relating to Patient Dose At Mayo Clinic Sites

- Arizona Radiation Regulatory Agency
  Must be under control of licensed practitioner in healing arts
- Florida Bureau of Radiation Control
  Must be under control of licensed practitioner in healing arts
- Minnesota Department of Health
  Only physicians may operate fluoroscopic system
  Record radiation dose for all patients
  Report exam cumulative skin dose events exceeding 6,000 mGy to Mayo Radiation Safety Committee
- The Joint Commission
  Investigate cumulative skin doses exceeding 15,000 mGy
  Actual localized skin dose that exceeds 15,000 mGy is a medical sentinel event
4732.0545 UTILIZATION LOG.

A. Excluding dental facilities, facilities performing radiographic or fluoroscopic procedures must maintain a utilization log containing:

(1) patient identification;
(2) the type of procedures;
(3) the dates the procedures were performed;
(4) the name of the individual performing the x-ray procedure;
(5) the number of exposures and retakes involved;
(6) the name of the human holder when the patient or film must be provided with human auxiliary support;

(7) utilization logs for fluoroscopic equipment without a dose-area-product monitor must include the patient's exposure received per fluoroscopic procedure in excess of five minutes; and

(8) utilization logs for fluoroscopic equipment with a dose-area-product monitor must include the patient's exposure received per fluoroscopic procedure in excess of five minutes.
Number of FGI Cases Performed at MCR in 2010

- CV Cath Lab: 6000
- CV Heart Rhythm Services: 2500
- Radiology Neurology: 2000
- Radiology VIR: 8000
- Vascular Surgery: 500
Percentage of FGI Cases > 6000 mGy

![Bar chart showing the percentage of FGI cases > 6000 mGy for different departments.]

- CV Cath Lab: 0.2%
- CV Heart Rhythm Services: 0.2%
- Radiology Neurology: 0.2%
- Radiology VIR: 0.2%
- Vascular Surgery: 1.8%
Fluoroscopy Patient Overexposure
A Case Study

• 40 yr old male with coronary disease

• Received on same day:
  • Coronary angiography
  • Coronary angioplasty
  • Coronary angiography (due to complications)
  • Coronary artery by-pass
6-8 Weeks Post Exposure
16-21 Weeks Post Exposure
Fluoroscopy Patient Overexposure
A Case Study

• 23 year old, fair skinned male 5 ft 8 in (172 cm) and 255 lbs (116 kg)
• Scheduled for IVC filter removal under fluoroscopic guidance
• Patient supine
• Lateral view used
• After 1.1 hour of “beam-on”, case aborted due to failed recovery
Fluoroscopy Patient Overexposure
A Case Study

• One month later patient went to a different hospital and biplane system was used.
• Second case went for 4 hours and delivered approximately 10 Gy (est skin dose 15 Gy).
• Lesion developed on right flank even with the lower ribs.
• Turned red the same day, opened up at 6 weeks, healed over and reopened at 13 weeks post-irradiation.
• Remained open for several months.
Fluoroscopy Patient Overexposure
A Case Study

• 41 year old morbidly obese patient underwent aneurysm embolizaton and celiac and SMA stenting procedure on 12/20/11 requiring 247 minutes of fluoro. Surgical procedure thought to be too risky.

• Patient required restenting on 12/22/11 requiring an additional 221 minutes of fluoro.

• Peak skin dose conservatively estimated to be 52 Gy (TJC Sentinel Event if > 15 Gy)
Patient Information
- Patient Name: 
- Patient ID: 00000000
- Date: 1/27/2011

End of Exam Dosimetry
- Total KAP: 1.51 Gy
- Reference point Air Kerma: 102.51 Gy
- Total Acquisition Air Kerma: 26.57 Gy
- Total Fluoroscopy Air Kerma: 75.94 Gy
- Total Fluoroscopy Time: 3018.0 sec

Quality Assurance
- Peak Skin Dose including Fluoro: 52.17 Gy
- Skin area with more than 95% of the peak skin dose: 20 cm²
- Action Level 2 exceeded?: Yes
- Sentinel event occurred?: Yes

High dose52.bmp
Type: BMP File
Size: 2.47 MB
Changes Resulting From Event

- Recommendations from RSC and RCA process
- Reviewed by CPC on 2/6/12
- Mandatory radiation safety training for all fluoro users
  - Part of credentialing process
  - Conducted at initial hire and then biennially
- Dose Tracker system to be installed in high fluoro areas
- Fluoro ‘pause’ after 60 minutes accumulated fluoro time