Establishing a patient safety program in Interventional Radiology

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Disclosure

- I am co-owner of Fluoroscopic Safety, LLC, a company that provides training for physicians in the safe use of fluoroscopy
- Fluoroscopic Safety is not discussed in this presentation

Why?

- We are practicing in an era of increased emphasis on quality and patient safety
- Reimbursement models are changing with emphasis on outcomes and minimizing/managing complications
- Ethical considerations
- Accreditation and regulatory considerations

Updates to TAC 289.227

- Requires creation of a Fluoroscopy Radiation Protocol Committee
  - RSC for fluoroscopy
- Required tasks
  - Meet
  - Restrict use of fluoroscopy
    - Radiologist, R.O., or physician completing 8 hrs Cat. 1 CME + 1 hr hands on training
    - aka privileges
  - Record dose descriptors
  - Establish reference levels and review process

RISKS OF FLUOROSCOPICALLY GUIDED PROCEDURES

Who is at risk?

- Physicians
- Nurses
- Technologists
- Anesthesiologists
- Patients
- Facilities

Risks to the operator and staff

- Infection
- Back injury
- Falls
- Heavy objects
- Litigation
- Radiation-induced cataracts
- Radiation-induced cancer

Risks to the patient

- Death
- Puncture of vessel
- Contrast reaction
- Hematoma
- Infection
- Stochastic effects from radiation exposure
- Tissue effects from radiation exposure

Stochastic effects

- Stochastic effect – risk ↑ linearly with dose
- Risk depends on
  1. Volume of tissue irradiated
  2. Type of tissue irradiated
  3. Total dose delivered to tissue
  4. Age of patient
  5. Patient genetics
- There is always a risk of stochastic effects if we use ionizing radiation, but these risks can be managed

Stochastic effects

- In some cases the risk to the patient can be reduced
- Procedural planning and situational awareness are key

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Vañó E, Arranz L, Sastre JM, et al. Dosimetric and radiation protection considerations based on some cases of patient skin injuries in interventional cardiology. Br J Radiol 1998;71:510-516

Tissue effects

- Tissue effects have a threshold
  - Risk = 0 below a certain dose*
  - Severity increases with increasing dose above threshold dose
- Our understanding of tissue effects has been evolving
- In most cases, can be prevented
  - Training of operators
  - Safety program
  - QC of equipment

Threshold doses for tissue effects

- For many years, hard thresholds for various types of tissue effects were quoted
- It has become apparent that these "thresholds" can vary widely between patients
- Depends on
  1. Patient genetics
  2. Prior skin irradiation
  3. Disease state/treatment

Table 1

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)*	NCI Skin Reaction Grade†	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‡; 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‡; 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, 6–52 weeks; long term, >40 weeks.

* 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 (57). Skin dosimetry is unlikely to be more accurate than ± 50%. NA = not applicable.

† NCI = National Cancer Institute

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

Balter et al. Fluoroscopically guided interventional procedures: A review of radiation effects on patients' skin and hair. Radiology 254:326-341, 2010.

Radiation injuries

- Radiation-induced skin injuries are particularly troublesome for several reasons
  - Patient does not experience any sensations
  - Latent period means that cause and effect may not be connected by patient or physician

Multiple coronary angiography, angioplasty, and bypass graft on a single day – estimated peak skin dose > 20 Gy

6-8 weeks post procedure

16-21 weeks post procedure

18-21 months post procedure

Shope TB . Radiation-induced skin injuries from fluoroscopy. http://www.fda.gov/RadiationEmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm116682.htm U.S. Food and Drug Administration.

Radiation injuries

- Radiation injuries can be particularly gruesome and, depending on severity, may never completely heal

Copyrighted image removed

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Wagner LK, Archer BR. Minimizing Risks from Fluoroscopic X Rays: Bioeffects, Instrumentation, and Examination, 3rd edition; Houston, TX; R. M. Partnership, 2000

Wagner LK, McNesse MD, Marx MV, Siegel EL. Severe skin reactions from interventional fluoroscopy: case report and review of literature. Radiology 1999;213:773-776

What can we do?

- **Reduce** the risk of stochastic effects for operator, staff, and patient
- **Prevent** most tissue effects such as radiation-induced cataracts and skin injuries
- **Recognize** situations where a high probability for injury exists so the patient can be appropriately medically managed

Three-pronged approach

- Pre-procedure actions
- Intra-procedure actions
- Post-procedure actions

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RadioGraphics

Quality Initiatives

Establishing an Interventional Radiology Patient Radiation Safety Program

Joseph R. Steele, MD • A. Kyle Jones, PhD • Elizabeth P. Ninan, PA-C

ONLINE-ONLY CME

See www.rsna.org/education/rg_cme.html

LEARNING OBJECTIVES

After completing this journal-based CME activity, participants will be able to:

- List the radiation dose descriptors that should be recorded at the conclusion of a fluoroscopy-guided procedure.
- Describe the actions that may be taken during the three phases of a fluoroscopy-guided procedure to enhance patient safety.
- Discuss how to recognize cases that are outside the normal control limits of an interventional radiology practice.

TEACHING POINTS

See last page

The Interventional Radiology Patient Radiation Safety Program was created to better educate patients who are scheduled to undergo high-dose interventional radiologic procedures about the risks of radiation, better monitor the delivered doses, and reduce the risk for deterministic effects. The program combines preprocedure evaluation and counseling, intraprocedure monitoring, and postprocedure documentation and counseling with the guidelines of the National Cancer Institute and the Society of Interventional Radiology. Between July 2009, when the program was implemented, and September 2010, over 3500 interventional radiologic procedures were monitored and documented, and 63 procedures with an adjusted cumulative dose of more than 3 Gy were identified and further analyzed; four procedures were found to be outside the control limits. Additional review of these four procedures resulted in practice modifications. Anecdotal feedback from physician assistants and attending physicians indicated that the program had another positive effect: Patients who required postprocedure counseling about the potential for radiation-induced skin injuries were no longer surprised by this information. Implementation of this program is straightforward, requires little infrastructure and few resources, and may be applied in most interventional radiology practices. Supplemental material available at *http://radiographics.rsna.org/lookup/suppl/doi:10.1148/rg.321115002/-/DC1.*

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Abbreviations: CD = cumulative dose, CD_{adj} = adjusted cumulative dose, DAP = dose-area product, RAD-IR = Radiation Doses in Interventional Radiology Procedures

RadioGraphics 2012; 32:277–287 • **Published online** 10.1148/rg.321115002 • **Content Codes:** IR QA

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PRE-PROCEDURE ELEMENTS

Informed consent

"Informed consent is a patient's right to be presented with sufficient information, by either the physician or their representative, to allow the patient to make an informed decision regarding whether or not to consent to a treatment or procedure."

http://www.med-ed.virginia.edu/courses/rad/consent/

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I (we) also realize that the following risks and hazards may occur in connection with this particular procedure: ***Specific Information Here***

☐ Arteriography ☐ Venography ☐ Interventional

1. Injury to artery or vein
2. Loss of function or damage to parts of the body supplied by the artery or vein
3. Swelling, pain, tenderness or bleeding at site of blood vessel perforation
4. Aggravation of the condition that necessitated the procedure
5. Allergic reaction to injected contrast media
6. Possible kidney damage from injected contrast media
7. _____

- Pain
- Bleeding
- Infection
- Damage to surrounding structures
- Pneumothorax
- Hemoptysis (coughing up blood)
- Headache
- Nausea/Vomitting
- Nerve damage
- Paralysis
- Side effects of intrathecal chemo therapy
- Stroke
- _____

Just as there may be risk and hazards in continuing my present condition without treatment, there are also risks and hazards related to the performance of the surgical, medical, and/or diagnostic procedures planned for me.

I (we) realize that common to surgical, medical, and/or diagnostic procedures, is the potential for infection, blood clots in veins and lungs, hemorrhage, pain, emergent coronary bypass surgery, myocardial infarction, arrhythmia's, renal failure, stroke, allergic reactions, and even death.

Informed consent

- Lack of informed consent is grounds for malpractice lawsuit
- Ethical considerations

I (we) also realize that the following risks and hazards may occur in connection with this particular procedure: ***Specific Information Here***

☐ **ARTERIOGRAPHY/☐ VENOGRAPHY**

1. Injury to artery or vein.
2. Loss of function or damage to parts of the body supplied by the artery or vein.
3. Swelling, pain, tenderness, or bleeding at site of blood vessel perforation.
4. Aggravation of the condition that necessitated the procedure
5. Allergic reaction to injected contrast media.
6. Possible kidney damage from injected contrast media
7. _____

☐ **INTERVENTIONAL**

- ☐ Pain
- ☐ Bleeding
- ☐ Infection
- ☐ Damage to Surrounding Structures
- ☐ Pneumothorax (Collapsed Lung)
- ☐ Hemoptysis (Coughing Up Blood)
- ☐ Risk of radiation-induced skin injury; In rare cases of lengthy or complex procedures utilizing x-ray, radiation-induced skin injuries have been reported (<1% of cases)
- ☐ _____

☐ **Off-Label Use**

Patient education

- PA/physician must have the tools and knowledge to simply explain the risks to the patient without inducing panic
- One approach to this is a pamphlet/handout
  - Mechanisms of injury
  - How we prevent injuries
  - Decisions made during the case

Identify high-risk patients

- Certain conditions are suspected to pre-dispose patients to radiation induced skin injuries
  - Diabetes mellitus
  - Connective tissue disorders
  - Ataxia telangiectasia
  - Drug interactions
- Also, a recent high dose procedure can result in the induction of effects at lower doses in the future

Wagner et al, Severe skin reactions from interventional fluoroscopy: Case report and review of the literature. *Radiology*;**213**:773-776, 1999.

Koenig TR, et al. Skin injuries from fluoroscopically guided procedures: Part I, characteristics of radiation injury. AJR **177**:3-11, 2001.

Balter et al. Fluoroscopically guided interventional procedures: A review of radiation effects on patients' skin and hair. Radiology 254:326-341, 2010.

Identify high-risk patients

- Most easily done during the consenting process
- The RIS can be used to automatically identify and flag these patients
- High-risk patients can be routed to a dose sparing protocol, physician can be advised
  - Fewer acquisition runs, more storing of fluoro
  - Alternate $K_{a,r}$ thresholds
  - Postpone procedure?

Multiple and repeated procedures

- Two scenarios
  1. By performing a very complex case in multiple sessions, fx can be used to reduce late effects
  2. If a procedure is repeated, an unexpected skin reaction may occur as the Biologically Equivalent Dose from the two procedures is greater than the dose from either individual procedure
- We can look to radiobiology for guidance on managing multiple irradiations of the skin

Balter et al. Fluoroscopically guided interventional procedures: A review of radiation effects on patients' skin and hair. Radiology Appendix E1, 2010.

Training of physicians and staff

- Physicians performing fluoroscopically-guided procedures should be trained in the safe use of fluoroscopic equipment
  - NCRP 168
  - State regulations
- Continuing education
- Understand dose saving features of each type of equipment on which they work
  - Hands-on component

Recommendation 28

An FGI procedure *shall* be performed or supervised only by a physician or other medical professional with fluoroscopic and clinical privileges appropriate to the specific procedure.

NCRP 168

Training resources

http://www.aapm.org/education/ERG/

Privileging of physicians and staff

- *Credentials* relate to training, education , and experience
  - Medical degree/residency/fellowship
  - Board certification
- *Privileges* delineate which medical procedures a staff member may perform
  - Specific to institutions/departments

Privileging of physicians and staff

- AAPM Task Group 124 has published their report:

A Guide for Establishing a Credentialing and Privileging Program for Users of Fluoroscopic Equipment in Healthcare Organizations

which is the definitive resource

INTRA-PROCEDURE ELEMENTS

Recommendation 14

Interventionalists *shall* be responsible for patient radiation levels during FGI procedures and *shall* ensure that radiation dose accumulation is continuously monitored during the procedure.

NCRP 168

Reference air kerma ($K_{a,r}$) thresholds

- All equipment manufactured after June 2006 is required by law to display the $K_{a,r}$
- Alerting the physician at certain points guarantees there are no surprises at the end of a case
- Decisions can be made based on medical management at each threshold
  - Pace of procedure
  - Good practice (YDNKWIHUYKWIH)

Establishing $K_{a,r}$ thresholds

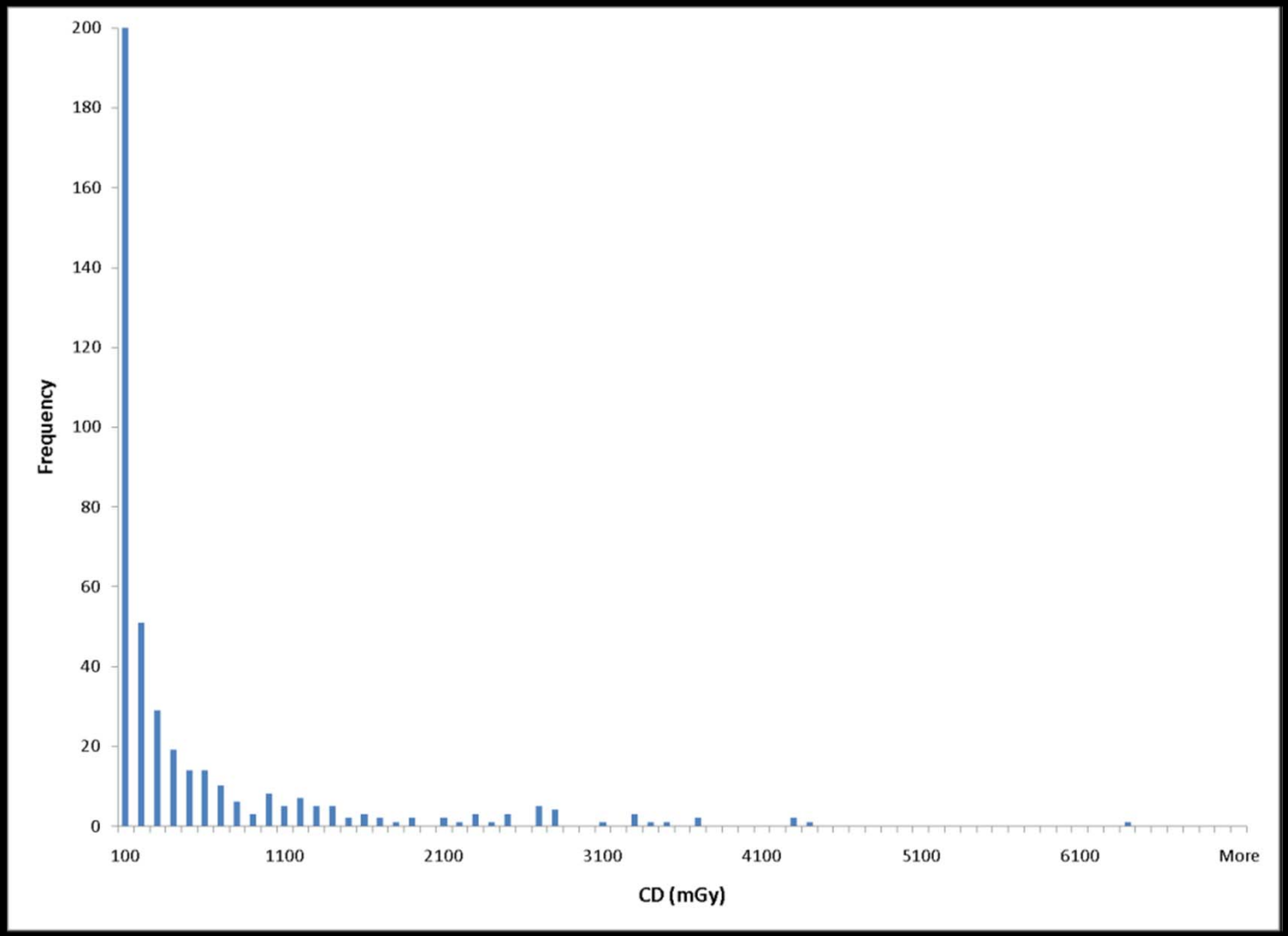


TABLE 4.7–*Suggested values for first and subsequent notifications and the SRDL.*

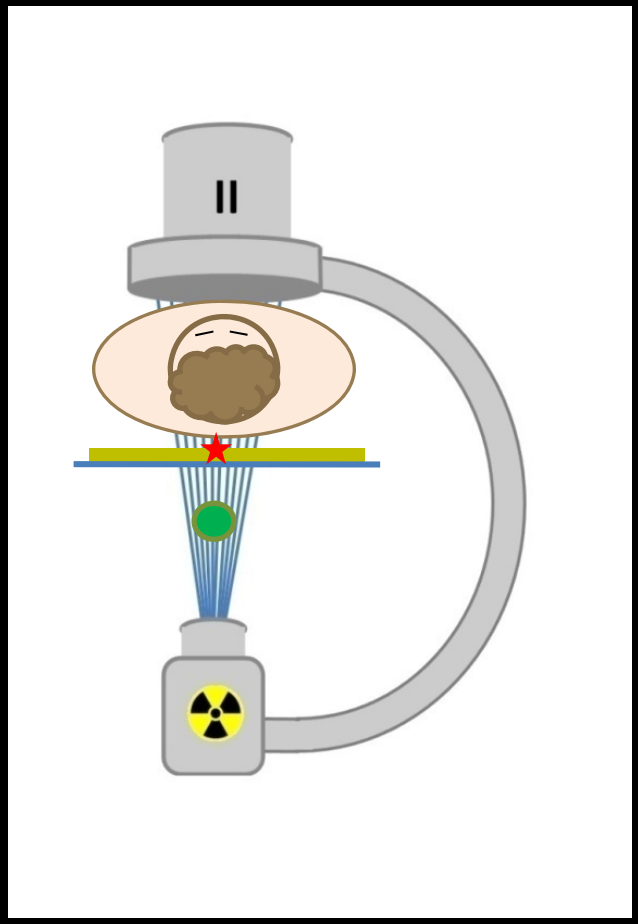
Dose Metric	First Notification	Subsequent Notifications (increments)	SRDL
$D_{skin,max}$	2 Gy	0.5 Gy	3 Gy
$K_{a,r}$	3 Gy	1 Gy	5 Gy[a]
P_{KA}	300 Gy cm^2 [b]	100 Gy cm^2 [b]	500 Gy cm^2 [b]
Fluoroscopy time	30 min	15 min	60 min

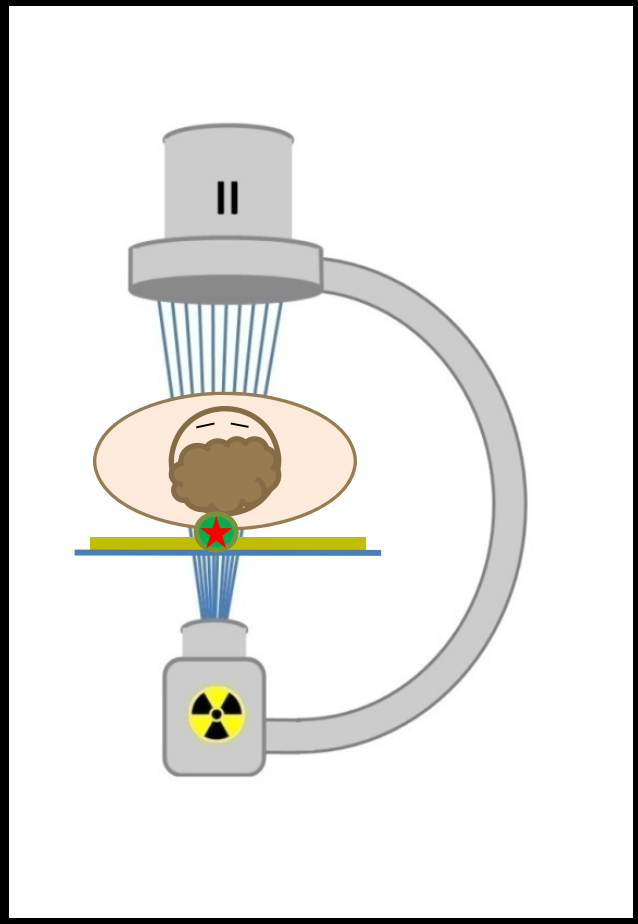
[a]See additional discussion concerning the value 5 Gy in Section 4.3.4.2.
[b]Assuming a 100 cm^2 field at the patient's skin. For other field sizes, the P_{KA} values should be adjusted proportionally to the actual procedural field size (*e.g.*, for a field size of 50 cm^2, the SRDL value for P_{KA}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

NCRP 168

Setting notification levels

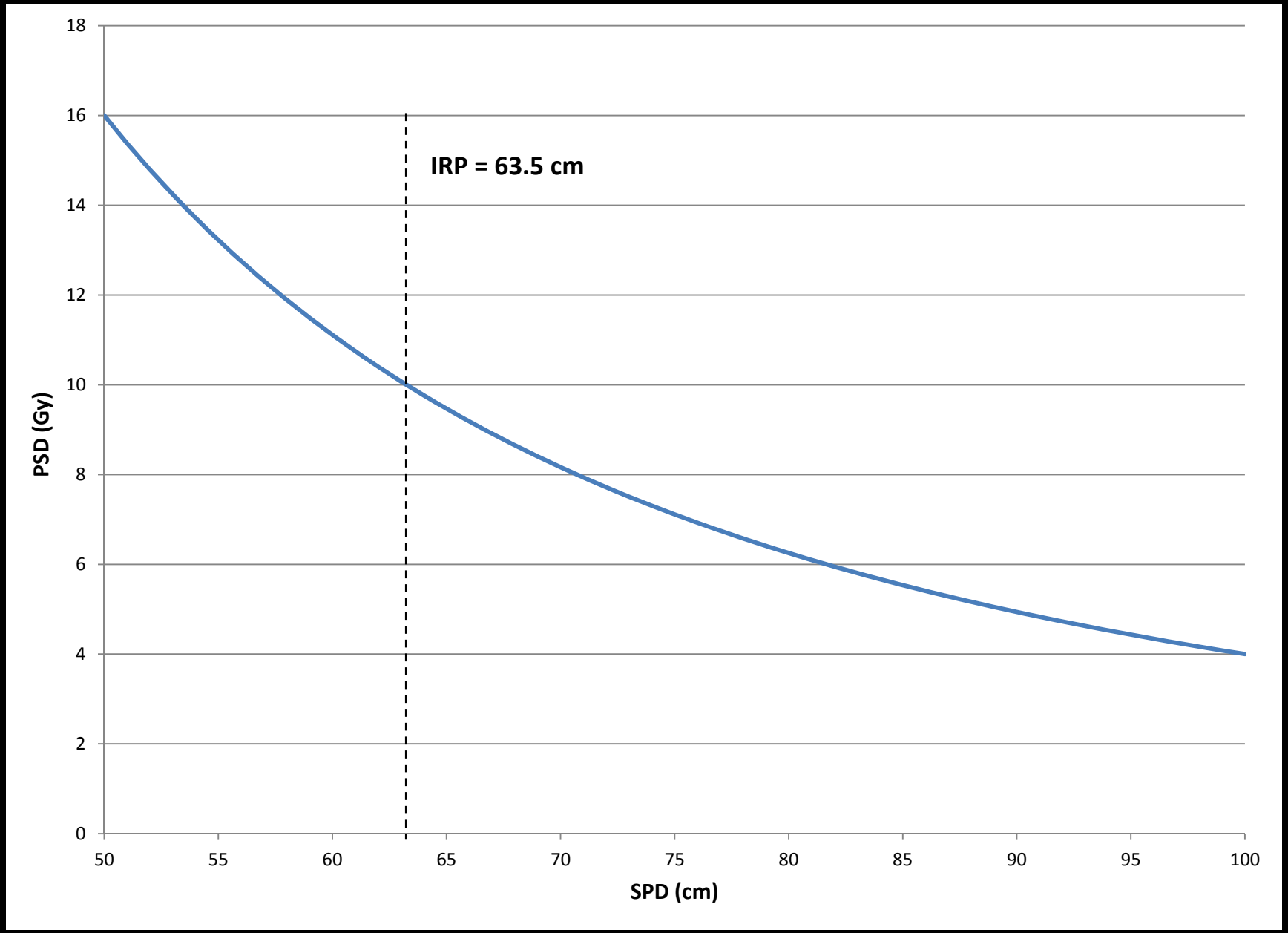
- Use a representative phantom and perform a "procedure" on the phantom
  - Measure ESD (cannot used lead-backed dosimeter)
  - Correct geometry
  - Distribution of acquisition/fluoroscopy
- Apply f-factor, use ratio of $K_{a,r}$/PSD to determine notification levels
  - VIR ~ 1
  - Cardiology ~ 0.7-0.8
  - Neuro ~ 0.8-1.0
- Some manufacturers allow a number of notification levels to be programmed in the system





A very important piece of information

- Estimating the PSD with any degree of accuracy REQUIRES knowledge of the source-to-patient distance (SPD)
- If this information is not available in DICOM headers or the RDSR, it must be recorded manually
- Provide instructions to the technologist or other staff for measuring and recording the SPD when the SRDL is reached


IRP = 63.5 cm
PSD (Gy)
SPD (cm)
0
2
4
6
8
10
12
14
16
18
50
55
60
65
70
75
80
85
90
95
100

Situational awareness

- For patients who have undergone a recent high dose procedure, use a different projection to reduce the cumulative skin dose
  - Reduce 95% area load
  - May not reduce PSD
- May not be able to completely eliminate overlap, but for angled projections can have large benefit
  - Importance of tight collimation

LABORATORY INVESTIGATION

Does "Spreading" Skin Dose by Rotating the C-arm during an Intervention Work?

Alexander S. Pasciak, PhD, and A. Kyle Jones, PhD

ABSTRACT

PURPOSE: To determine if C-arm rotation is beneficial for reducing peak skin dose (PSD) in interventional radiology (IR) and, if so, under what circumstances.

MATERIALS AND METHODS: The Monte Carlo method was used to perform ray tracing for detailed analyses of the effect of C-arm rotation on PSD across a range of patient sizes, C-arm configurations, and procedure types. Automatic dose-rate control curves on modern fluoroscopic systems were measured for input into the simulations.

RESULTS: Rotating the C-arm to reduce the PSD is in most cases contraindicated and results in increased PSD when the C-arm is rotated from an original posteroanterior projection, in some cases resulting in a PSD increase by a factor of 5 or more. When prophylactic rotation was performed before a procedure, however, and the C-arm was rotated between opposed, distinct oblique angles, substantial reduction in PSD was achieved for patients of any size.

CONCLUSIONS: Rotating the C-arm during a procedure with the aim of "spreading" dose on the skin of the patient may not result in a reduction in PSD and may increase PSD. However, when used as a prophylactic measure combined with tight x-ray beam collimation, C-arm rotation can be used as a tool to reduce PSD. Tight collimation greatly increases the benefit of C-arm rotation.

ABBREVIATIONS

ADRC = automatic dose rate control, $K_{a,r}$ = reference point air kerma, LAO = left anterior oblique, PSD = peak skin dose, RAO = right anterior oblique, SSD = source-to-skin distance

Fluoroscopically guided interventional procedures, which are minimally invasive and have fast recovery times, have become the preferred treatment for many conditions that previously required open surgical intervention. In addition, modern fluoroscopic imaging systems, and in particular adjuncts such as three-dimensional rotational angiography, have increased the scope of interventional radiology (IR) procedures (1–5). As the scope of fluoroscopically guided IR has increased, so has the complexity of the procedures, sometimes necessitating extensive use of ionizing radiation or repeated applications, which may put the patient at risk for deterministic skin injury (6,7). Radiation-induced skin injuries are a rare but potentially debilitating side effect of lengthy IR procedures (7–11).

Methods for reducing peak skin dose (PSD) (this term and others that appear in this article are defined in Table 1) have been addressed extensively (6,12–17). One technique that has often been recommended is rotation of the C-arm at various times during a procedure (6,12,14–16). Although one such recommendation is specific to interventional cardiology (12), most authors make general recommendations. This practice is common and is often taught to radiology residents and fellows during clinical training and in commercially available credentialing programs (15). The technique is often applied in a random fashion, with little knowledge of how the rotation actually affects the PSD, especially for different patient and x-ray field sizes. Also, timing of C-arm rotation, doses, angles, electronic magnification modes, patient size, and the radiographic magnification factor each impacts the effectiveness of varying the C-arm angle and should be considered individually.

Interventional cardiology and IR procedures are performed with different imaging geometries. Because it is often necessary to rotate the C-arm in interventional cardiology procedures to obtain different projections for diag-

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DOI: 10.1016/j.jvir.2010.12.025

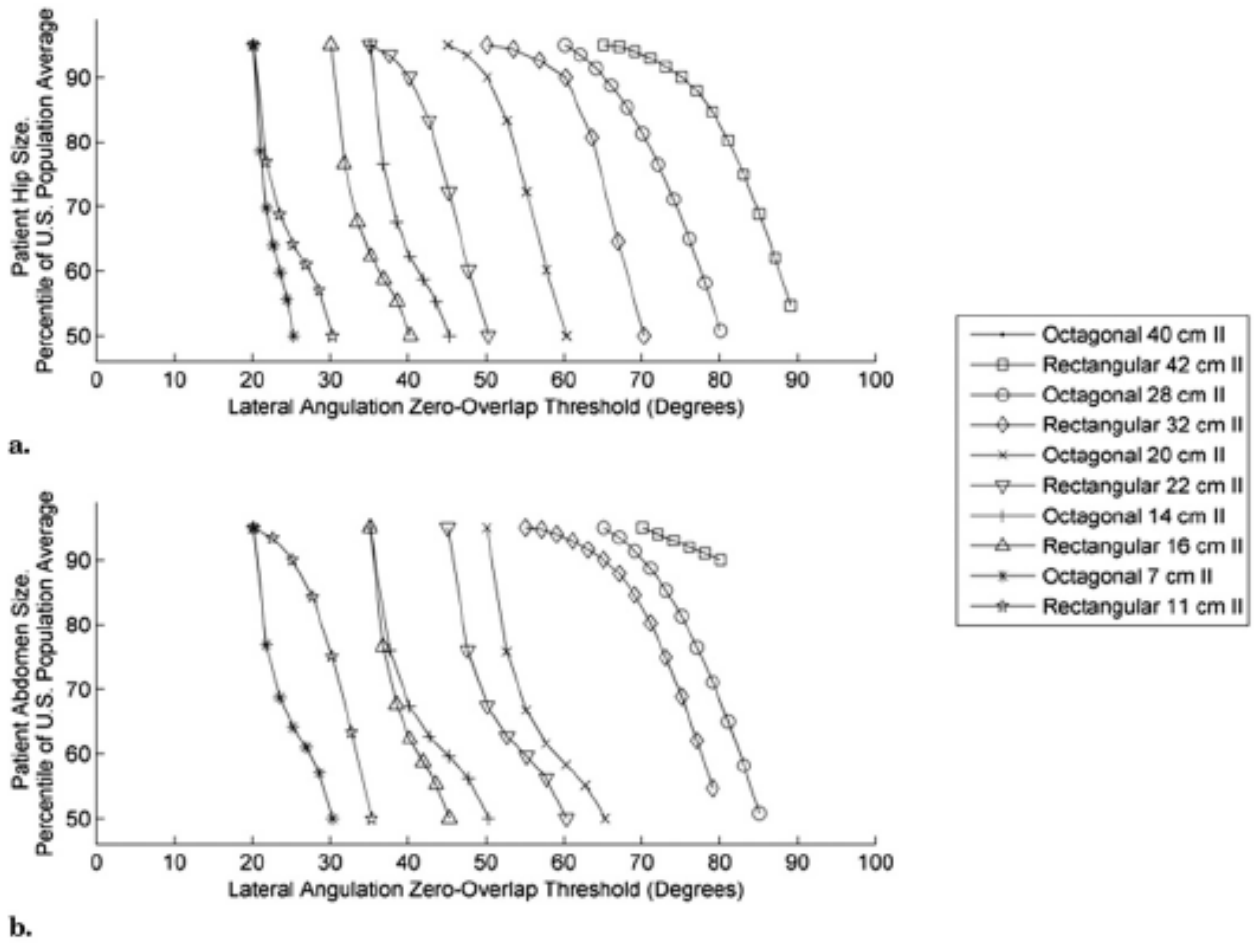
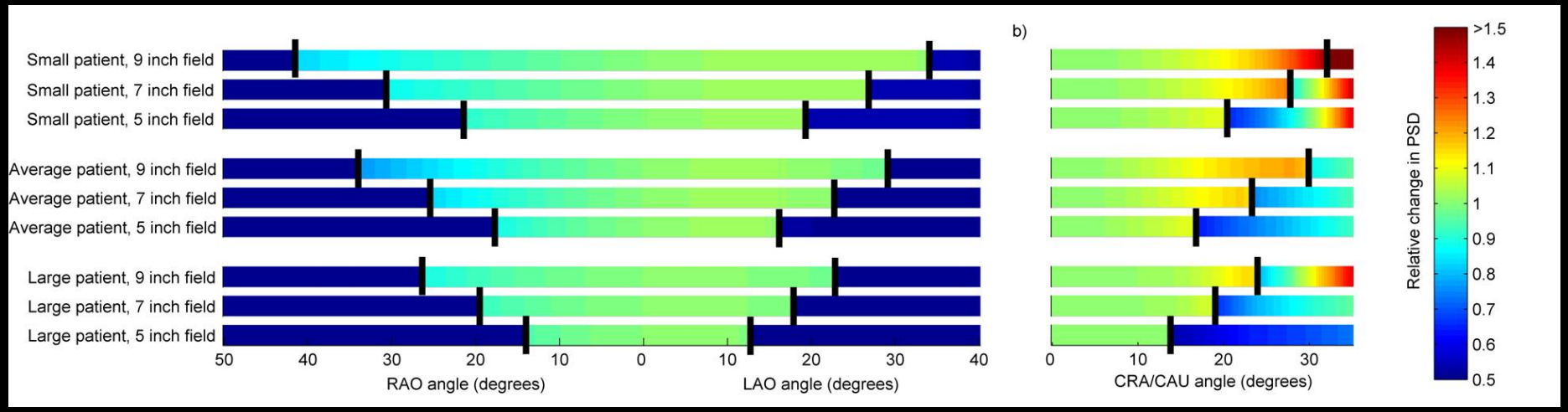


Figure 5. Zero-overlap angle as a function of patient size for rotation from initial posteroanterior projection. (a) Abdominal interventions. (b) Pelvic interventions. Lines show the minimum angle to which the C-arm must be rotated, as a function of patient size, to avoid completely overlap between the x-ray field entrance sites on the patient's skin. Each different line corresponds to a different x-ray field size or shape or both.


Small patient, 9 inch field
Small patient, 7 inch field
Small patient, 5 inch field
Average patient, 9 inch field
Average patient, 7 inch field
Average patient, 5 inch field
Large patient, 9 inch field
Large patient, 7 inch field
Large patient, 5 inch field
50 40 30 20 10 0 10 20 30 40
RAO angle (degrees)
LAO angle (degrees)
b)
0 10 20 30
CRA/CAU angle (degrees)
Relative change in PSD
>1.5
1.4
1.3
1.2
1.1
1
0.9
0.8
0.7
0.6
0.5

SU-E-I-24

POST-PROCEDURE ELEMENTS

Record dose descriptors

- Medical record has been suggested
  - Perhaps difficult
  - May not be searchable
    - Dictated
    - Scanned
  - What is and what is not part of the medical record?
- DICOM Structured Dose Reporting is here
  - Recently installed our first system (VC14)
  - Legacy systems may never support
  - Third party options are available
- DICOM headers contain some information

Recommendation 15

Patient dose data *shall* be recorded in the patient's medical record at the conclusion of each procedure. This *shall* include all of the following that are available from the system: $D_{\text{skin,max}}$, $K_{\text{a,r}}$, P_{KA}, fluoroscopy time, and number of fluorographic images.

NCRP 168

THE UNIVERSITY OF TEXAS MD ANDERSON CANCER CENTER

Date: _____
Time: _____

EXAM PROTOCOL

Patient Info:
Name [redacted] Sex: [redacted] ID: [redacted]

Patient ,
ACCT#
DOB

Print Date
FC SEX Location

MDA #

Patient Position: HFS 17-Apr-09 13:29:39

1	DR		FIXED	Native			*****	1F/s	17-Apr-09	14:26:13			
A	66kV	475mA	115.0ms	0.0CL small	0.2Cu	48.0cm	45.4µGym²	1.3mGy	0LAO	0CRA	1F		
2	DR		FIXED	Native			*****	1F/s	17-Apr-09	14:27:13			
A	66kV	486mA	118.1ms	0.0CL small	0.2Cu	48.0cm	47.7µGym²	1.4mGy	0LAO	0CRA	1F		
3	DR		FIXED	Native			*****	1F/s	17-Apr-09	14:32:10			
A	68kV	436mA	105.6ms	100CL small	0.1Cu	48.0cm	69.1µGym²	2.0mGy	0LAO	0CRA	1F		
4	DR		FIXED	Native			*****	1F/s	17-Apr-09	14:33:19			
A	68kV	437mA	105.8ms	100CL small	0.1Cu	48.0cm	69.4µGym²	2.0mGy	0LAO	0CRA	1F		

Accumulated exposure data 17-Apr-09 15:06:32
Phys: Exposures: 4 Fluoro: 2.0min Total: 769.4µGym² 22.2mGy

==========

Page 1 of 1

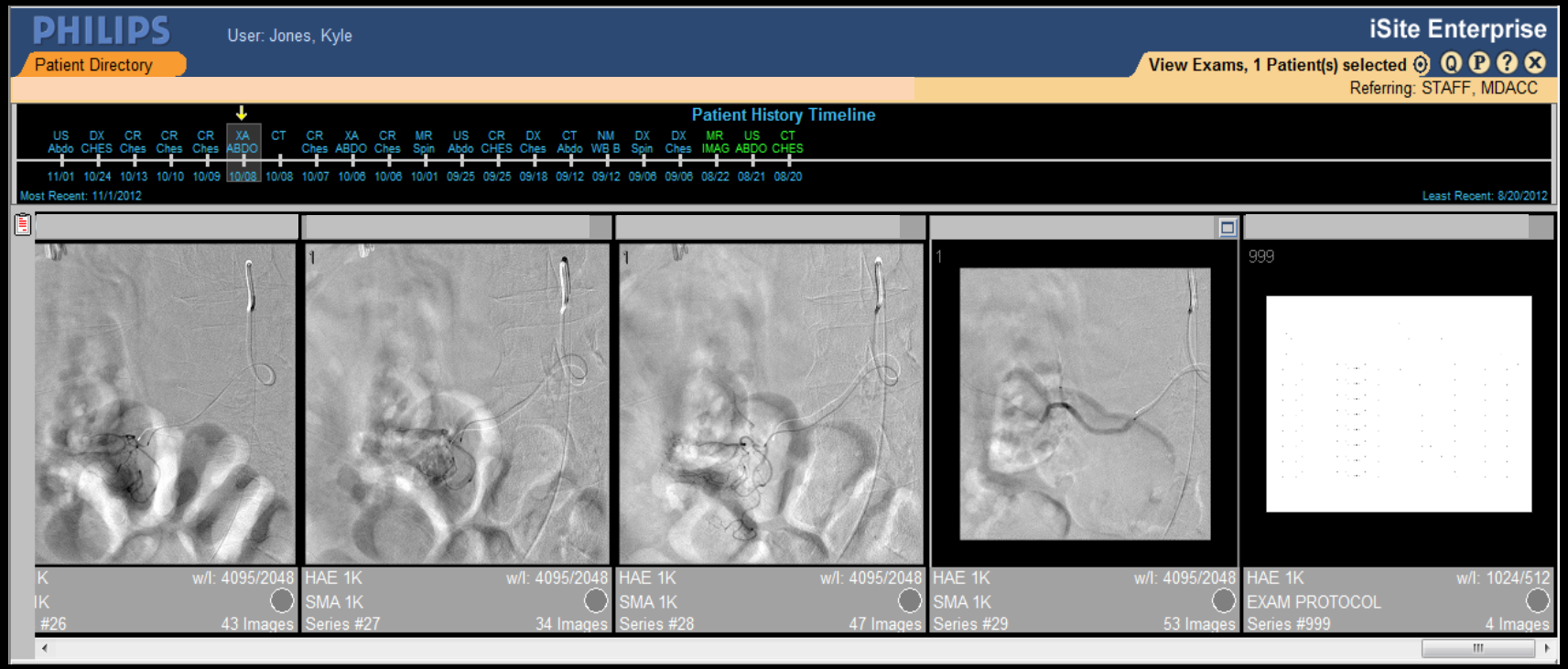
Interventional Radiology Technical Summary

Signature/Credentials/ID#

Print / Stamp Name

Interventional Radiology Technical Summary
Page 1 of _____
File Under: Diagnostic Imaging / Nuclear Medicine

DIC650077 (4/21/09)


PHILIPS
User: Jones, Kyle
iSite Enterprise
Patient Directory
View Exams, 1 Patient(s) selected
Referring: STAFF, MDACC
Patient History Timeline
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DX CHES 10/24
CR Ches 10/13
CR Ches 10/10
CR Ches 10/09
XA ABDO 10/08
CT 10/08
CR Ches 10/07
XA ABDO 10/06
CR Ches 10/06
MR Spin 10/01
US Abdo 09/25
CR CHES 09/25
DX Ches 09/18
CT Abdo 09/12
NM WB B 09/12
DX Spin 09/06
DX Ches 09/06
MR IMAG 08/22
US ABDO 08/21
CT CHES 08/20
Most Recent: 11/1/2012
Least Recent: 8/20/2012
w/l: 4095/2048
43 Images
HAE 1K
SMA 1K
Series #27
34 Images
Series #28
47 Images
Series #29
53 Images
w/l: 1024/512
EXAM PROTOCOL
Series #999
4 Images

Exam Protocol

Patient Info:

Patient Position: HFS 08-Oct-12 04:37:32

1	DSA		VARIABLE SMA 1K				16s	4F/s	08-Oct-12	05:59:04		
A	79kV	392mA	100.0ms	******	large	0.1Cu 48cm	4918.3µGym²	166mGy	0LAO	0CRA	59F	
2	DSA		VARIABLE SMA 1K				10s	4F/s	08-Oct-12	06:05:17		
A	81kV	381mA	100.0ms	******	large	0.0Cu 32cm	3460.8µGym²	213mGy	0LAO	0CRA	38F	
3	DSA		VARIABLE SMA 1K				6s	4F/s	08-Oct-12	06:07:38		
A	82kV	378mA	100.0ms	******	large	0.0Cu 32cm	2114.7µGym²	130mGy	0LAO	0CRA	23F	
4	DSA		VARIABLE SMA 1K				12s	4F/s	08-Oct-12	06:12:17		
A	80kV	387mA	100.0ms	******	large	0.0Cu 32cm	4045.3µGym²	249mGy	0LAO	0CRA	45F	
5	DSA		VARIABLE SMA 1K				12s	4F/s	08-Oct-12	06:13:56		
A	82kV	376mA	100.0ms	******	large	0.0Cu 32cm	4242.9µGym²	261mGy	0LAO	0CRA	46F	
6	DSA		VARIABLE SMA 1K				17s	4F/s	08-Oct-12	06:17:11		
A	80kV	386mA	100.0ms	******	large	0.0Cu 32cm	5841.4µGym²	359mGy	0LAO	0CRA	65F	
7	DSA		VARIABLE SMA 1K				14s	4F/s	08-Oct-12	06:20:56		
A	81kV	381mA	100.0ms	******	large	0.0Cu 32cm	4647.8µGym²	286mGy	0LAO	0CRA	51F	
8	DSA		VARIABLE SMA 1K				16s	4F/s	08-Oct-12	06:27:55		
A	82kV	378mA	100.0ms	******	large	0.0Cu 32cm	5612.6µGym²	345mGy	0LAO	0CRA	61F	

Exam Protocol

Patient Info:

A 100kV 311mA 100.0ms ****** large 0.0Cu 22cm 2014.2µGym² 357mGy 3RAO 5CRA 53F

Accumulated exposure data 08-Oct-12 08:32:19

Phys: Exposures: 25

TotalFluoro: 42.4min Total: 86792.3µGym² 8208mGy

==========

DICOM SR

Record dose descriptors

- Other possibilities include RIS or logbooks
  - Would like it to be searchable
    - Tracking
    - Practice improvement
    - Identify/prevent sentinel events
- We went with the RIS
  - Manual entry into designated fields
  - Reports can be generated, already linked with procedure (accession number)
  - Automatic analysis of data/entry into database

Record dose descriptors

- What we record:
  - $K_{a,r}$
  - KAP
  - Number of rotational angiography runs (DynaCT)
  - Fluoroscopy time
- Track repeated or multiple procedures

KAP meter calibration

- FDA (2006)/IEC 60601-2-43 (2010) requirement for accuracy ($K_{a,r}$): +/- 35%
  - IEC 60580 (2000) requires +/- 25% accuracy under specific conditions for KAP
- Take the time to measure a single- or double-point calibration factor for the KAP meter in each of your interventional labs

- NEMA XR-27 – facility to store calibration factor(s) in the RDSR
- AAPM TG 190 standardizing measurement procedures

Table 1. Mean values of response ratio R cm^2(calc)/R cm^2(indic) observed for a particular Diamentor system for ranges of several of the parameters of irradiation.

Parameter	Measured range	No of readings	$\frac{R\ cm^2(calc)}{R\ cm^2(indic)}$ (mean ± SE)
Cumulative exposure	1.9–11.3 R	6	1.08 ± 0.02
Exposure rate	20–800 mA (0.1–3.4 R s^{-1})	8	1.05 ± 0.02
Beam area	10 × 10–35 × 35 cm^2	8	1.06 ± 0.02
Radiation quality	50–140 kV	10	1.09–0.02

Shrimptom PC and Wall BF. An evaluation of the Diamentor transmission ionisation chamber in indicating exposure-area product (R cm2) during diagnostic radiological examinations. Phys Med Biol 27:871-878, 1982

My experience (1 manufacturer) for $K_{a,r}$ accuracy:

- Generally +/- 15% across all FOV and rates (FLU, ACQ, CINE)
- Generally less accurate as FOV is reduced
- Taking advantage of lenient limits?

Automated solutions

- Clinical Microsystems
- GE DoseWatch
- Siemens CareAnalytics
- Radimetrics

Flagging and follow up

- A case where our substantial radiation dose level (SRDL) is reached is flagged by the technologist, triggering our f/u protocol (PA):
  - Patient informed that SRDL (>= 5 Gy) was reached and why
  - Patient instruction provided (one sheet)
    - Signs/symptoms (red area the size of your hand)
    - Instructions (do not scratch or itch)
    - Actions (call us)
  - Telephone or in-person f/u scheduled for 4 weeks
  - Verify that dose report is archived

Recommendation 16

If a substantial radiation dose level (SRDL) (Table 4.7 and Section 4.3.4.2) is exceeded while performing an FGI procedure, the interventionalist *shall* place a note in the medical record, immediately after completing the procedure, that justifies the radiation dose level used.

Recommendation 17

If an SRDL is exceeded for an FGI procedure, the patient and any caregivers *should* be informed, prior to discharge, about possible deterministic effects and recommended follow-up.

If fluoroscopy time exceeds the SRDL, but other measured dose metrics do not exceed the SRDL, patient information and follow-up *may not* be necessary.

NCRP 168

Interventional Radiology:
Post Procedure Radiation Exposure Information Sheet

Procedure: _____ **Procedure Date:**_____

Affected Area: _____

The procedure you recently underwent is one of the more complex interventions performed by our service. This type of procedures is done with x-ray imaging and requires the use of higher radiation doses compared to other diagnostic imaging studies like chest x-rays or CAT scans.

How much radiation you are exposed to depends on what procedure you have and your specific condition. We make every attempt to minimize the radiation dose but we must weigh the minimal risks of higher exposure to the benefits of the procedure. In general, the risk of complications related to radiation exposure is very small, and substantially less than the other risks of the procedure. Your procedure required a dose of radiation at the upper end of our usual range and while we do not expect to see any effects of the radiation there is a small chance that it could cause skin changes in the area that was treated. These changes might include an area of redness, localized hair loss, itching or flaking of the skin in the exposed area. These changes are usually temporary and fade away within a few days or weeks. In very rare situations more severe damage to skin can require medical attention.

The Physician Assistant (PA) will schedule a telephone follow-up with you next month. During this follow-up, the PA will ask you a few questions about the area of skin that was exposed to high levels of radiation to determine if further treatment or observation is needed.

Please watch for any of these symptoms. The easiest way is to have someone look at your skin, as the area of skin exposed to radiation is on your back. If no one else can help you, do your best by looking in a mirror.

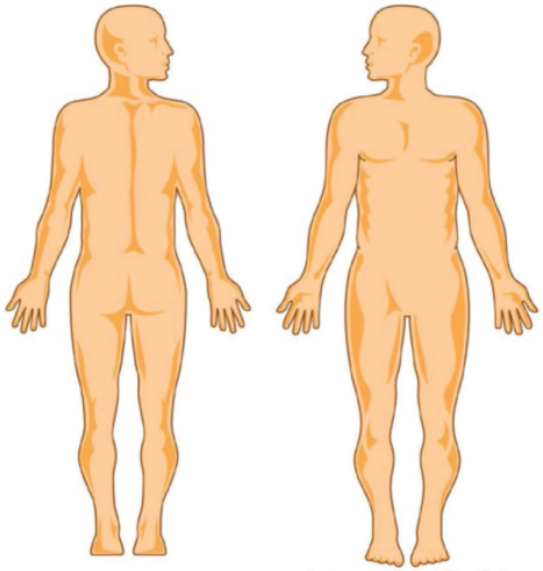
Signs to look for:

- A red area, about the size of your hand
- Flaking skin, like a sunburn
- Areas of localized hair loss
- Constant itching in the affected area

If you see any of these signs, make a note of them and bring them to the attention of the PA during the telephone follow-up. This information will be used to determine if any further treatment is needed, or if the changes will resolve without intervention.

Please do your best not to scratch the irritated area. This can lead to further changes in your skin.

On the diagrams to the right, circle the areas where you are experiencing skin changes. Report these changes to your health care provider on your next visit.



Interventional Radiology
Monday through Friday
8:00 a.m. – 5:00 p.m.
713-563-7900

Steele JS, Jones AK, Ninan EP. Quality initiatives: establishing an interventional radiology patient radiation safety program. Radiographics 32(1):277-87, 2012.

Medical management of skin reactions

- Acute skin doses greater than a few Gy are only seen in medicine as a result of fluoroscopically guided procedures
- Knowing who to consult regarding skin reactions is tricky
- Dermatologists may never have seen these types of reactions
- Radiation oncologists seem to be the best to discuss these matters with
  - Typically do not see late/acute effects of same severity

PRACTICE AND QUALITY IMPROVEMENT

Practice improvement

- Dose information collected can be used to calculate dose metrics that can be used to accomplish data driven practice improvement
  - Compare dose metrics to national averages
    - RAD-IR study
  - Identify procedures/physicians/etc. for improvement
  - Control charts for identifying exceptional variation
    - Discuss SRDL/reactions at QI conference or M+M

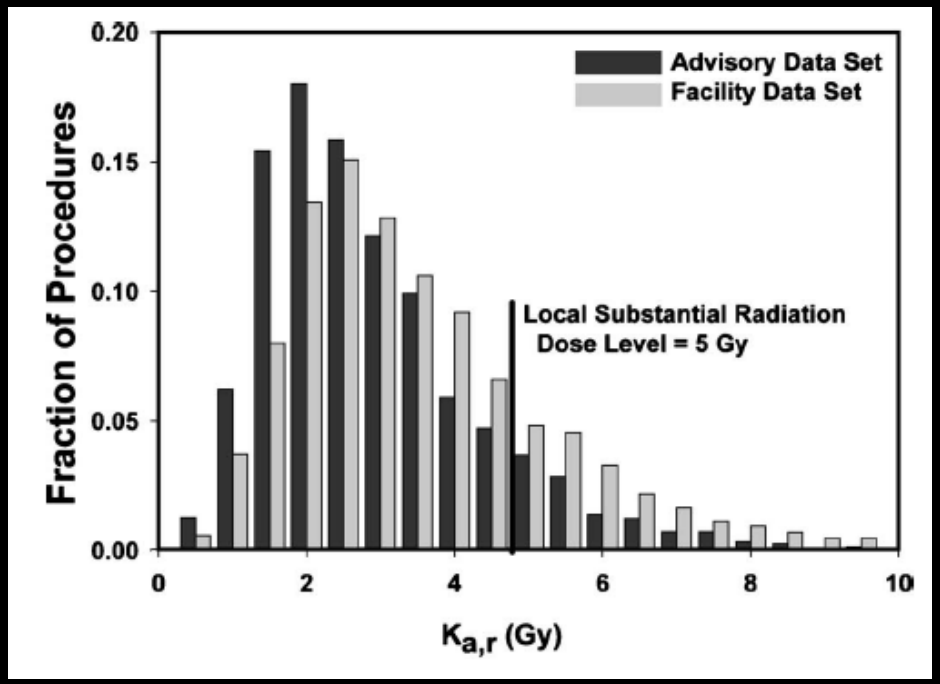
Recommendation 19

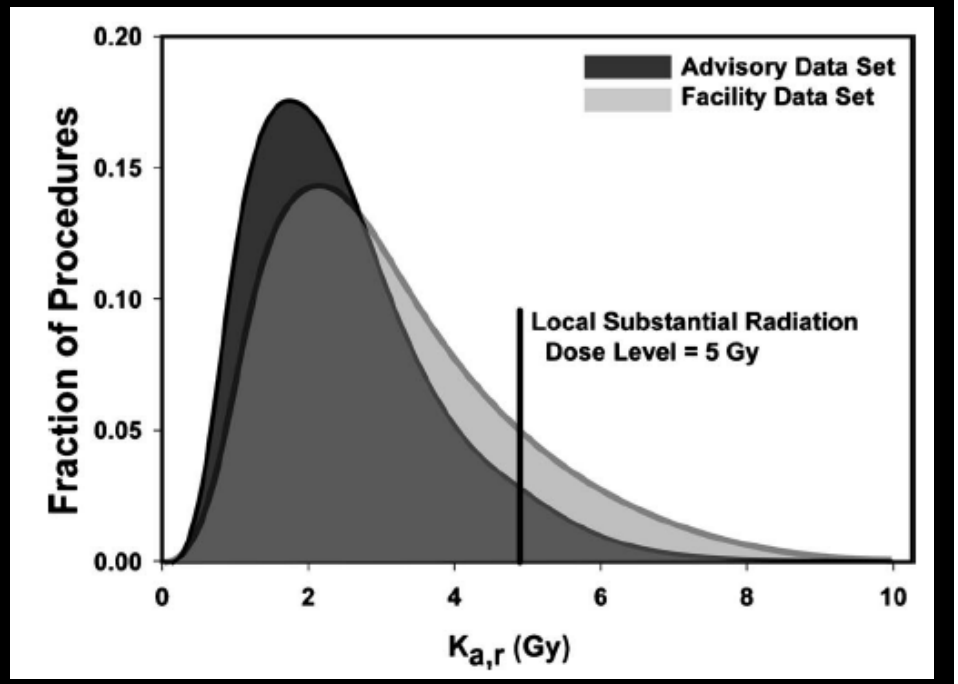
Facilities *shall* have a process to review radiation doses for patients undergoing FGI procedures.

Advisory data based on measured dosimetric quantities (in particular P_{KA} or $K_{a,r}$ to manage overall performance, and $K_{a,r}$ to manage deterministic effects) *should* be used for quality assurance purposes.

NCRP 168

Radiation dose audits





Balter S et al. Patient radiation dose audits for fluoroscopically guided interventional procedures. Med Phys 38(3):1611-18, 2011.

Don’t audit only “high dose” cases…

07/19/2012	12:27	INFUSION CATHETER PLACEMENT HEPA	8	56323.7	2036
07/12/2012	13:10	EMBOLIZATION CHEMO HEPATIC	20	53472.6	2206
07/27/2012	11:28	EMBOLIZATION VISCERAL	22	43193.2	2351
07/11/2012	10:55	INFUSION CATHETER PLACEMENT HEPA	26	32108.3	2372
07/30/2012	10:17	INFUSION CATHETER PLACEMENT HEPA	17	48574.3	2404
07/10/2012	15:55	ANGIOGRAPHY CELIAC/SMA DIAGNOSTI	25	52016.4	2420
07/13/2012	10:45	ANGIOGRAPHY CELIAC/SMA DIAGNOSTI	10	84710	2671
07/26/2012	15:21	EMBOLIZATION CHEMO HEPATIC	33	59199	2715
07/27/2012	11:37	EMBOLIZATION CHEMO HEPATIC	10	55297	2784
07/03/2012	11:54	VENOGRAPHY. PORTAL VENOUS W/ PRE	53	36332.4	2790
07/20/2012	16:53	ANGIOGRAPHY CELIAC/SMA DIAGNOSTI	20	59134	3265
07/14/2012	21:47	EMBOLIZATION VISCERAL	38	64950	3276
07/16/2012	15:28	RENAL SELECT 1 OR MORE 2ND ORDER	11	41883.5	3309
07/09/2012	17:21	EMBOLIZATION HEPATIC	19	86674.6	3949
07/21/2012	16:37	ANGIOGRAPHY CELIAC/SMA DIAGNOSTI	20	89628	4332
07/13/2012	21:00	EMBOLIZATION VISCERAL	23	90885	4565
07/25/2012	12:38	EMBOLIZATION HEPATIC	25	69267.4	4670
07/06/2012	20:06	EMBOLIZATION VISCERAL	22	49531	4712
07/26/2012	10:40	NEPH. CATHETER EXCHANGE	42	25663.5	4850

Hepatic chemoembolization

	Fluoro time	KAP (cGy-cm^2)	$K_{a,r}$ (mGy)
MEAN	22	40713	1809
MEDIAN	19	34898	1604
RAD-IR MEAN	16.8	28232	1406

Pelvic arterial embolization (tumor)

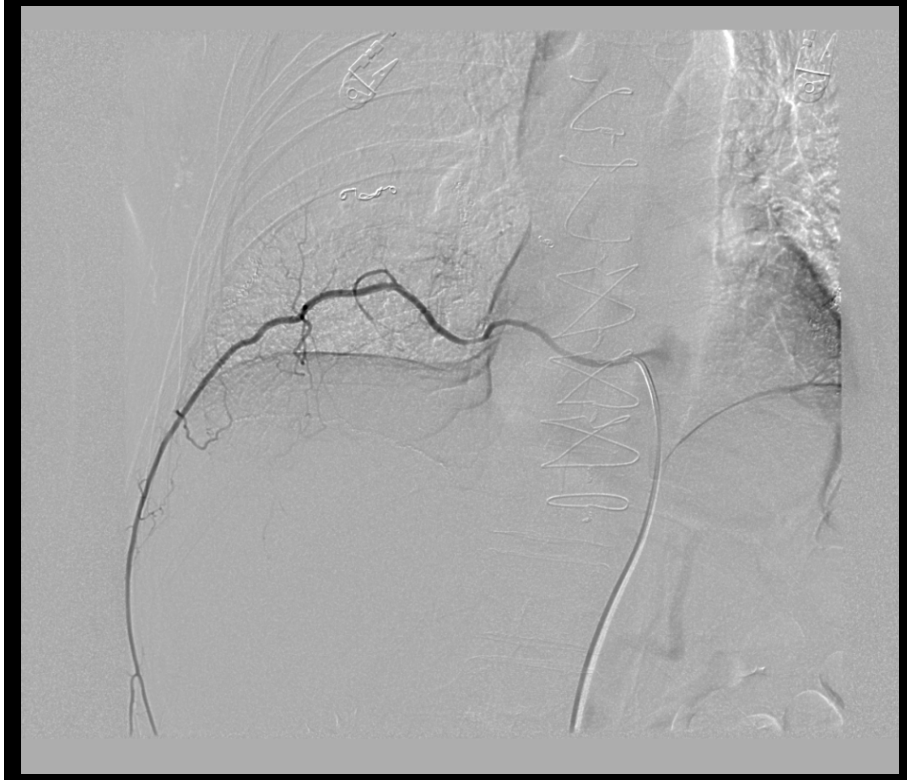
	Fluoro time	KAP (cGy-cm^2)	$K_{a,r}$ (mGy)
MEAN	17	39023	1836
MEDIAN	19	32309	1964
RAD-IR MEAN	28.4	30284	1846

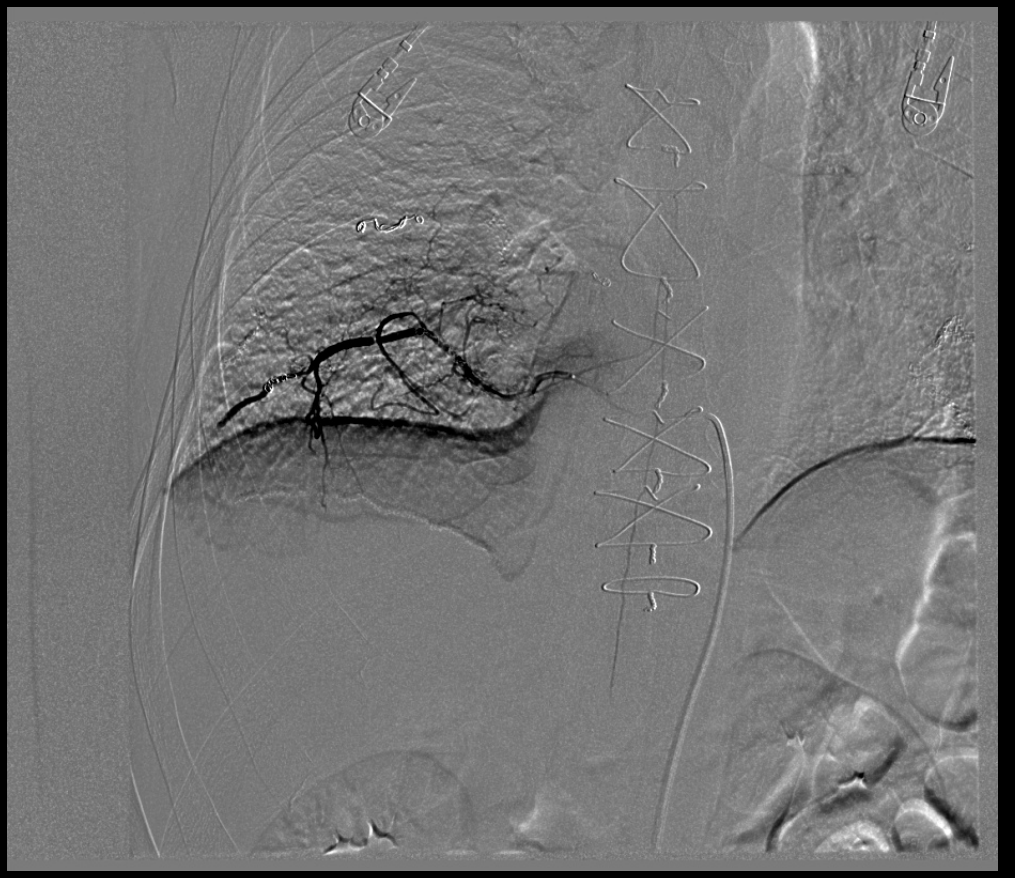
Nephrostomy placement

	Fluoro time	KAP (cGy-cm^2)	$K_{a,r}$ (mGy)
MEAN	6	1838	115
MEDIAN	4	1024	50
RAD-IR MEAN	10.5	2555	257

In certain circumstances

- It is necessary and appropriate to administer a high dose of radiation during a fluoroscopically guided procedure
- One must still be conscious of how much radiation has been used
- The risk of injury must be commensurate with the benefits of the procedure
- Medical management after the procedure must be appropriate





Acknowledgements

- Lou Wagner, Ph.D.
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Further reading

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  - SIR Standards of Practice Committee
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- Stecker et al., Guidelines for patient radiation dose management. *J Vasc Interv Radiol* **20**:S263–S273, 2009.
  - SIR Safety and Health Committee
  - Discharge/consenting examples
- Archer BR and Wagner LK, Protecting patients by training physicians in fluoroscopic radiation management. *J Appl Clin Med Phys* **1:**32-37, 2000.
- Wagner LK and Archer BR, Minimizing Risks from Fluoroscopic X Rays, 2nd ed., R.M. Partnership, The Woodlands, TX.
- Balter S, et al. Fluoroscopically guided interventional procedures: A review of radiation effects on patients' skin and hair. Radiology, 254:326-341
- NCRP Report 168