Patient Radiation Management in Interventional Fluoroscopy

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  - D. Miller, M.D.; National Naval Medical Center
  - L. Wagner, Ph.D.; U. Texas, Houston
- Partial support from
  - SIR Foundation (CIRREF)
  - Philips Medical Systems

Zero Radiation Interventional Imaging

How Much Radiation Is Needed?

- Image frequency must be high enough to minimize motion uncertainty.
- Imaged volume must cover clinical ROI.
- Single image dose should be sufficient to reduce noise to a clinically acceptable level

Low Dose (fluoro LIH) High Dose (cine frame)

Concepts

Peak Skin Dose
- Maximum dose delivered to a zone defined by the skin surface to a depth of a few cm. (including backscatter)

Effective Dose
- The sum of the products of the dose equivalent to the organ or tissue and the weighting factor for each organ or tissue irradiated.
  - E always a calculated value
  - Is E an appropriate risk metric for individual patients?

Radiation Injury is an Old Story

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Estimated frequencies
Approx 2 million interventions per year in the US
Less than 10 injuries per year reported to FDA

PROCEDURE DEPENDENT:
Frequency of significant radiation injury is probably between 1/20,000 and 1/200,000
Frequency of significant non-radiation interventional complications is much higher (Death ≈ 1/1000)

Types of Radiation Injury
- Deterministic
  - Skin Damage (burn)
  - Hair Loss
  - Chronic Changes
    ➢ (No Natural Background)
- Stochastic
  - Ca Risk
  - Genetic Risk
    ➢ (Natural Background Rate)

Causes of Deterministic Injuries
- Defective, inappropriate, or inadequate equipment
  ± High dose rate technique
  + Long and complex procedures
    (medical complications and emergencies)
  + Multiple procedures
  + Long beam paths

ICRP 85: Rad Injuries: Interventional Procedures
Used by an increasing number of clinicians not adequately trained in radiation safety or radiobiology.
Operators not aware of the potential for injury or the simple methods for decreasing their incidence.
Patients are not counseled on the radiation risks, or followed up when radiation doses from difficult procedures may lead to injury.
Some patients suffer radiation-induced skin injuries and younger patients may face an increased risk of future cancer.
In some procedures, skin doses to patients approach those experienced in some cancer radiotherapy fractions.
Skin injuries are occurring due to inappropriate equipment and, more often, due to poor operational technique.

Deterministic Injuries

Deterministic Injury Thresholds

<table>
<thead>
<tr>
<th>Effect of a Single Dose</th>
<th>Threshold (Gy)</th>
<th>Onset</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early transient erythema</td>
<td>2</td>
<td>Hours</td>
</tr>
<tr>
<td>Main erythema</td>
<td>6</td>
<td>~10 days</td>
</tr>
<tr>
<td>Temporary (permanent) epilation</td>
<td>3 (7)</td>
<td>~3 weeks</td>
</tr>
<tr>
<td>Dry (moist) desquamation</td>
<td>14 (18)</td>
<td>~4 weeks</td>
</tr>
<tr>
<td>Secondary ulceration</td>
<td>24</td>
<td>&gt;6 weeks</td>
</tr>
<tr>
<td>Ischemic dermal necrosis</td>
<td>18</td>
<td>&gt;10 weeks</td>
</tr>
<tr>
<td>Dermal atrophy</td>
<td>10</td>
<td>&gt;1 year</td>
</tr>
<tr>
<td>Late dermal necrosis</td>
<td>&gt;127</td>
<td>&gt;1 year</td>
</tr>
<tr>
<td>Skin cancer</td>
<td>stochastic</td>
<td>&gt;5 years</td>
</tr>
</tbody>
</table>
Mechanism

- Not a Thermal Burn!!
  Energy delivered can only cause an increase of << 1 degree.
- Radiation Damage To Cells
  - Lethal
  - Potentially Lethal
- Injury is expressed when sufficient numbers of cells die
- Typical depth of major injury ≈ cm

Biological Variability

- % Effect vs. Dose
- Least Sensitive Patient
- Most Sensitive Patient
- Threshold

Time Progression of PTCA Injury

2 months 6 months 2 years post graft
Source: FDA/CDRH

Time Progression of TIPS Injury

6 m 7.5 m 10 m 22 m 23 m Post graft
This patient had 3 TIPS procedures within one week

Long Path Lengths

Different Patient

Unnecessary Body Part in Beam

Wagner – Archer, Minimizing Risks from Fluoroscopic X Rays, 3rd ed, 2000
Non Radiation Injuries

Nickel Dermatitis

- Burn is actually a skin reaction to the disinfectant used to clean x-ray couch.

Dose Metrics

- **Fluoroscopy Time and Image Count**
  - Poor: Lacks patient size, collimation, beam motion, and SSD
- **Dose Area Product (DAP)**
  - Most interventional systems have this capability (EURATOM directive)
  - Better: Lacks collimation, beam motion, and SSD
  - Can be used for operations and QA
- **Cumulative Dose**
  - IEC 60601-2-43 compliant systems; New FDA regs (?)
  - Better: Lacks collimation, beam motion, and SSD
  - Still Better when combined with DAP
- **Skin Dose Measurements or Calculations**
  - Measurements seldom provide real-time feedback
  - Calculations have their own sets of assumptions

IEC60601 – 2 – 43: Cumulative Dose

- Does not reflect beam collimation or motion; approximates skin position

Skin Dose Maps

- GC or Film
- CareGraph
- Siemens
- All Different Cases

The RAD-IR Study (SIR) - Completed

- Prospective and non-blinded
- Goals:
  - Determine mean cumulative dose for 21 different IR procedures
  - Determine how often IR procedures require cumulative doses > 1 Gy, 2 Gy or 3 Gy
- Best Practice
  - State-of-the-art dose-saving technology
  - Built-in dosimetry
  - Some had skin dose mapping software
  - Experienced Operators
  - Hawthorn Effect

RAD-IR: Cumulative Dose > 3 Gy

<table>
<thead>
<tr>
<th>Procedure (no.)</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal Angioplasty</td>
<td>156</td>
</tr>
<tr>
<td>Liver Chemoembolization</td>
<td>126</td>
</tr>
<tr>
<td>TIPS (135)</td>
<td></td>
</tr>
<tr>
<td>GI Bleeder Dx/Rx</td>
<td>94</td>
</tr>
<tr>
<td>UFE (90)</td>
<td></td>
</tr>
<tr>
<td>Head Embolization</td>
<td>382</td>
</tr>
<tr>
<td>Spine Embolization</td>
<td>24</td>
</tr>
</tbody>
</table>

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Neuroembolization CD

Cardiac DAP {not part of RAD-IR}

Fluoro Time v. DAP

Neuroembolization, Head PSD

PSD v. DAP and CD

Deterministic Injury Decisions

• There is no regulatory maximum dose!
• Operator must have sufficient real time information to reevaluate radiation risk against patient benefits of continuing
  "Would you continue if you are certain that the next time that you step on the peddle the patient will be injured?"
• Almost always avoidable
• Should never be a post-procedure surprise!
Stochastic Effects

- Probability proportional to dose
- Severity independent of dose
- Assumed zero threshold (ICRP 2005 ??)

Stochastic risks are:
- Radiogenic cancer
- Genetic damage

Cancer Risk from Dx X-Rays

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Per Year</th>
<th>Per Million procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdomen</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>Barium Meal</td>
<td>40</td>
<td>11</td>
</tr>
<tr>
<td>Barium Enema</td>
<td>170</td>
<td>55</td>
</tr>
<tr>
<td>Chest</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Coronary Angio.</td>
<td>280</td>
<td>41</td>
</tr>
<tr>
<td>CT Scan</td>
<td>60</td>
<td>70</td>
</tr>
<tr>
<td>Cerebral Angio.</td>
<td>180</td>
<td>2</td>
</tr>
<tr>
<td>Hip or Pelvis</td>
<td>30</td>
<td>24</td>
</tr>
</tbody>
</table>

These sites are 54% of all radiation inducible cancers

Risk Coefficients (E)

<table>
<thead>
<tr>
<th></th>
<th>NCRP - 60</th>
<th>ICRP - 110</th>
</tr>
</thead>
<tbody>
<tr>
<td>Workers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatal Cancer</td>
<td>4.0 x 10^{-2} Sv^{-1}</td>
<td>4.0 x 10^{-2} Sv^{-1}</td>
</tr>
<tr>
<td>Nonfatal Cancer</td>
<td>0.8 x 10^{-2} Sv^{-1}</td>
<td>0.8 x 10^{-2} Sv^{-1}</td>
</tr>
<tr>
<td>Severe Genetic</td>
<td>0.8 x 10^{-2} Sv^{-1}</td>
<td>0.8 x 10^{-2} Sv^{-1}</td>
</tr>
<tr>
<td>Public</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatal Cancer</td>
<td>5.0 x 10^{-2} Sv^{-1}</td>
<td>5.0 x 10^{-2} Sv^{-1}</td>
</tr>
<tr>
<td>Nonfatal Cancer</td>
<td>1.0 x 10^{-2} Sv^{-1}</td>
<td>1.0 x 10^{-2} Sv^{-1}</td>
</tr>
<tr>
<td>Severe Genetic</td>
<td>1.3 x 10^{-2} Sv^{-1}</td>
<td>1.3 x 10^{-2} Sv^{-1}</td>
</tr>
<tr>
<td>Embryo / Fetus</td>
<td>10 x 10^{-2} Sv^{-1}</td>
<td></td>
</tr>
</tbody>
</table>

This table does not totally account for acute/chronic dose rate effects

Coronary Angioplasty Risk Calculation

From NCRP and ICRP:

\[(4+0.8) \times 10^{-2} = 4.8 \times 10^{-2} \text{ per Sv E}\]

Removing Dose Rate Factor \(= 9.6 \times 10^{-2}\)
Risk rate \(= 9.6 \times 10^{-4} \text{ per mSv E}\)

From literature:

- 1 Gycm² yields \(= 0.2 \text{ mSv E}\)
- Extreme case \(= 500 \text{ Gycm}^2 = 100 \text{ mSv E}\)
- Risk \(= 9.6 \times 10^{-4} \times 100 = 9.6 \times 10^{-3}\)
- Risk (max) \(\approx 1\%\)

Multiple procedures ???

Age Specific Risks

Percent Diagnosed With Cancer in the following 10, 20 and 30 Years

<table>
<thead>
<tr>
<th>Cancer Free at Current Age</th>
<th>10</th>
<th>20</th>
<th>30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>0.17 (0.13), 0.07</td>
<td>0.18</td>
<td>0.33 (0.27)</td>
</tr>
<tr>
<td>10</td>
<td>0.14 (0.12), 0.15</td>
<td>0.16</td>
<td>0.51 (0.47)</td>
</tr>
<tr>
<td>20</td>
<td>0.13 (0.21), 0.05</td>
<td>0.15</td>
<td>0.50 (0.50)</td>
</tr>
<tr>
<td>50</td>
<td>0.77 (0.76), 0.03</td>
<td>0.75</td>
<td>4.03 (4.03)</td>
</tr>
<tr>
<td>100</td>
<td>1.5 (1.5), 0.15</td>
<td>1.5</td>
<td>6.1 (6.1)</td>
</tr>
<tr>
<td>200</td>
<td>3.0 (3.0), 0.25</td>
<td>3.0</td>
<td>12.2 (12.2)</td>
</tr>
<tr>
<td>500</td>
<td>6.4 (6.4), 0.35</td>
<td>6.4</td>
<td>26.6 (26.6)</td>
</tr>
<tr>
<td>1000</td>
<td>15.9 (15.9), 0.45</td>
<td>15.9</td>
<td>51.3 (51.3)</td>
</tr>
</tbody>
</table>

Lifet ime Risk of Ca lci um \(= 45.19\%\)
Lifet ime Risk of Ca lci um \(= 33.65\%\)
Lifet ime Risk of Dying \(= 15.50\%\)

Angioplasty Ca Induction: 0.01% - 1.0% Laboratory Death \(= 0.1\%\)

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Special Populations

- **Children**
  - More critical organs in beam increases effective dose per unit of X-ray input
  - Increased risk age specific factors and years of remaining life.
  - Less total radiation needed for small people

- **Adolescent**
  - Female breast has known radiosensitivity
  - Total radiation needed is in the adult range

Possible Patient Risk Topics

A slightly elevated risk for cancer several years later in life. This risk is typically low in comparison to the normal incidence of human cancer.

Hair loss occurs in many patients following complex neurointerventional procedures. This is usually temporary; regrowth of hair may be incomplete.

Skin rashes occur infrequently; on very rare occasions may result in tissue breakdown and possibly severe ulcers. The likelihood of this occurring depends on the difficulty of the procedure and whether you are sensitive to radiation due to previous procedures, disease, or genetic conditions.

Cataracts are rarely induced following neurointerventional procedures. This can be avoided in most cases.

Operator Should Be Dose Aware

IEC 60601-2-43

New FDA?

<table>
<thead>
<tr>
<th>TUBE POSITION</th>
<th>30 L</th>
<th>20 CR</th>
<th>FLUORO MODE</th>
<th>NORMAL</th>
</tr>
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<tbody>
<tr>
<td>EER DOSE AT IIP</td>
<td>125 cGy</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

MD: Managing Patient Radiation

- **Prior to procedure**
  - Previous radiation history
  - Patient size and planned procedure
  - **Patient consent considered**

- **During procedure**
  - Active dose (rate) management
  - Clinical benefit / risk evaluation
  - Similar to iodine management

- **After procedure**
  - Record keeping
  - Patient discussion
  - Follow up with and from patient

Imaging Geometry

Based on Wagner (AAPM SS 02)

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IEC 60601-2-43

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<td></td>
<td></td>
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Nursing Radiation Monitoring

- Alert the operator when:
  - Cumulative dose = 2§ Gy
  - Total Dose Area Product = 200§ Gycm²
  - Example is cardiac angio
  - This replacing a fluoro time alert.

- Record final dose info for 100% of cases

- Radiation should be managed as well as contrast (iodine)
Post-Procedure Patient Discussions

- If doses exceeded facility investigatory level, then discuss possible effects and their management with the patient and family.
  § (procedure) e.g. cardiac angio
  DAP = 300 Gycm² or CD = 3 Gy
- Document clinical reason(s) in chart
- Plan clinical follow-up with the patient.
- Request a contact from the patient or family member if deterministic effects occur.
- View irradiated area during any follow-up visits in the following year.

Clinical Dose Records

- FDA 94
  - High Dose Procedures
  - Potential for Repeat Procedures
- SIR Statement: All Interventions
- MD should document medical necessity for significant radiation use immediately after procedure.
- IEC - DICOM (work in progress): Radiation Dose Structured Report

DICOM – DOSE Project

Physics QA

- Protocol should cover the full working range of the equipment.
- All normal clinical modes tested?
- Accuracy of built-in instruments?
- Exposure rates at realistic locations.
- Dose recording policy implementation?

Physicist’s To Do List

- Watch some clinical cases
  - Planned complex angioplasty
  - Heavy patients
- Observe
  - Equipment operating modes actually used
  - Operator’s handling of equipment
  - X-ray parameters (how often at max?)
  - Check out information in present DICOM headers
- Physics measurements
  - Measure using actual operating modes
  - Measure at maximum clinical parameters
  - Measure at the collimator (spacer) face

Patient Radiation Management

- Justified procedure
- Appropriately informed patient
- Appropriate equipment
- Efficient performance
- Real-time monitoring
- Minimum waste radiation
- Continuing clinical judgment of benefit / risk
  Manage radiation as if it was iodine
- Appropriate follow-up
- Incorporate in Clinical QA process