Biological Effects and Risks of Radiation from Fluoroscopic Procedures

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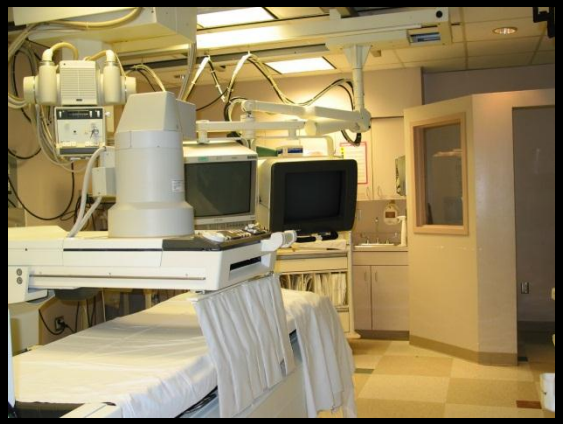
Medical School

Many images in handout removed to protect copyright

Mini C-arm

Mobile C-arm



GI (R&F) Room

Image intensified angiography

Bi-Plane angiography

Flat Panel angiography

Fluoroscopically guided procedures:

1. Minimally invasive diagnostic
    1. GI study
    2. Diagnostic angiogram
2. Simple invasive
    1. PICC line placement
3. Simple intervention
    1. Setting a broken hand
4. Moderate intervention
    1. Pain management
5. Complex intervention
    1. Angioplasty
    2. Stent placement
    3. Electrophysiological and ablation
    4. TIPS
    5. Embolization procedures

Reference: Vañó E et al, BJR 1998; 71, 728-733

Effects from inappropriate use of fluoroscopy

In workers effects commonly due to long-term accumulation (chronic build-up) of radiation dose.

In patients effects typically due to accumulation of high radiation doses in a short time period, except for…….

…potential hypothetical stochastic effects --

Induced neoplasm
Heritable genetic effects

--which are hypothesized as possible at any dose.

Priority of concerns for fluoroscopy :

1. Short-term (weeks to months) debilitating deterministic effects (e.g., radiation injury)
2. Long-term (years to decades) debilitating deterministic risks (e.g., cataract, osteonecrosis)
3. Long-term stochastic risks (e.g., cancer) [Typically this is primary concern in abdominothoracic procedures in small children]
4. Short-term cosmetic risks (e.g., epilation)

Special concern:

1. Pregnancy (pregnancy test required for many procedures that potentially deliver high doses to uterus – e.g., hysterosalpingogram)








Some images courtesy Fred Mettler , Ron Vlietstra, R. M. Partnership

Radiation injury associated with wide range of complex procedures

Injuries have occurred in a wide variety of anatomical locations

Injuries have occurred around the world

Consent Topics for Complex Interventions

- *Hair loss*
  - Usually temporary; regrowth of hair may be incomplete.
- *Skin rashes*
  - Infrequent, on very rare occasions they may result in tissue breakdown and possibly severe ulcers.
- *Slightly elevated risk for cancer*
  - Later in life. This risk is typically low compared to the normal incidence of human cancer.
- *Cataracts* occur rarely.

Courtesy of anonymous contributor

Radiation risk as an appropriate part of the informed consent process.

- **Patient size**
- **Anticipated complexity**
- **Coexisting diseases or conditions**
  - Scleroderma; systemic lupus erythematosus; possibly rheumatoid arthritis; Hyperthyroidism; poor nutritional status; compromised skin integrity (diabetes mellitus – thought to negatively impact recovery from raidation damage)
- **Genetic factors**
  - heterozygous for the *ATM gene;* Fanconi anemia; Bloom syndrome; xeroderma pigmentosum; Familial polyposis; Gardner syndrome; hereditary malignant melanoma; dysplastic nevus syndrome; Neurofibromatosis; Li-Fraumeni syndrome; Hereditary retinoblastoma
- **Medication use**
  - actinomycin D; doxorubicin; bleomycin; 5-fl uorouracil; methotrexate; when given in conjunction with radiation therapy: paclitaxel, docetaxel, and possibly tamoxifen can result in cutaneous toxicity
- **Radiation history**
- **Pregnancy**

Most important facts about radiation injury from fluoroscopy:

1. A delay of weeks often occurs between irradiation and recognizable symptoms of injury, shorter delays also occur;
2. This delay results in a lack of association on the parts of physicians and patients between the fluoroscopy and the injury;
3. Patients are often unaware that fluoroscopy procedures use x rays and are usually totally unaware that fluoroscopy can cause injury;
4. Physicians are often unaware that fluoroscopy can cause injury;
5. Physicians are often poorly trained in dose management.

Prevalent features of radiation injury (burn) cases

- Large patient
- Vessel hard to see - small, overlap with spine, high angle needed
- Trouble passing lesion, calcium, dissection
- Less experienced interventionalist
- Long fluoroscopy, many cines, hi-dose used
- Interventionalist unaware of radiation risk to patient
- No monitoring of dose – not available or not used

Diagnosis of Radiation Injury

- Skin absorbed dose must be high (beam mostly fixed on same skin site)
- Must be located at entrance beam site
- Temporal patterns must fit with progression of injury
- Pattern must match collimation in size and shape (with consideration to movement of beam during procedure)
- Biopsy generally unnecessary and to be avoided if possible

30 weeks

38 weeks
(NCRP)

Recent communications on radiation injury

•no one knows...nor does anyone want to know...what do I do...please help me.
•Happened during stent placement December 2008.@ well-known hospital, two lengthy procedures with-in 3 days.
•No one advised me nor informed me that I was exposed to excessive radiation. I recently received my records,(Dec 2010). I had a long duration of radiation exposure and yet not one person told me so.
•I went through months of infection and pain and to this day it still hurts and unbearable itching.
•In January 2010 I had a quad by pass and the surgeon said,and I quote, "in my opinion,when they placed the stents on wednesday and there was a serious problem,they should not have replaced the stents on friday but rather done a bypass“
•I understand that I may be looking at cancer down the road. I don't know,I'm not a doctor. What kind of test can be made to keep a eye on this? Who should be responsible for any damage?
•I had a endoscopy in February 2010 and the doctor said he thinks the radiation has thinned the wall of my esophagus and must watch it closely. Attached are photos I had taken through different stages and the wound appears to be getting red once again. Please if you can be of any help,please call me or Email me.

Recent communications on radiation injury

- As you know, radiation is the gift that keeps on giving.
- After several weeks of having a different kind of pain on top of his usual ongoing pain, K had an MRI, showing rib fractures, posterior T9, possible nonunion, and a fracture at posterior T8.
- With his debilitating ongoing pain, K does very little in the way of physical activity so it is baffling to try to figure a cause of two fractured ribs. The doctor who did the surgery for K's latissimus flap diagnosed it as osteoradionecrosis.
- Ribs T9 ad T8 are in direct line of what he figures to be the strongest blast of radiation from K's two heart ablation procedures
- It has been over four years since his first ablation procedure and over three years since the latissimus flap surgery.
- At this point K is not certain what his next step will be to fix the fractured ribs; there are a few options, none of which are attractive to him.
- In your studies have you come across a delay in radiation injury to the ribs? And if so, do you know how the injury was addressed? Or once the radiation starts its grip on the ribs, how long will it continue to cause damage? If you are aware of anyone who has gone through, or is going through, this particular injury, could you please ask that they contact us?

Five weeks after procedure

9 ½ Months after procedure

i really don't know how much more of this i can stand!!!!..do you have any idea looking at the photos, what i might be up against? it is so amazing but it seems i know more about my condition than all the doctors i have been to HOW CAN THAT BE???? do you have any stats on how many people suffer thru this????

Former major league professional athlete

Recognizing radiation injury and effects

Fluoroscopically Guided Interventional Procedures: A Review of Radiation Effects on Patients' Skin and Hair

Stephen Balter, PhD,
John W. Hopewell, DSc,
Donald L. Miller, MD,
Louis K. Wagner, PhD and
Michael J. Zelefsky, MD

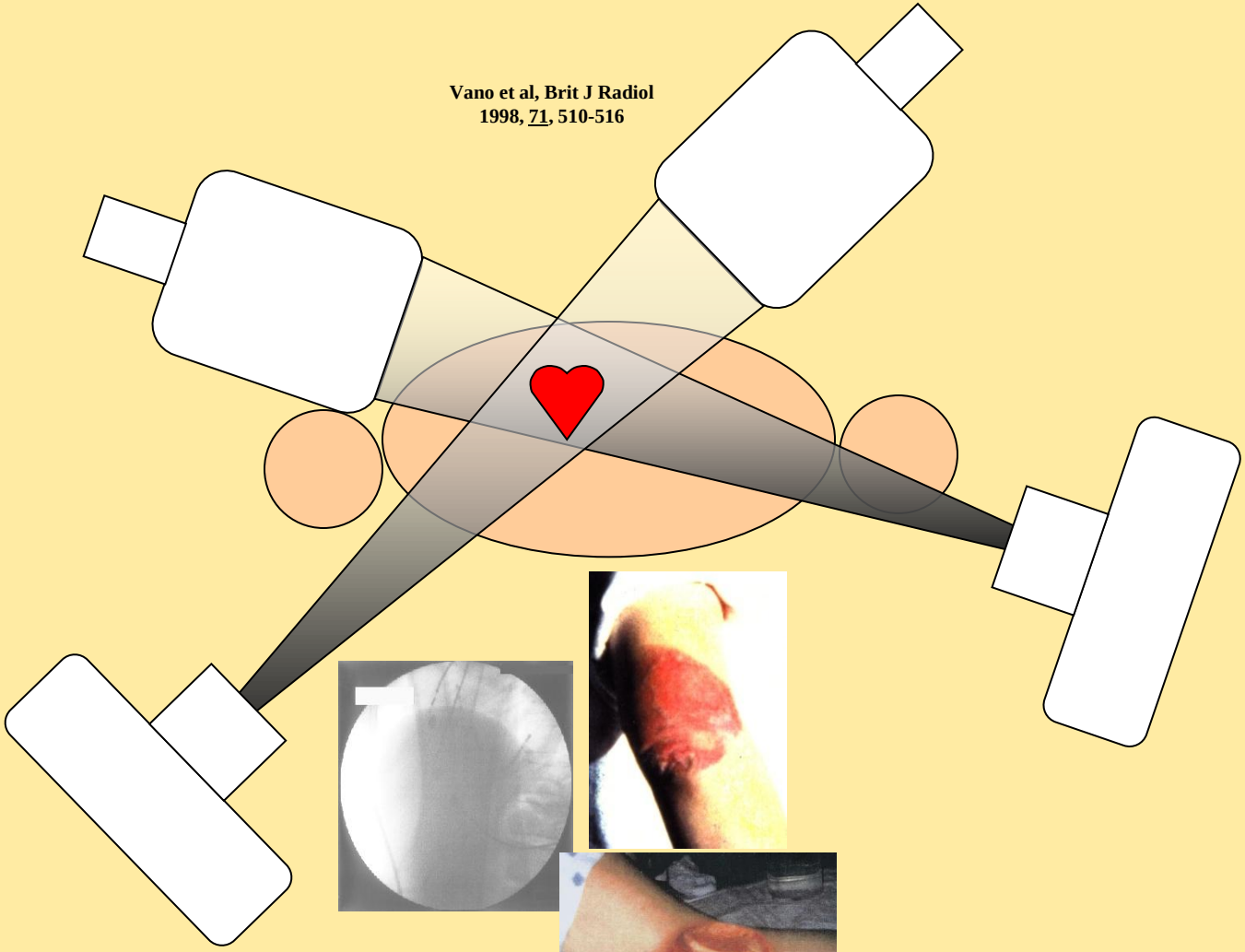
February 2010 Radiology, 254, 326-341.

Recognizing radiation injury and effects

Case Report

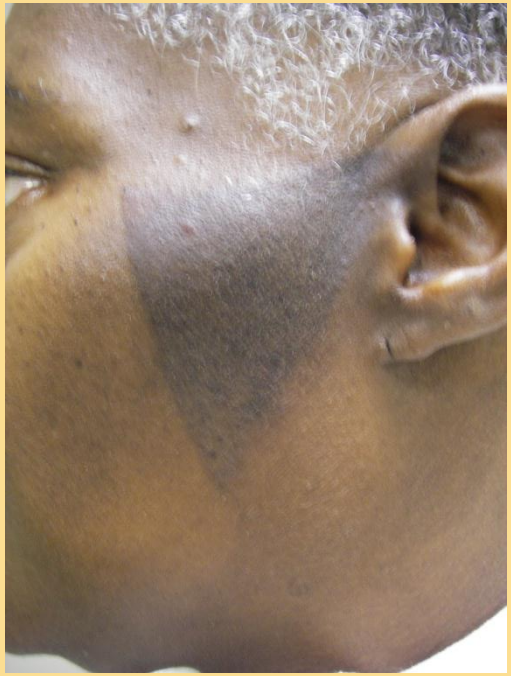
- Patient required coronary intervention.
- Had had surgery and previous FGI procedures at different facility by different doctors.
- Patient refused further surgery.
- Present cardiologist examined patient and found skin erythema from his previous procedures.
- What should he do?

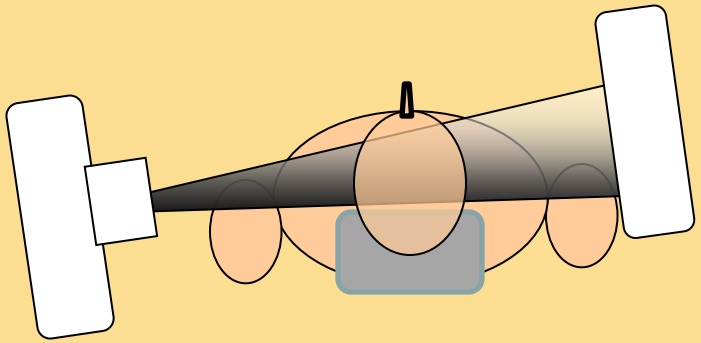
Vano et al, Brit J Radiol
1998, 71, 510-516



Wagner – Archer, Minimizing Risks from Fluoroscopic X Rays, 3rd ed, Houston, TX, R. M. Partnership, 2000

From Vlietstra et al., Radiation Burns as a Severe Complication of Fluoroscopically Guided Cardiological Interventions Journal of Interventional Cardiology
Volume 17, Issue 3, pages 131-142, 9 JUN 2004 DOI: 10.1111/j.1540-8183.2004.09885.x
http://onlinelibrary.wiley.com/doi/10.1111/j.1540-8183.2004.09885.x/full#f3





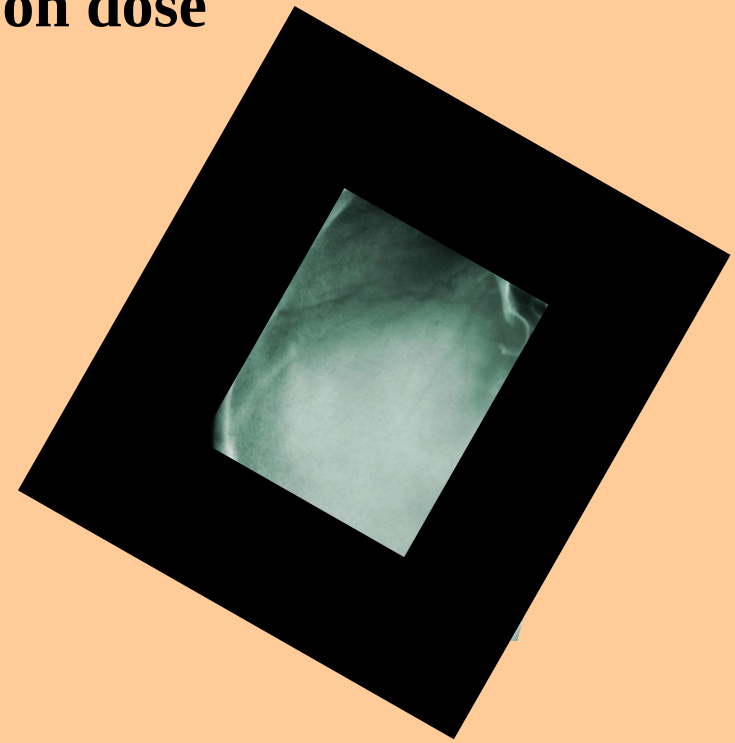
7th July (treatment was on the 15th June)

19th July

Radiation Risks

Induced Cataract

- **Threshold < 0.7 Gy**
- **Onset depends on dose**



Radiation-induced cataract in medical personnel

❖PA orientation delivers only exit dose
❖Shield eyes from lateral beam using collimation

Cataracts among Chernobyl Clean-up Workers: Implications Regarding Permissible Eye Exposures

Worgul BV, Kundiyev YI, Sergiyenko NM, Chumak VV, Vitte PM, Medvedovsky C, Bakhanova EV, Junk AK, Kyrychenko OY, Musijachenko NV, Shylo SA, Vitte OP, Xu S, Xue X, Shore RE

Radiation Research 167, 233-243, 2007

- Prospective study of 8607 Chernobyl clean-up workers assessed at 12 and 14 years after exposure
- Cohort young and prevalence of cataracts prior to clean-up assumed similar to prevalence of age-dependent cataract in non-cleanup cohorts.
- Baseline reference was individuals exposed to less than 100 mGy.
- Dose response effect found
- Threshold for induction of Stage 1 opacities ~350 mGy, perhaps less, and not in excess of 700 mGy.

Radiation injury and anatomy

Except for hair loss, scalp less sensitive to radiation, but neck and back more susceptible.

Courtesy of Kent Ogden, PhD

Courtesy of anonymous contributor

Radiation injury and anatomy

Young female breast is most sensitive organ for induced cancer.

Avoid if possible the direct entrance irradiation of the breast.

Follow-Up Plan

- Necessary when large radiation doses are used
- Self-exam at 2 –3 weeks
  - May not cause symptoms
  - The patient can’t see his/her own back
  - Patient needs to know location of the radiation field
- May need follow-up for > 1 yr
- Useful for operator QI

Without a Plan…

- Patient goes to dermatologist, not you
- Neither dermatologist nor patient may consider fluoroscopy as the etiology
  - Patient doesn't think it is relevant
  - Dermatologist thinks dose is too low
- Unnecessary skin biopsy performed
  - Biopsy not pathognomonic
  - May result in non-healing ulcer
  - Diagnosis can be made from a careful history and the appearance of the lesion
- Diagnosis likely to be delayed

Case Report

- Patient scheduled for anticipated long and difficult coronary intervention.
- Patient not a candidate for surgery.
- Cardiologist explained benefits/risks to patient.
- After very long and difficult procedure, patient advised of radiation exposure and that erythema was likely to develop. Patient told what to expect and what to do if symptoms arose.
- Patient called two weeks later indicating that the itching had begun and erythema was developing.
- Patient referred to dermatologist. Cardiologist advised dermatologist that radiation was likely cause of skin effects.
- Dermatologist studied up on radiation treatment and prepared a course for the patient.

Result: Patient treated early for skin effect and not surprised by the development. Patient has more confidence in physician's quality of care. Case is ongoing.

Organs at highest risk for induced cancer

Female Breast (under ~35)

Lung

Childhood thyroid

Colon

Bone marrow (Leukemia)

Bladder

Risk for induced cancer from a whole-body dose:

For 20-year-olds, induced risk somewhere ~0.6% - 2.0% per 100 mGy

For infants it's about twice that of 20-year-old.

For 50-year-olds it's about half that of 20-year-old.

Mortality risk is about half that of incidence.

Females are at greater risk than males by about a factor of 1.3 – 2.0, depending on age at exposure.

TABLE 12D-1 Lifetime Attributable Risk of Cancer Incidence[a]

Cancer Site	Age at Exposure (years) 0	5	10	15	20	30	40			80
Males										
Stomach	76	65	55	46	40	28	27	25	20	7
Colon	336	285	241	204	173	125	122			30
Liver	61	50	43	36	30	22	21			3
Lung	314	261	216	180	149	105	104			34
Prostate	93	80	67	57	48	35	35			5
Bladder	209	177	150	127	108	79	79			23
Other	1123	672	503	394	312	198	172			23
Thyroid	115	76	50	33	21	9	3			0.0
All solid	2326	1667	1325	1076	881	602	564			126
Leukemia	237	149	120	105	96	84	84	84	82	48
All cancers	2563	1816	1445	1182	977	686	648	591	489	343	174
Females										
Stomach	101	85	72	61	52	36	35			11
Colon	220	187	158	134	114	82	79			23
Liver	28	23	20	16	14	10	10			2
Lung	733	608	504	417	346	242	240			77
Breast	1171	914	712	553	429	253	141			4
Uterus	50	42	36	30	26	18	16			2
Ovary	104	87	73	60	50	34	31	25	18	11	5
Bladder	212	180	152	129	109	79	78	74	64	47	24
Other	1339	719	523	409	323	207	181	148	109	68	30
Thyroid	634	419	275	178	113	41	14	4	1	0.3	0.0
All solid	4592	3265	2525	1988	1575	1002	824	678	529	358	177
Leukemia	185	112	86	76	71	63	62	62	57	51	37
All cancers	4777	3377	2611	2064	1646	1065	886	740	586	409	214

NOTE: Number of cases per 100,000 persons exposed to a single dose of 0.1 Gy.

100,000 women aged 30

Single dose of 100 mGy

Over their lifetime

Risk Models

- Lifetime Attributable Risk (LAR)
  - "Because of the various sources of uncertainty it is important to regard specific estimates of LAR with a healthy skepticism, placing more faith in a range of possible values" (BEIR VII, page 278)

AAPM Position Statement (selected quote)

Risks of medical imaging at patient doses below 50 mSv for single procedures or 100 mSv for multiple procedures over short time periods are too low to be detectable and may be nonexistent. Predictions of hypothetical cancer incidence and deaths in patient populations exposed to such low doses are highly speculative and should be discouraged. These predictions are harmful because they lead to sensationalistic articles in the public media that cause some patients and parents to refuse medical imaging procedures, placing them at substantial risk by not receiving the clinical benefits of the prescribed procedures.

Health Physics Society Position

- Recommends against quantitative estimation of health risks below an individual dose of 50 mSv in one year or a lifetime dose of 100 mSv above that received from natural sources

…because

- For doses below 50–100 mSv risks of health effects are either too small to be observed or are nonexistent.

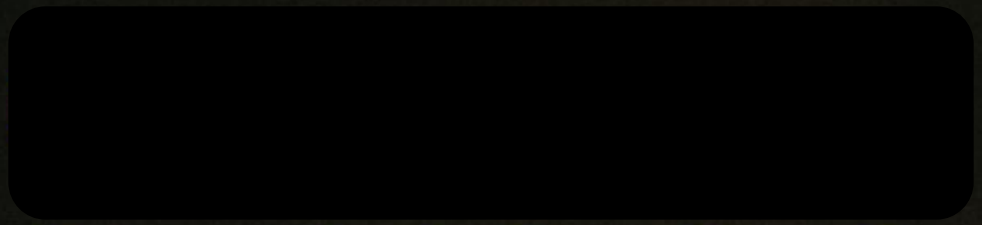
How should low-dose risk estimates be used?

As an inaccurate gauge by which we can assess the prudence of what we are doing with our medical imaging.

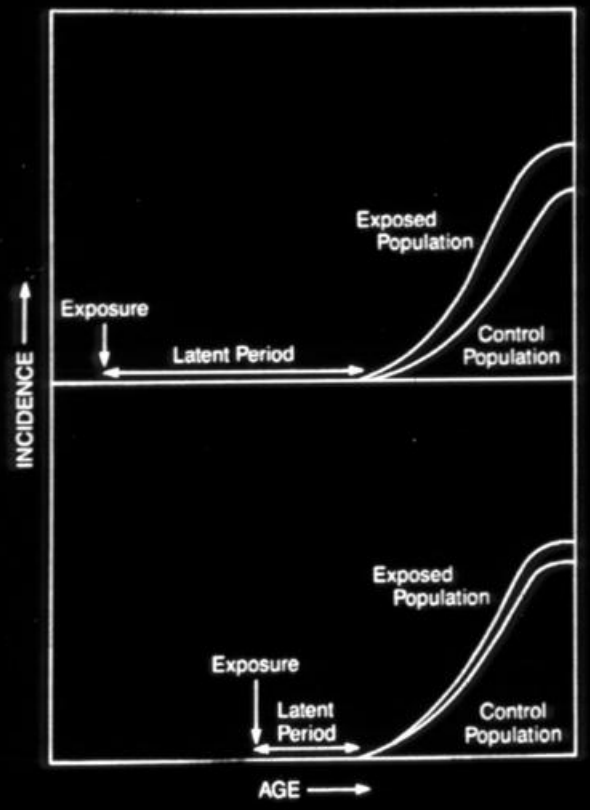
Conclusion: it is prudent to assess whether our medical benefit/risk is AHARA (As High As Reasonably Achievable)

Latent Periods

Leukemia: At least 2 yrs, peak ~12 −15yrs, >25 yrs unusual



Others: Typically at least 5 yrs, may occur at more than 40 yrs later



Siegel et al. Radiation Bioeffects Test and Syllabus, ACR, 1991

Cancer risk related to low-dose ionizing radiation from cardiac imaging in patients after acute myocardial infarction

Interpretation:

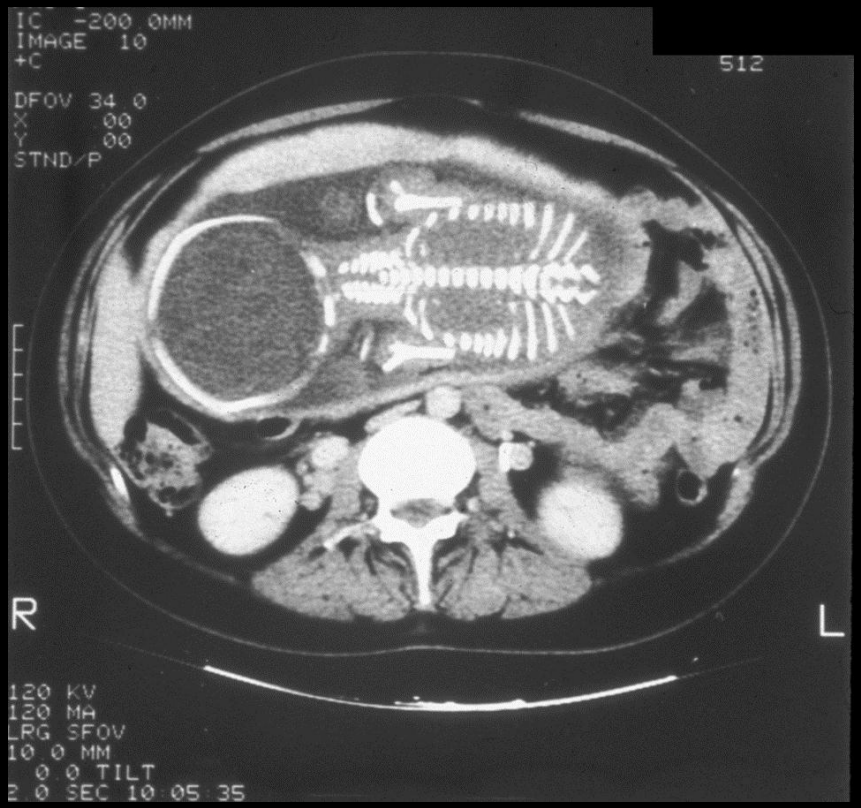
- **Exposure to low-dose ionizing radiation from cardiac imaging and therapeutic procedures after acute myocardial infarction is associated with an increased risk of cancer.**

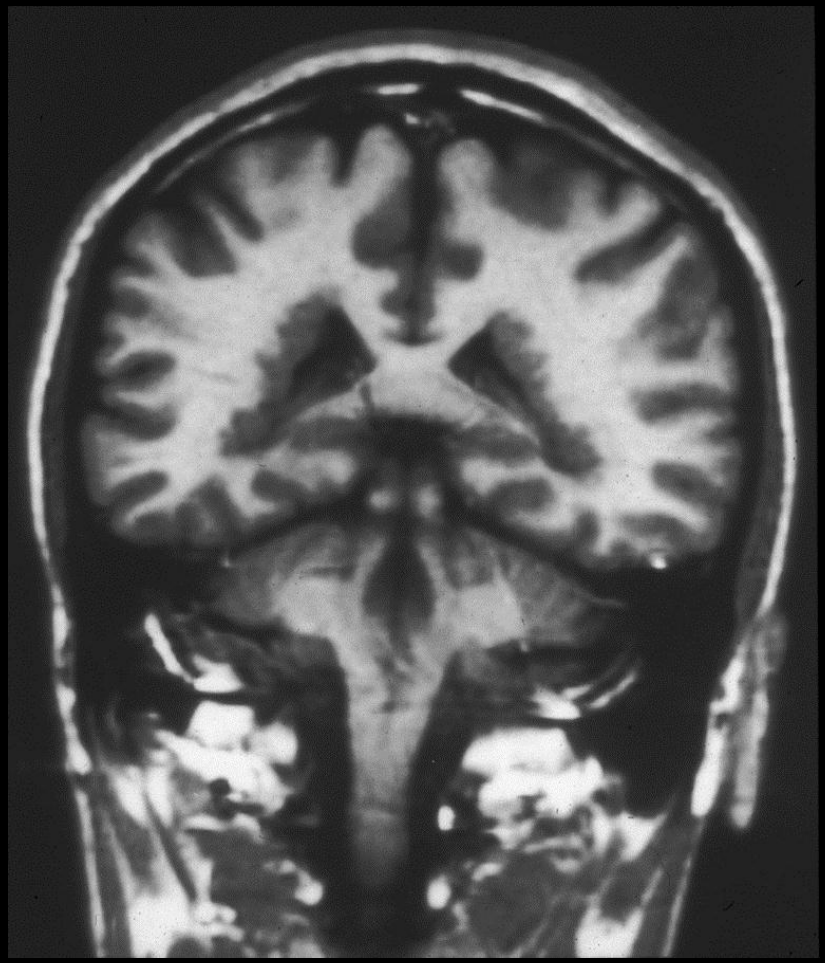
Cancer risk related to low-dose ionizing radiation from cardiac imaging in patients after acute myocardial infarction

Critique:

- **Percutaneous coronary intervention is a high dose procedure.**
- **Skin doses from such procedures are in the Gray range even though effective dose is 15 mSv.**

What we know about in-utero irradiation





Potential Risks at Doses under 200 mGy

Risk	Probable single-dose threshold (mGy)	Vulnerable postconception age
Cancer	~ 0	All stages??
Early Termination	~100	<2wks
Malformation	~100	>2, <9 wk
Small head size	> 50	>2, <16 wk
IQ deficit	~100	>7, <16 wk
Severe mental retardation	~150	>7, <16 wk

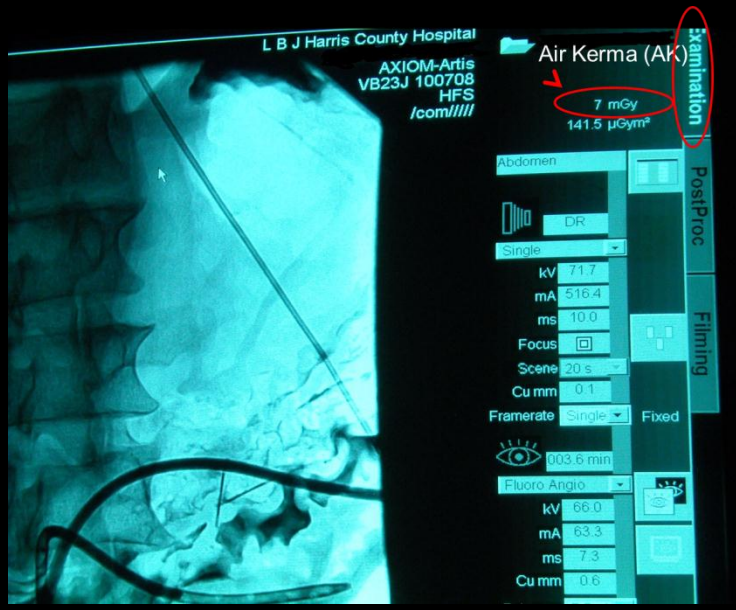
Roles of the medical physicist

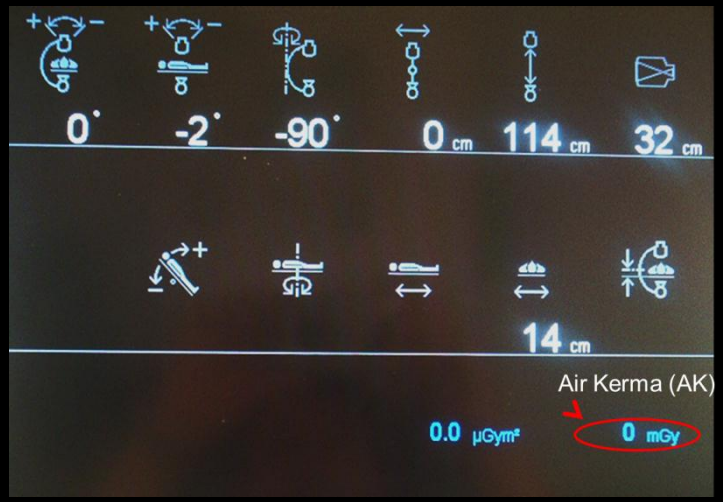
- Teacher
- Dose monitoring advisor
- Counselor

Teacher

- I had the pleasure to take your course for my radiation safety requirement at XXXX. It is this first time in 9 years of doing cardiac EP that someone actually explained the concepts in digestible form for clinicians. After your talk, I met with the Philips team (all of our fluoroscopy equipment is Philips) and I asked them to set-up the fluoroscopy to the lowest dose that still provides clinical utility. They were able to make adjustments and the Air Kerma readouts are significantly lower for us in EP (this is the unit they adjusted) compared to the unadjusted units for the Cath/Interventionalists.
-
- For example: we had a tough VT ablation and used 60minutes of fluoroscopy on the new settings and generated an Air Kerma of roughly 400mGy. When I looked at recent cardiac cath procedures that take 7-10 minutes of fluoroscopy, they are generating an Air Kerma of roughly 1000mGy. I am currently speaking with the Chief of Cardiology to team up with Philips to get the radiation dose down in the cath lab and yet still provide adequate visualization.
-

Dose Monitoring Advisor





1	3000 mGy	FYI – to assist physician in projecting how much radiation might be required to complete procedure.
2	5000 mGy	Alert – threshold for erythema might have been reached.
3	7000 mGy	Warning – benefit/risk decision must be dictated in report; doses are at level that requires mandatory review by radiation safety.
4	9000 mGy	Warning – dose has potentially exceeded threshold of desquamation, requires mandatory review by medical staff and radiation safety.
5	12000 mGy	Warning – dose potentially at level of severe wound generation. Dose potentially at level defined by JCAHO as a reviewable sentinel event
6+	All additional +3000 mGy	For the information of the physician

1. Verify accuracy of AK readout
2. Develop action charts based on AK
3. Assist in recording dose for patient records and QC

Counselor

- Actively assist before, during and after procedures. Be a Medical Physicist, not a physicist who works in medicine.