Establishing a patient safety program in Interventional Radiology

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Or...Complying with JC standards

• JC Sentinel Event
  – Defined as:

  “Prolonged fluoroscopy with cumulative dose >1500 rads [15 Gy] to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose”

• “Sentinel event” and “medical error” are not synonymous
Definitions

• Interventional reference point (IRP)
• FDA reference point
• Cumulative dose
  – $K_{nr}$
  – Reference point dose
• Kerma area product
  – Dose area product
• Peak skin dose
• 95% area load
• Dose index
Relative merits of each

THE SKIN – A BRIEF REVIEW
The skin – a review

• The skin is composed of three layers
  – Epidermis
  – Dermis
  – Hypodermis (subQ fat)

• Three structures are of particular importance when we consider radiation
  – Stratum basale (germinative)
  – Fibroblasts
  – Vasculature

Stratum basale

• The *stratum basale* is a germinative layer of clonogenic cells that forms new epidermal cells
  – 14 days to surface

• Depletion of these cells can lead to changes in the skin
Fibroblasts

- Fibroblasts are stem cells that secrete the collagen fibers and other components of connective tissue, including the skin.
- Fibroblasts can also be damaged or killed by radiation.

Blood vessels

- Early effects – damage to epithelial cells, increased permeability.
- Late effects
  - Death and abnormal proliferation of epithelial cells.
  - Expression of damage to smooth muscle tissue.
- Thrombosis, poor microvascular circulation.

Marieb, Essentials of Human Anatomy and Physiology, 9th ed.
RISKS IN FLUOROSCOPICALLY GUIDED PROCEDURES

Who is at risk?

• Physicians
• Nurses
• Technologists
• Anesthesiologists
• Patient
• Facility
Risks to the operator and staff

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

Risks to the patient

• Death
• Puncture of vessel
• Hematoma
• Infection
• Radiation-induced cancer
  – Solid tumor
  – Leukemia
• Deterministic skin injury
• Radiation-induced epilation
Radiation induced cancer

• 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 we can minimize

Stochastic effects

• Stochastic effects, most notably cancer, can also be induced (but not linked) by prolonged fluoroscopic procedures
• In some cases the risk to the patient can be reduced

http://www.uth.tmc.edu/radiology/exhibits/koenig_wagner/index.html, July 12, 2010
Radiation induced skin injury

• Deterministic effect
  – Risk = 0 below a certain dose, risk = 1 above*
  – Severity increases with increasing dose above $D_{th}$
• In most cases, can be prevented
  – Training of operators
  – Safety program
  – QC of equipment

Thresholds

• For many years, hard thresholds for various types of deterministic skin injuries 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

<table>
<thead>
<tr>
<th>Single Dose Acute</th>
<th>Multi-Dose Acute</th>
<th>Approximate Time Period of Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>D1 6–10</td>
<td>NA</td>
<td>No observable effects expected</td>
</tr>
<tr>
<td>D2 10–15</td>
<td>1–2</td>
<td>transient erythema</td>
</tr>
<tr>
<td>B 10–15</td>
<td>transient erythema, changes in skin color, hair loss, alopecia</td>
<td></td>
</tr>
<tr>
<td>C 15–10</td>
<td>2–3</td>
<td>transient erythema, changes in skin color, hair loss, alopecia</td>
</tr>
<tr>
<td>D &gt;15</td>
<td>3–4</td>
<td>transient erythema, changes in skin color, hair loss, alopecia</td>
</tr>
</tbody>
</table>

Note: – Applicable to certain range of patient and examination/ treatment parameters. – Not applicable to certain examination/ treatment parameters. – indicates uncharacterized changes. – Latent period means that cause and effect may not be connected by patient or physician.
Radiation injuries

- Also, radiation injuries can be particularly gruesome and, depending on severity, may never completely heal.

http://www.uth.tmc.edu/radiology/exhibits/koenig_wagner/index.html, July 12, 2010

Stages of skin injury

1. Initial response
2. Main response
3. Late effects
4. Permanent changes
Initial response

• The initial response of the skin to x-radiation is much like a sunburn
  – UV and x-radiation are both ionizing
• Erythema caused by vasodilation and release of histamine and other inflammatory agents by mast cells
• The initial response occurs within a few hours and subsides within a few days
  – Presence can be indicative of high likelihood for severe response

Main response

• Main responses include
  – Erythema
  – Dry desquamation
  – Moist desquamation
  – Epilation
    • Temporary or permanent
• Dry and moist desquamation are caused by depopulation of clonogenic cells in the stratum basale
• Epilation is caused by damage to hair follicles
Dry desquamation/epilation

Healing

• Healing of early effects is a result of repopulation of healthy skin cells
• Repopulation occurs from
  1. Surviving clonogenic cells within the irradiated area or
  2. Migration of healthy clonogenic cells from outside the field
Late effects

- Late effects include dermal atrophy, ulceration, telangiectasia, dermatitis, sclerosis, and necrosis
- Occur months to years after main effects
- Caused primarily by vascular damage to the dermis

Permanent skin changes

- Certain radiation-induced skin changes can be permanent
- Hyper- or hypopigmentation
- Telangiectasia
- Scarring
- Induration


http://www.uth.tmc.edu/radiology/exhibits/koenig_wagner/index.html
What can we do?

• **Reduce** the risk of radiation-induced cancer for operator, staff, and patient
• **Prevent** most deterministic 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
Pre-Procedure

• Consent ing process
  – Medico-legal aspects
  – Lou Wagner’s “advice”
• Patient education
  – Requires staff education
  – Easy-to-understand pamphlets
• Identification of at-risk patients
  – Certain conditions may pre-dispose patient to injury
    • Diabetes mellitus, connective tissue disorders
  – Prior high-CD procedures (JC aspects)
  – RIS
• Credentialing of users of fluoroscopic equipment
  – AAPM TG124
• Procedure planning

Intra-Procedure

• Cumulative dose (CD) thresholds
• Ongoing faculty and staff education
  – Removal of grid
    • Fellow credentialing
  – Store loop/store monitor, not acquisition
    • Dr. Tam
  – Be in the room
    • YDNKIHUYKWKI
• Reduced-dose protocols
  – Patients identified during pre-procedure process
• Situational awareness
  – Prior high-CD procedure – projection considerations
    • Irradiate different skin site, prevent sentinel event(?)
Post-Procedure

- Follow-up protocol
- Record dose descriptors somewhere
  - CD/DAP/#of DynaCT/# of exposures/time
    - RIS
    - Medical record
    - PACS
      - Structured dose reporting (DICOM dose) is coming

- Flag high-CD cases
  - 3 Gy (SIR)
  - Procedure-dependent?

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/web/consent/

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
- 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. 

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.

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
  - Mechanism 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 (microvascular disease)
  – Connective tissue disorders
    • Marfan syndrome
  – Ataxia telangiectasia
  – Drug interactions
• Also, a recent high-CD procedure can result in the induction of injuries at lower CD levels


Identify “high-risk” patients

• Most easily done during the consenting process
• The RIS can be a valuable tool for automatically identifying and flagging these patients
• “High-risk” patients can perhaps be routed to a dose-sparing protocol, physician can be advised
  – Fewer acquisition runs, more storing/saving
  – Alternate CD thresholds
  – Delay 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 the most recent procedure
• We can look to radiobiology for an idea of how to manage this

Fractionation and late effects

• Fractionation has long been used in radiotherapy to reduce normal tissue complications
  – Little impact on early effects (tumor + normal)
  – Reduces severity of late effects
• The benefit of fx depends on $\alpha/\beta$

$$E = \alpha D + \beta D^2$$

$$BED = D \left( 1 + \frac{D}{\alpha/\beta} \right)$$
Determining BED for multiple procedures

- $\alpha/\beta$ for skin is $\sim 3$ Gy$^*$ for early effects and $\sim 10$ Gy$^*$ for late effects
- We can use these to calculate the BED for any number of procedures
  - Assumes only repair and no repopulation
  - Independent procedures

$$BED_n = d_1 \left(1 + \frac{d_1}{\alpha/\beta}\right) + d_2 \left(1 + \frac{d_2}{\alpha/\beta}\right) + \ldots + d_n \left(1 + \frac{d_n}{\alpha/\beta}\right)$$

Physician/staff credentialing

- Physicians performing complex procedures should be credentialed in the safe use of fluoroscopic equipment
  - AAPM TG 124
  - Credentialing course
- Continuing education
- Understand dose-saving features of each type of equipment on which they work
INTRA-PROCEDURE ELEMENTS

Cumulative dose (CD) thresholds

- All equipment manufactured after June 2006 is required by law to display cumulative air kerma*
- Alerting the physician at certain CD thresholds 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
  - Continuation of procedure at a later time (how long?)
Establishing CD thresholds

<table>
<thead>
<tr>
<th>Threshold</th>
<th>Actions Taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000 mGy</td>
<td>Technologist will notify radiologist that a CD of 2000 mGy has been reached. Radiologist will ensure that radiation is being used appropriately and sparingly. Procedure continues normally.</td>
</tr>
<tr>
<td>3000 mGy</td>
<td>Technologist will notify radiologist that a CD of 3000 mGy has been reached. Radiologist will ensure that radiation is being used appropriately and sparingly. Case should be flagged upon completion.</td>
</tr>
<tr>
<td>4000 mGy</td>
<td>Technologist will notify radiologist that a CD of 4000 mGy has been reached. Radiologist will ensure that radiation is being used appropriately and sparingly.</td>
</tr>
<tr>
<td>5000 mGy</td>
<td>Technologist will notify radiologist that a CD of 5000 mGy has been reached. Radiologist will assess risk/benefit of procedure. Radiologist will ensure that radiation is being used appropriately and sparingly. Technologist considers calling on-duty medical physicist.</td>
</tr>
<tr>
<td>7000 mGy</td>
<td>Technologist will notify radiologist that a CD of 7000 mGy has been reached. Radiologist will ensure that radiation is being used appropriately and sparingly. Threshold for severe skin effects may have been reached. Radiologist will assess risk/benefit of procedure and consider continuing the procedure at a later time, depending on patient's condition. If procedure continues, radiologist will ensure that radiation is being used appropriately and sparingly. Extreme caution should be exercised past this point, and all possible dose reduction methods used, including restricting use of acquisition mode and DSA.</td>
</tr>
<tr>
<td>8000 mGy</td>
<td>Technologist will notify radiologist that a CD of 8000 mGy has been reached. Radiologist will ensure that radiation is being used appropriately and sparingly.</td>
</tr>
<tr>
<td>&gt;10000 mGy</td>
<td>Technologist will notify radiologist that a CD of &gt;10000 mGy has been reached. Radiologist will ensure that radiation is being used appropriately and sparingly.</td>
</tr>
</tbody>
</table>

* Dynamic CT runs do not contribute significantly to peak skin dose (PSD). This should be considered in cases that utilize DynaCT heavily. An average DynaCT run contributes approximately 200 mGy to the displayed CD.
Other recommendations

Table 3

<table>
<thead>
<tr>
<th>Parameter</th>
<th>First Notification</th>
<th>Subsequent Notifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peak skin dose (PSD)</td>
<td>2,000 mGy</td>
<td>500 mGy</td>
</tr>
<tr>
<td>Reference point-air kerma (KERp)</td>
<td>3,000 mGy</td>
<td>2,000 mGy</td>
</tr>
<tr>
<td>Kerma-area-product (KCA)</td>
<td>500 Gy - cm²</td>
<td>300 Gy - cm²</td>
</tr>
<tr>
<td>Fluoroscopy time (FT)</td>
<td>30 min</td>
<td>15 min</td>
</tr>
</tbody>
</table>

* Assuming a 100-cm² field at the patient’s skin. The value should be adjusted to the actual procedural field size.

Reduced-dose protocols

- Many elements of a protocol can be adjusted to reduce radiation dose to the patient
  - Reduce IAKRD for fluoroscopy
  - Reduce IAKRD for acquisition
  - Reduce frame rate for acquisition*
  - Reduce pulse rate for fluoroscopy*
  - Use lower-dose ADRC curve (have to know them)
  - Use additional filtration*
Situational awareness

• For patients who have undergone a recent high-CD procedure, use a different projection to reduce 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
POST-PROCEDURE ELEMENTS

Record dose descriptors

• Medical record has been suggested
  – Perhaps difficult
  – May not be searchable
    • Dictated
    • Scanned

• DICOM Structured Dose Reporting is coming soon
  – S. Balter talk at AAPM 09
  – Just begin adopted my manufacturers
  – Current generation of objects not supported by many PACS (use RIS)

• DICOM headers contain some information
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 (not intended)
  – Reports can be generated, already linked with procedure (accession number)
  – Automatic analysis of data/entry into database
Record dose descriptors

• What we record:
  – CD
  – DAP
  – Number of acquisition runs
  – Number of rotational angiography runs
  – Fluoroscopy time

• Track repeated or multiple procedures

Flagging and follow-up of high CD cases

• A high CD case is flagged by the technologist, triggering a follow-up protocol (PA):
  – Patient informed that high CD (>= 3 Gy) was reached
  – Patient instruction (pamphlet)
    • 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
  – Print protocol and archive

• Flag = 3 Gy
  – SIR Safety and Health Committee
Peak skin dose (PSD) reconstruction

- Ideally you have some summary report of the dose descriptors
  - On the monitor
  - Exam protocol
- Otherwise, information from the DICOM header(s) will be needed, along with fluoroscopy time

PSD reconstruction

- The aforementioned information is used along with information from the DICOM header
  - Magnification factor (patient position)
  - Images (position of radiation field)
  - Need collimator positions in absence of CD data
- All of these data can be used in conjunction with
  - Backscatter factor
  - f-factor

to estimate PSD
Measuring PSD

- GAFCHROMIC® film can be used to measure PSD
- Dose information can be assessed in two ways:
  - A calibrated strip can be used to estimate PSD
  - The film can be scanned and decalibrated to determine PSD

http://online1.ispcorp.com/_layouts/Gafchromic/content/products/rr/pdf/doseverstripguide.pdf,10/08

http://online1.ispcorp.com/_layouts/Gafchromic/content/products/en/pdf/doseverstripguide.pdf,10/08
Know your allies

• We as diagnostic folks rarely see these doses
  – Folks = physicians and physicists
• Thus we need some help when we encounter them
• Dermatologists may not have a good handle either
• Radiation oncologists seem to be the best to discuss these matters with
  – May not see late/acute effects of same severity

Other areas for concern

• Effective doses
• Marrow doses (organ dose)

Table 3

<table>
<thead>
<tr>
<th>Examination</th>
<th>Average Effective Dose (mSv)**</th>
<th>Values Reported in Literature (mSv)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radial and pelvic angiography</td>
<td>5</td>
<td>0.8–10.6</td>
</tr>
<tr>
<td>Coronary angiography (diagnostic)</td>
<td>7</td>
<td>2.0–13.8</td>
</tr>
<tr>
<td>Coronary percutaneous transluminal angioplasty,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>stent placement, or radiofrequency ablation</td>
<td>15</td>
<td>0.7–32</td>
</tr>
<tr>
<td>Thoracic angiography of pulmonary artery or aorta</td>
<td>5</td>
<td>4.1–16.0</td>
</tr>
<tr>
<td>Abdominal angiography or nephrostomy</td>
<td>12</td>
<td>4.5–40.0</td>
</tr>
<tr>
<td>Transplant infrarenal portocaval shunt placement</td>
<td>70</td>
<td>20–140</td>
</tr>
<tr>
<td>Parietal gastrostomy</td>
<td>90</td>
<td>44–78</td>
</tr>
</tbody>
</table>

* Values can vary markedly on the basis of the skill of the operator and the difficulty of the procedure.
Other areas for concern

- Wound healing
  - Pre-surgery spinal embolization
  - 8, 10, 12 Gy cases
  - How do wounds heal after these doses are delivered < 24 hr prior to surgery?
    - Damage to fibroblasts
    - Literature – only a few papers about mouse experiments

Further reading

  - SIR Standards of Practice Committee
  - SIR Safety and Health Committee
  - Discharge/consenting examples
Acknowledgements

- Louis K Wagner, Ph.D.
- Joseph Steele, M.D.