Radiation Safety In the Cardiac Catheterization Laboratory

SCAI Fall Fellow’s Course
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Faculty Disclosures

- None
Lecture Outline

- Imaging Basics
- Dose Assessment
- Biologic Effects
- Determinants of Procedural Dose
- Personal Protection
- Radiation Dose Management

ionizing radiation

alpha
neutron
beta
gamma ray
x ray
X-ray Image Formation

- Ideal X-ray imaging balances the requirements for contrast, sharpness, and patient dose.
  - Optimal X-ray imaging requires a kVp (peak tube voltage) and mA (cathode current) that produces the best balance of image contrast, and patient dose. **Automatic dose rate controls** increase x-ray tube output for a specific size and projections for adequate detector entrance dose rate and image quality.

X-ray Dose

- “Dose” a measure of energy absorbed by tissue.
- The dose delivered to the pt is derived from the X-ray photons that enter but do not leave.
X-ray Image Formation

- **Image Noise**
  - Noise decreases as the X-ray dose increases.
  - Point-to-point variations in brightness is called *image noise*.
  - Noise should be apparent in *fluoroscopic* imaging.

- **Scattered radiation**
  - Principal source of exposure to the patient and staff.
  - The amount of scattered radiation (Compton interactions within the patient) is directly related to the primary dose.
  - Produced when the beam interacts with the patient.
  - This constitutes noise and reduces image quality.
  - Increases with field size and intensity of the X-ray beam.
Image Quality Assessment: Objective and Clinical

- Overall Image Quality
  - average and heavy patient

- Spatial Resolution
  - visibility of stents and wires

- Dynamic Range
  - visibility of arteries overlying spine, diaphragm, and lung

- Low Contrast Detectability
  - visibility of small arteries

- Temporal Resolution
  - motion blur and image ghosting

- Dose Measurements
  - Dose improves image quality

The NEMA/SCAI XR-21 Phantom
Fluoroscopic Time least useful.

Total Air Kerma at the Interventional Reference Point \((K_{a,r}, Gy)\) is the x-ray energy delivered to air 15cm from for patient dose burden for deterministic skin effects.

Air Kerma Area Product \((P_{KA}, Gy cm^2)\) is the product of air kerma and x-ray field area. \(P_{KA}\) estimates potential stochastic effects (radiation induced cancer).

Peak Skin Dose \((PSD, Gy)\) is the maximum dose received by any local area of patient skin. No current method to measure PSD, it can be estimated if air kerma and x-ray geometry details are known. Joint Commission Sentinel event, >15 Gy.
Fluoroscopy Time

- Until 2006, only method required by FDA
- Does not include dose from digital images or the effect of fluoroscopic dose rate
KERMA

- **Kinetic Energy Released in Matter**
- A measure of energy delivered (dose)
- **Air Kerma** = kerma measured in air (low scatter environment)
Total Air Kerma at the Interventional Reference Point

- a/k/a Reference Air Kerma, Cumulative Dose
- Measured at the IRP, may be inside, outside, or on surface of patient
- Iso-center is the point in space through which the central ray of the radiation beam intersects with the rotation axis of the gantry.

- Patient
- Isocenter
- 15 cm
- Interventional Reference Point (fixed to the system gantry)
- Focal Spot
Air Kerma-Area Product ($P_{KA}$)

- Also abbreviated as KAP, DAP
- Dose $\times$ area of irradiated field ($\text{Gy} \cdot \text{cm}^2$)
- Total energy delivered to patient:
  - Good indicator of stochastic risk
  - Poor descriptor of skin dose
Biologic Effects of Radiation

- **Deterministic injuries**
  - When large numbers of cells are damaged and die immediately or shortly after irradiation. Units of Gy.
  - There is a **threshold dose** for visible post procedure injury ranging from erythema to skin necrosis.

- **Stochastic injuries**
  - Post radiation damage, cell descendants are clinically important. Higher dose, the more likely the process.
  - There is a **linear non-threshold dose** identifiable for radiation-induced neoplasm and heritable genetic defects. This is in units of Sv.
<table>
<thead>
<tr>
<th>Skin Dose</th>
<th>&lt;2wks</th>
<th>2-8 wks</th>
<th>6-52wks</th>
<th>&gt;40 wks</th>
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<td>0-2 Gy</td>
<td>no observable effects expected</td>
<td></td>
<td></td>
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<tr>
<td>2-5 Gy</td>
<td>transient</td>
<td>epilation</td>
<td>recovery</td>
<td>none</td>
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<tr>
<td>5-10 Gy</td>
<td>transient</td>
<td>erythema</td>
<td>recovery</td>
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<tr>
<td></td>
<td>ulcer</td>
<td>desquamation</td>
<td>necrosis</td>
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Sample Size of a Cohort Required to Detect a Significant Increase in Cancer Mortality

Typical Effective Doses From Cardiac Imaging

Simplified Hiroshima Atomic Bomb Dosimetry

5-100 mSv Group: 65% of Exposed Cohort
Mean Dose: 29 mSv
Excess Relative Risk: 0.02
p<0.05
Risks

Is radiation an important consideration?

Deterministic Effects
“Real”...but...“rare”
Skin injury infrequent

Stochastic Effects
Challenging to assess

What are the Risks of Not Diagnosing and Treating?

Life is full of risks
Determinants of Patient X-ray Dose

- **Equipment**
- **Procedure/Patient**
  - Obese patient
  - Complex/long case
- **Operator**
  - Training
  - Equipment use
Imaging Equipment

- **Purchase** X-ray units with sophisticated dose-reduction and monitoring features.

- **Maintain** X-ray equipment in good repair and calibration.

- **Utilize** the *Medical Physicist* to assess dose & image quality.
As patient size increases:
- Image quality deteriorates
- Input dose of radiation increases exponentially
- Scatter radiation increases

As the complexity increases (CTO):
- Increase fluoro/cine time
- Steeper angles/single port
- Repeat procedures
Know Previous Case(s) and Current Case

- If no entrance beam port overlap, each session is considered separately.
- If re-irradiate of exposed skin, increase time between stages.
- Examine pt’s skin before next case.
- Previously irradiated skin reacts abnormally if doses above 3–5 Gy.
- After skin doses of > 10 Gy, tissue will never return to normal.
- Erythematous reactions is reduced in previously irradiated skin.
- Increased skin sensitivity/complications from minor trauma or topical agents.

Pt presented to MSHMC clinic with no complaints 2 months following 5 stents, 105 mins fluoro, no Dose recorded, no F/u at performing institution provided...exam showed-
The Operator

*It is the Physicians’ Responsibility*

*Provide “Best Patient Care”*

Avoid any unnecessary study utilizing ionizing radiation by exposure **justification**, one of the basic principles of radiation protection.

**A knowledgeable physician**, well trained in radiation safety, who knows the patient is essential to obtain the best patient outcomes.

Avoid the “just one more procedure”
Training

- Establish a radiation safety education program to include:
  - **Initial training** or verification of prior training for all staff
  - **Annual updates**
  - **Hands on training** for newly hired operators and current operators on newly purchased equipment.

- The following topics should be addressed:
  - Physics of x-ray production and interaction
  - Technology and modes of operation of the fluoroscopy machine
  - Characteristics and technical factors affecting image quality
  - Dosimetry, quantities and units
  - Biological effects of radiation
  - Principles of radiation protection in fluoroscopy
  - Applicable federal, state, and local regulations and requirements
  - Techniques to minimize patient and staff dose.
Personnel Protection

“An ounce of prevention is worth a pound of cure”

Protecting the patient protects the operator and visa versa...
Staff Radiation Protection

- **Shielding**
  - Portable: above/below table shielding
  - Lead > 90%; Proper care of aprons
  - Thyroid shielding; most important < 40
  - Glasses - 0.25 mm; must fit
  - Hats: BRAIN Study
  - Drapes (Bismuth-barium-lead?)

- **Personnel Dosimeters: For Your Protection**
  - ICRP 2 - Outside collar, inside waist
  - *However, one worn correctly is better than two worn improperly.*
  - Single badge at Waist - Not acceptable
  - Ring badge - Key if “need” hand in field
NCRP Staff Exposure Limits

- **Whole Body***
  5 rem (50 mSv)/yr

- **Eyes***
  15 rem (150 mSv)/yr

- **Pregnant Women**
  50 mrem (0.5 mSv)/mo

- **Public**
  100 mrem (1.0 mSv)/yr

*ICRP movement to 20 mSv/yr

1 rem = 10 mSv (0.001 Sv)

Cataract in eye of interventionist after repeated use of over table x-ray tube

www.ircp.org
Radiation Dose Management

Pre-Procedure Issues

**Assessment of Risk**
- the obese patient
- complex PCI/CTO
- repeat procedures within 30-60 days
- other radiation-related procedures

**Informed Consent Components**
- procedures are performed using x-ray ionizing radiation
- x-rays are delivered to help guide the equipment as well as to acquire images for long term storage
- your physicians will deliver the dose required for the procedure
- although risk is present, this rarely results in significant injury
- in complex cases, local tissue damage to the skin or even underlying layers may occur that may require additional follow up and treatment
Procedure Related Issues to Minimize Exposure to Patient

- Keep table height as high as comfortable possible for the operator
- Vary the imaging beam angle to minimize exposure to any 1 skin area
- Keep patient’s extremities out of the beam

Protecting the patient will protect the staff and visa, versa
Procedure Related Issues to Minimize Exposure to Patient and Operator

- Utilize radiation only when imaging is necessary
- Minimize use of cine
- Minimize steep angles
- Minimize use of magnification
- Minimize frame rate of fluoroscopy and cine
- Keep the image receptor close to the patient
- Utilize collimation to the fullest extent possible
- Monitor real time rad. dose

**DRAPE**

- **D**-distance: inverse square law
- **R**-receptor: close to patient and collimate
- **A**-angles: avoid steep angles
- **P**-pedal: limit foot on pedal only if looking at the monitor
- **E**: extremities-keep patient/operator extremities out of the beam
- **D**-dose: limit cine, adjust frame rate, where personal dosimeter
Higher head and eye exposure occurs during oblique angle projections when the x-ray tube is tilted toward the operator or staff (II away). Radiation exposure decreases when the tube is tilted away (II toward). If given the option, stay on the II side. Note: scatter is still directed toward the waist regardless of tube tilt.
**Procedure Related Issues to Specifically Minimize Exposure to Operator**

- Use and maintain appropriate protective garments
- Maximize distance of operator from X-ray source and patient
- Keep above-table and below-table shields in optimal position at all times
- Keep all body parts out of the field of view at all times

**Inverse Square Law**

\[
I_1 / I_2 = (d_2)^2 / (d_1)^2
\]

This relationship shows that doubling the distance from a radiation source will decrease the exposure rate to 1/4 the original.
Post Procedure Issues

- **Cardiac Catheterization Reports** should include Fluoroscopic Time, and Total Air Kerma at the Interventional Reference Point (IRP) Cumulative Air Kerma ($K_{a,r}$, Gy), and/or Air Kerma Area Product ($P_{KA}$, Gycm$^2$).

- FT is the least useful, $P_{KA} \times 100$ in Gy/cm$^2$ of the $K_{a,r}$ in Gy.

- **Chart Documentation** following procedure for $K_{a,r}$ doses $\geq 5$ Gy.

- **Follow up** at 30 day is required for $K_{a,r}$ of 5-10 Gy. (Call/Visit)

- **For $K_{a,r} > 10$ Gy**, a qualified physicist perform a analysis.

- Contact risk management $< 24$ hr for calculated PSD $\geq 15$ Gy.

- **Adverse Tissue Effects** is best assessed by history/exam. Biopsy only if uncertain diagnosis. Wound from the biopsy may result in a secondary injury potentially more severe.
Physician Responsibilities: Follow-up

- **Properly document** high dose cases.
  - 15 Gy sentinel event by JACHO.
- **Patients** with “significant” skin doses should be **followed up**.
- **Establish a system** to identify repeat procedures.
- **Patient and family education**
  - Radiation skin injury may present late.
  - Avoid biopsy of suspected lesions.
Class I

Cardiac catheterization laboratories should **routinely record relevant patient procedural radiation dose data** (e.g., total air kerma at the interventional reference point ($K_{ar}$), air kerma area product ($P_{KA}$), fluoroscopy time, number of cine images), and **should define thresholds with corresponding follow-up protocols for patients who receive a high procedural radiation dose.** *(Level of Evidence: C)*
Individualized management by an experienced radiation wound care team should be provided for wounds related to high dose radiation.

For any patient exposed to significant high dose, > 10 Gy, not only is medical follow-up essential, full investigation of the entire case is desirable to minimize the likelihood of such an event being repeated.
Implementing a Culture of Safe Practice

At Home…
Radiation Dose Management

...IN THE CATH LAB

- **Justification of Exposure**
  - benefit must offset risk
- **ALARA**
  - As Low As Reasonably Achievable
- **Training**
  - Initial and Updates
- **Optimizing Patient Dose**
  - From Onset Of Procedure
- **Radiation Safety Program**
  - CCI Paper
Radiation Dose Reduction... It Works!

Implementing a Culture & Philosophy of Radiation Safety resulted in a 40% reduction in Cumulative Skin Dose over a 3 yr period.

**Objective**
This paper investigates the effects of sustained practice and x-ray system technical changes on the radiation dose administered to adult patients during invasive cardiovascular procedures.

**Background**
It is desirable to reduce radiation dose associated with medical imaging to minimize the risk of adverse radiation effects to both patients and staff. Several clinical practice and technical changes to elevate radiation awareness and reduce patient radiation dose were implemented under the guidance of a cardiovascular invasive labs radiation safety committee. Practice changes included: Intraprocedure radiation dose announcements; reporting of procedures for which the air-karma exceeded 6,000 mGy, including procedure air-karma in the clinical report; and establishing compulsory radiation safety training for fellows. Technical changes included establishing standard x-ray imaging protocols, increased use of x-ray beam spectral filters, reducing the detector target dose for fluoroscopy and acquisition imaging, and reducing the fluoroscopy frame rate to 7.5 s⁻¹.

**Methods**
Patient- and procedure-specific cumulative skin dose was calculated from air-karma values and evaluated retrospectively over a period of 3 years. Data were categorized to include all procedures, percutaneous coronary interventions, coronary angiography, noncardiac vascular angiography and interventions, and interventions to treat structural heart disease. Statistical analysis was based on a comparison of the cumulative skin dose for procedures performed during the first and last quarters of the 3-year study period.

**Results**
A total of 18,115 procedures were performed by 27 staff cardiologists and 65 fellows-in-training. Considering all procedures, the mean cumulative skin dose decreased from 969 to 568 mGy (40% reduction) over 3 years.

**Conclusions**
This work demonstrates that a philosophy of radiation safety, implemented through a collection of sustained practice and x-ray system changes, can result in a significant decrease in the radiation dose administered to patients during invasive cardiovascular procedures.
In January 2013, institutional application of a comprehensive initiative to reduce doses in patient and physicians:

- Default fluoroscopy frame rate 7.5fps
- Emphasis on “low dose acquisition”
- Optimal imaging practices-manage dose
- Monthly Review/critic of dosimetry

- 2838 Cath/ 209 PCI; Matched 2012/2013
- Siemens Artís Zee Ceiling mounted systems
- Median Total Air Kerma at IRP ($P<0.001$)
  - 2012: Cath-798mGy; PCI-2463mGy
  - 2013: Cath-625mGy; PCI-1675
  - Cath 22% and PCI 32% Reduction

“Although the term cine is still used in cath terminology, the modern digital systems are no longer cine based. The images that are acquired for storage are said to be captured in acquisition mode. Fluoroscopy is simply live imaging using lower radiation dose, which is usually not stored”
Radiation Dose Management in PCI

1. Pre-Proceduer
   - Radiation safety program for cath lab
   - Dosimeter use, shielding, training/education
   - Equipment and operator knowledge
   - On screen dose assessment ($K_{a,r}$, $P_{KA}$)
   - Dose saving: store fluoro, adj. pulse and frame rate, and last image hold
   - Pre-proceduer dose planning
     - assess patient and procedure including
     - patient’s size and lesion(s) complexity
   - Informed patient with appropriate consent

2. Procedure
   - Limit fluoro: use petal only when looking at screen
   - Limit cine: store fluoro if image quality not key
   - Limit magnification, frame rate, and steep angles
   - Use collimation and filters to fullest extent possible
   - Vary tube angle if possible to change skin exposed
   - Position table & image receptor: x-ray tube close to pt increases dose; high image receptor incr. scatter
   - Keep pt & operator body parts out of field of view
   - Maximize shielding and distance from x-ray source for all personnel
   - Manage and monitor dose in real time from the beginning of the case

3. Post Procedure

Have Follow-up in place

• Chambers CE. Radiation Dose in PCI. OUCH…Did that hurt?
Summary

- Physics of Imaging
  - Image noise and dose

- Assessment of Dose
  - More than Fluoroscopy time

- Determinant of Dose
  - Equipment/Procedures

- Exposure Justification
  - Benefit must offset risk

- Operator Training
  - Initial and Updates

- Optimizing Dose
  - From Onset Of Procedure

Manufactured by CCC*

*CCC-Chambers Construction Company
Radiation Safety in Cardiovascular Care

Training

Appropriateness

Justification

+ vs. +

ALARA = As Low As Reasonably Achievable;

NIWID = No Idea What I’m Doing

Good

Patient Outcomes

Bad
Suggested Reading


Questions
#1.

The following is **not** true regarding X-ray imaging:

a. Scattered radiation is the principle source of exposure to patient and staff.

b. Noise increases proportional to X-ray dose and decreases image quality.

c. The dose delivered to the patient is derived from the X-ray photons that enter but do not leave.

d. Optimal X-ray imaging requires a kVp (peak tube voltage) and mA (cathode current) that produces the best balance of image contrast and patient dose.
#1. Annotation: Correct Answer B. All are true except that increase dose decrease noise and improves image quality.
#2. Which of the following is true:

a. Dose at the interventional reference point (IRP) is the absorbed dose.

b. Fluoroscopic time is an acceptable predictor of peak skin dose.

c. The stochastic effect increases with dose with an identifiable threshold.

d. Factors that influence the patient absorbed dose include the equipment, the procedure/patient, and the operator.
#2. Annotation: Correct Answer D. Dose at the interventional reference point (IRP) is used to reflect the skin dose. Fluoroscopic time does not account for patient size, beam motion, or acquisition images and therefore is a poor predictor of peak skin dose. The deterministic effect increases with dose with an identifiable threshold. The stochastic effect increases with a linear dose response but no identifiable threshold. Factors that influence the patient absorbed dose include the equipment, the patient, and the procedure.
#3. Which of the following is **not** true regarding physicians role in reducing patient dose:

a. Minimize beam-on time.
b. Use the collimators to limit field size.
c. Limit angulation, particularly in the obese patient.
d. Keep the image receptor up & the X-ray tube down.
e. Keep tube current (mA) as low as possible
f. Keep tube voltage (kVp) as high as possible.
#3. Annotation: Correct Answer D. All are correct except one should keep the image receptor down & the X-ray tube up.
#4. A deterministic effect of ionizing radiation skin injury...

a. Rarely appears within one week of the procedure.
b. May have the healing process delayed by biopsy.
c. Typically occurs with radiation exposures greater than 5Gy.
d. Is reduced by collimation and changing angulation.
e. All of the above.
#4. Annotation: Correct Answer E, all are true. The diagnosis of deterministic radiation skin injury should be by history and physical with biopsy potentially worsening the lesion and delaying healing. The lesion usually appears several weeks to a month post procedure. At least 2 Gy and more likely >5 Gy exposure is needed for radiation skin injury. Changing beam angles reduces skin injury; collimation, though not impacting total dose, decreases area of skin at risk for radiation injury.
#5. Which of the following is true?

a. Patient’s dose is dependent upon the inverse square law.

b. Specific lead equivalent eye wear, though recommended, is unlikely to be beneficial.

c. For personal dosimetry, a single dosimeter at waist level is adequate for operator exposure.

d. Air Kerma Area Product also known as **Dose Area Product (DAP)** better reflects stochastic than deterministic effects.

e. None of the above.
#5. Annotation: Correct answer is D. Operator and staff dose is affected by the Inverse square law. Eye protection should be worn by all operators so as to decrease incidence of posterior sub capsular cataract formation. A single dosimeter at collar level may be acceptable, though ICRP recommends two dosimeters, one at collar outside and one at waist inside. Though DAP can reflect deterministic effects, Total Air Kerma at the Interventional Reference Point also called cumulative air kerma, in Gy is the more commonly used parameter for identifying the high risk patient for radiation induced deterministic skin injury.
1. Correct Answer B. All are true except increase dose decreases noise and improves image quality.

2. Correct Answer D. Dose at the interventional reference point (IRP) is the **skin dose**. Fluoroscopic time does not account for patient size, beam motion, or acquisition images and therefore is a poor predictor of peak skin dose. The deterministic effect increases with dose with an identifiable threshold. The stochastic effect increases with a linear dose response but no identifiable threshold. Factors that influence the patient absorbed dose include the equipment, the patient, and the procedure.

3. Correct Answer D. All are correct except one should keep the image receptor down & the X-ray tube up.

4. Correct Answer E, all are true. The diagnosis of deterministic radiation skin injury should be by history and physical with biopsy potentially worsening the lesion and delaying healing. The lesion usually appears several weeks to a month post procedure. At least 2 Gy and more likely >5 Gy exposure is needed for radiation skin injury. Changing beam angles reduces skin injury; collimation, though not impacting total dose, decreases area of skin at risk for radiation injury.

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