# Interventional Fluoroscopy Procedures

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## Learning Objectives

- Effects on patient's skin, hair, eyes, and other tissues.
- The use of controls and real-time displays of radiation quantities; their relation to radiation risks.
- Adequate communication of radiation risk
  - As part of the informed consent process
  - Post-procedure




## Background

- Most FGI procedures have several associated major risks.
- Procedures might require a substantial amount of radiation for their completion.
- Radiation should be regarded as a toxic agent in the same sense as contrast-media and pharmaceuticals.
- Managing all toxic agents should be a part of a continuous benefit-risk assessment.




## Some non-radiation risks

- Serious allergic reaction to contrast materials (iodine).
- Kidney injury due to the contrast material.
- Damage to the blood vessel, bruising or bleeding at the puncture site, and infection.
- Blood forms a clot around the tip of the catheter, blocking the artery and making it necessary to operate to reopen the vessel.
- Stroke if the catheter dislodges plaque from a vessel wall that blocks blood flow within the brain.
- The catheter punctures an artery, causing internal bleeding.

Adapted from Cerebral Angiography @ radiologyinfo.org Accessed May 2013




## Justification and Optimization

- Operators need to know
  - Biological risks at different dose levels
  - Clinical factors that might modify risk
  - Radiation status during the procedure
- Optimization
  - Equipment construction and configuration
  - Physics QA (beyond regulatory minimum)
  - Operator's utilization of equipment features
  - Operator's clinical abilities




# BIOLOGY and CLINICAL

## Radiogenic Risk

- Hair loss (temporary or permanent)
- Injury of skin and subcutaneous tissues.
- Bone injury
- Radiogenic cataract
- Non-cancer vessel and organ damage




## Radiation Effects Chart

**Tissue Reactions from Single-Delivery Radiation Dose to Skin of the Neck, Torso, Pelvis, Buttocks, or Arms**

| Band | Single-Site Acute Skin-Dose Range (Gy)[a] | NCI Skin-Reaction Grade[b] | Approximate Time of Onset of Effects: Prompt | Early | Midterm | Long Term |
|---|---|---|---|---|---|---|
| A1 | 0–2 | NA | No observable effects expected | No observable effects expected | No observable effects expected | No observable effects expected |
| A2 | 2–5 | 1 | Transient erythema | Epilation | Recovery from hair loss | No observable results expected |
| B | 5–10 | 1–2 | Transient erythema | Erythema, epilation | Recovery; at higher doses, prolonged erythema, permanent partial epilation | Recovery; at higher doses, dermal atrophy or induration |
| C | 10–15 | 2–3 | Transient erythema | Erythema, epilation; possible dry or moist desquamation; recovery from desquamation | Prolonged erythema; permanent epilation | Telangiectasia[c]; dermal atrophy or induration; skin likely to be weak |
| D | >15 | 3–4 | Transient erythema; after very high doses, edema and acute ulceration; long-term surgical intervention likely to be required | Erythema, epilation; moist desquamation | Dermal atrophy; secondary ulceration due to failure of moist desquamation to heal; surgical intervention likely to be required; at higher doses, dermal necrosis, surgical intervention likely to be required | Telangiectasia[c]; dermal atrophy or induration; possible late skin breakdown; wound might be persistent and progress into a deeper lesion; surgical intervention likely to be required |

Note — Applicable to normal range of patient radiosensitivities in absence of mitigating or aggravating physical or clinical factors. Data do not apply to the skin of the scalp. Dose and time bands are not rigid boundaries. Signs and symptoms are expected to appear earlier as skin dose increases. Prompt is ~2 weeks; early, 2–8 weeks; midterm, 8–52 weeks; long term, >40 weeks.

[a] Skin dose refers to actual skin dose (including backscatter). This quantity is not the reference point air kerma described by Food and Drug Administration (21 CFR § 1020.32 [2008]) or International Electrotechnical Commission (ILT). Skin dosimetry is unlikely to be more accurate than ± 50%. NA = not applicable.

[b] NCI = National Cancer Institute

[c] Refers to radiation-induced telangiectasia. Telangiectasia associated with area of initial moist desquamation or healing of ulceration may be present earlier.




## Tissue Reactions



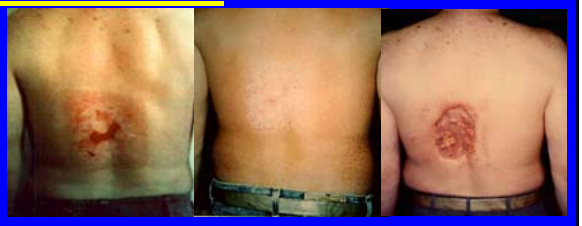

## Radiation Therapy Injuries

Bolus

Radiation Recall




## Time sequence



2 months 6 months 2 years

Source: FDA/CDRH




## Multiple procedures

- Biology
  - DNA repair complete in 24 hours
  - Skin cell death in approximately 30 days
  - Skin cells replaced in approximately 60 days
  - Microvasculature damage.
- "Routine" interval between stages
  - 4 to 6 weeks for different anatomy.
  - 8 to 12 weeks for same anatomy.
  - Examine patient's skin immediately before starting a new stage.

## Poor practice

2 m p 1

5 m p 1
1 m p 2

6 m p 1
2 m p 2

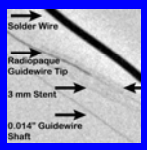
pre
op




## Management of a known reaction

1 m

2 m







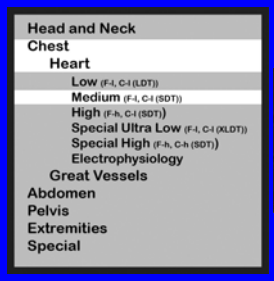
# TECHNOLOGY




## WIP – Real Time Skin Dose Mapping




## Clinical Selections




Control Panel


Table Side




## Dose rates - Mode

1 second of DSA
3-6 seconds of Cine
30-60 seconds of Fluoro

## Dose rates – Fluoro Frame Rate

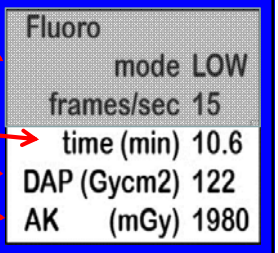



## In-lab cumulative radiation displays

System is set for low dose rate fluoroscopy using 15 fps

*Totals from the start of the procedure:*

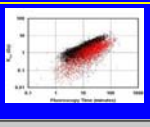
- Fluoroscopy time
- Air Kerma Area Product
- Air Kerma at the reference point

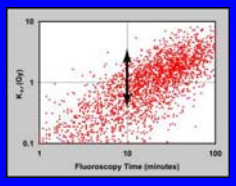


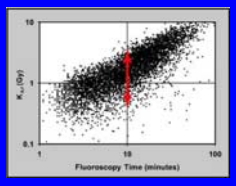

Provided so that the operator can track total radiation used as each procedure progresses !




## Fluoroscopy Time






≈2,100
non-cardiac interventions
$K_{a,r} = 0.41 + 0.037\ F_{min}$
$R^2 = 0.50$
RAD-IR I

≈1,700
coronary-artery procedures
$K_{a,r} = 0.53 + 0.12\ F_{min}$
$R^2 = 0.68$
IAEA-SRS 59




## Notifications (NCRP-168)

TABLE 4.7–Suggested values for first and subsequent notifications and the SRDL.

| Dose Metric | First Notification | Subsequent Notifications (increments) | SRDL |
|---|---|---|---|
| $D_{skin,max}$ | 2 Gy | 0.5 Gy | 3 Gy |
| $K_{a,r}$ | 3 Gy | 1 Gy | 5 Gy[a] |
| $P_{KA}$ | 300 Gy cm$^2$ [b] | 100 Gy cm$^2$ [b] | 500 Gy cm$^2$ [b] |
| Fluoroscopy time | 30 min | 15 min | 60 min |

[a]See additional discussion concerning the value 5 Gy in Section 4.3.4.2.
[b]Assuming a 100 cm$^2$ field at the patient's skin. For other field sizes, the $P_{KA}$ values should be adjusted proportionally to the actual procedural field size (*e.g.*, for a field size of 50 cm$^2$, the SRDL value for $P_{KA}$ would be 250 Gy cm$^2$).




## Radiation Dose Structured Report

- RDSR is a free-standing DICOM object without private fields.
- Provides shot-by-shot irradiation data.
- Initial post-procedure implementations are available on some new equipment.
- Streaming implementations coming.
- IEC standard under development to assure a consistant data set.




## c 1960 – Ad in Radiology

## Drilling down to the future?




# Patient Communication



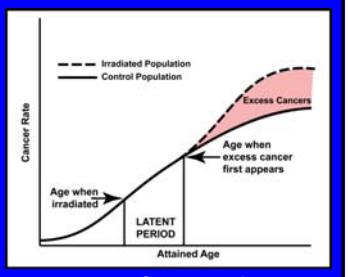

## Informed consent considerations

- Patient's age
- Patient's health details
- Patient's size
- Nature of the planned procedure
- Other irradiation of the same area
  - Previous interventional procedures
  - Previous or planned radiation therapy




## Latent Period (years)

- Leukemia
  Min 2 – 4
  Max 10 – 20
- Solid Cancer
  Min 10
  Max > 40




Conceptual cartoon




## Possible informed consent topics

- A slightly elevated risk of cancer several years or decades later in life. This risk is low in comparison to the natural risk of developing cancer.
- Skin rashes occur infrequently; on very rare occasions they may result in tissue breakdown and possibly severe ulcers.
- Hair loss may occur which can be temporary or permanent.
- Cataracts are rarely induced following neurointerventional procedures.
- You or your family will be advised if we actually used substantial amounts of radiation during the case. If this happens, you will be given appropriate instructions prior to discharge.

*Based on NCRP Report 168*




## Substantial Dose Procedures

- > 5,000 mGy – Less if clinically warranted.
- Lab provides 'hand-off' data:
- Patient receives radiation instructions
- Patient calls with possible reaction
  - Clinic visit with operator scheduled if PA can't absolutely rule out radiation.
- CUMC QA follow-up > 7,000 mGy
  - Proactive 30 – 40 days post procedure.
  - So far all patients contacted by QA with skin changes have already called us.
  - Continuing follow-up of known injuries.

## Radiation discharge instructions

- Have a family member look at your back 30 days from now.
- Call us (lab's 24 hour PA emergency number) if there is a red patch the size of your hand.

Catheterization and Cardiovascular Interventions 77:546–556 (2011)




## Substantial Dose (NCRP-168)

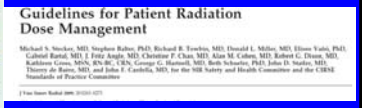
- If a substantial radiation dose level is exceeded, the patient and any caregivers *should* be informed, prior to discharge, about possible deterministic effects and recommended follow-up.
- Follow-up for possible deterministic effects *shall* remain the responsibility of the interventionalist for at least one year after an FGI procedure. Follow-up *may* be performed by another healthcare provider.

  All relevant signs and symptoms *shall* be regarded as radiogenic unless an alternative diagnosis is established.





## Further reading



Guidelines for Patient Radiation Dose Management