Ionizing Radiation Can be Harmful: Nothing New

Dr. Menard Submits it to Amputation for X-Ray Injury. Special Cable to The New York Times.

PARIS, June 9.—Dr. Maxime Menard, head of the radiology department of the Cochin Hospital, smoked a cigarette while an operation was being performed. A large, cancerous tumor was removed from the patient's left breast with the aid of X-rays, which were used by the patient's physician and his assistants. The patient has been discharged from the hospital.

July 30, 1897

The New York Times

Burned by the X Rays

Pitiful Condition of Miss Josie McDonald After Being Photographed by Them.

Hair Fell Out of Scalp

Two Dentists Had the Photograph Taken to Examine Her Jaw, and She Has Required Constant Medical Attention Ever Since.

June 10, 1914

The New York Times

X-Ray Wound Kills Him.

Dr. Wm. E. Sprunger Bursts a Blood Vessel, Following an Old Burn.

New Haven, March 13.—Dr. William E. Sprunger, a former member of the faculty of the Yale Medical School and well-known as an X-ray expert, is dead at the home of a daughter here. Death was due to the breaking of a blood vessel brought about by an X-ray burn several years ago. Dr. Sprunger served as a surgeon in the Franco-Prussian war, and received the decoration of the Maltese Cross from the German Government. He was 63 years old, and leaves three daughters.
Deterministic effects
- Those in which the number of cells lost in an organ or tissue is so great that there is a loss of tissue function, such as skin erythema and ulceration
- Has a threshold
- Skin changes, cataracts

Stochastic effects
- Occur if an irradiated cell is modified rather than killed and then goes on to reproduce
- Do not appear to have a threshold and the probability of the effect occurring is related to the radiation dose
- Cancer, genetic mutations
Dose Metrics:
Air Kerma (RP) in mGy
Peak Skin Dose in mGy

- **0-2 Gy**
  - < 2 Weeks: None
  - 2 – 52 Weeks: None
  - Permanent: None

- **2-5 Gy**
  - < 2 Weeks: Erythema
  - 2 – 52 Weeks: Epilation
  - Permanent: None

- **5-10 Gy**
  - < 2 Weeks: Erythema
  - 2 – 52 Weeks: Prolonged/Permanent Erythema/Epilation
  - Permanent: Dermal Atrophy

- **>10 Gy**
  - < 2 Weeks: Erythema/Ulceration
  - 2 – 52 Weeks: Desquamation
  - Permanent: Surgery

“Air kerma overestimates PSD in most instances [0.5 - 0.8]”
RAD-IR Study
The Joint Commission has identified a peak skin dose > 15Gy as a sentinel event (cumulative over 6-12 months)

RISK: Deterministic versus Stochastic

Dose Metrics:
- DAP in Gy cm$^2$
- Effective Dose in mSv

Risk Estimate $\approx 5.5\%$ per Sv

Known and Probable Human Carcinogens:
- Ultraviolet (UV) radiation, including UVA, UVB, and UVC rays
- Ultraviolet-emitting tanning devices
- Vinyl chloride
- Wood dust
- X- and Gamma-radiation
Biologic Effects of Ionizing Radiation (BEIR) The “Evidence”

- Series of publications from national academies concerning radiation health effects
  - Mainly epidemiological data
  - Studies on A-bomb survivors
    - More than 60% of A-bomb survivors with cancer received a dose < 100mSv
  - Studies from persons exposed to radiation for medical reasons
  - Nuclear workers exposed to radiation
Cancer and Cancer deaths from low level radiation (< 100 mSv)

<table>
<thead>
<tr>
<th></th>
<th>Males</th>
<th>Females</th>
<th>Males</th>
<th>Females</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excess cancer cases</td>
<td>800 (400-1600)</td>
<td>1300 (690-2500)</td>
<td>100 (30-300)</td>
<td>70 (20-250)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Excess Deaths</td>
<td>410 (200-830)</td>
<td>610 (300-1200)</td>
<td>70 (20-220)</td>
<td>50 (10-190)</td>
</tr>
</tbody>
</table>

(BEIR VII report 2006)
Linear-No-Threshold (LNT) Model

- At low (ped cath) doses linear dose-response relationship between exposure to ionizing radiation and development of solid cancers
- It is unlikely that there is a threshold below which cancers are not induced, but at low doses number of radiation induced cancers will be small

(BEIR VII report 2006)
Is it a ‘linear’ relationship?:
γ-H2AX foci as a quantitative biomarker of human low-level radiation exposure

- DNA double strand breaks (DSBs) ➞ most relevant lesions to DNA as a result of X-ray (difficult to repair)
- DSBs ➞ activate histone H2AX within 3 minutes after DNA damage (phosphorylation) ➞ γ-H2AX
- γ-H2AX foci essential for recruitment of repair or signaling proteins to DNA damage sites
- 1 γ-H2AX focus represents 1 DNA DSB
γ-H2AX foci per cell in pediatric patients after X-Ray exposure

Beel L et al, Circulation 2009
γ-H2AX foci per cell in pediatric patients after X-Ray exposure

- “Hypersensitivity” at low dose in γ-H2AX foci induction
- Damage not only to cell exposed to radiation but also surrounding cells (non-targeted effects in unexposed bystander cells)

- Lifetime attributable risk of cancer mortality:
  - LNT-model: 1 in 1,000
  - γ-H2AX foci data: 4 in 1,000

Beel L et al, Circulation 2009
Exposure to low level radiation and cardiovascular risk

- Higher incidence of cardiovascular disease may occur at lower radiation doses:
  - McGeoghegan et al, In J Epidem 2008:
    - 65,000 employees from British Nuclear Industry
    - Excess relative risk 0.65 (0.36 to 0.98)
  - Vrijheid et al, In J Epidem 2007:
    - 275,000 nuclear workers from 15 countries
    - Excess relative risk 0.48 (-0.23 to 1.31)
Early 1980's

- Medical: 14%
- Background: 82%
- Other: 4%

Total: 3.6 mSv Per Individual

Late 2000's

- Medical: 48%
- Background: 50%
- Other: 2%

Total: 6.2 mSv Per Individual

Medical Contribution:

- 0.5 mSv
- 600%
- 3 mSv

*NCRP Report 93 and 160*
## Radiation risk in paediatric radiology

<table>
<thead>
<tr>
<th>Examination</th>
<th>Effective dose (mSv)</th>
<th>Lifetime risk of fatal cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limbs</td>
<td>&lt;0.005</td>
<td>1/a few million</td>
</tr>
<tr>
<td>Chest (PA)</td>
<td>0.01</td>
<td>1/million</td>
</tr>
<tr>
<td>Spine (AP, PA, Lat)</td>
<td>0.07</td>
<td>1/150000</td>
</tr>
<tr>
<td>Pelvis</td>
<td>0.08</td>
<td>1/120000</td>
</tr>
<tr>
<td>AXR</td>
<td>0.10</td>
<td>1/100000</td>
</tr>
<tr>
<td>MCU</td>
<td>1.0</td>
<td>1/10000</td>
</tr>
<tr>
<td>CT Head</td>
<td>2</td>
<td>1/5000</td>
</tr>
<tr>
<td>CT Body</td>
<td>10</td>
<td>1/1000</td>
</tr>
</tbody>
</table>

Cook JV, Imaging, 13 (2001), Number 4
Stochastic Radiation Effects: The Pediatric Problem

Children are at potentially greater risk of stochastic effects due to:

- Greater radiation sensitivity of their tissue compared with adults
- More remaining years of life during which radiation-induced malignancies may develop
- Often multiple radiological procedures over lifetime with cumulative exposure not being tracked or monitored
### The Pediatric Problem

<table>
<thead>
<tr>
<th>Date</th>
<th>Type of cath</th>
<th>Fluoro time</th>
<th>Cum air KERMA</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007-Dec</td>
<td>Diagnostic</td>
<td>22 min</td>
<td>229 mGy</td>
</tr>
<tr>
<td>2008-Jun</td>
<td>Diagnostic</td>
<td>35 min</td>
<td>785 mGy</td>
</tr>
<tr>
<td>2008-Jun</td>
<td>Hybrid – PA Rehab</td>
<td>13 min</td>
<td>290 mGy</td>
</tr>
<tr>
<td>2008-Aug</td>
<td>PA Rehab</td>
<td>70 min</td>
<td>2,148 mGy</td>
</tr>
<tr>
<td>2008-Dec</td>
<td>PA Rehab</td>
<td>123 min</td>
<td>2,709 mGy</td>
</tr>
<tr>
<td>2009-May</td>
<td>PA Rehab</td>
<td>102 min</td>
<td>3,788 mGy</td>
</tr>
<tr>
<td>2009-Dec</td>
<td>PA Rehab</td>
<td>77 min</td>
<td>1,012 mGy</td>
</tr>
<tr>
<td>2011-Mar</td>
<td>PA Rehab</td>
<td>129 min</td>
<td>1,965 mGy</td>
</tr>
<tr>
<td>2011-Nov</td>
<td>Exit Angio</td>
<td>3 min</td>
<td>148 mGy</td>
</tr>
</tbody>
</table>
4 year male with PA VSD MAPCAS

- The Pediatric Problem -

• 9* Cardiac Catheterizations / Hybrid Procedures
• 84* CXR
• 16* AXR
• 4* CT chest
• 4* CT brain
• 2* NJ tube placement
• 1* cyturethrogram
Use of medical radiation for 1 year in USA may:

**Benefit**: 150+ million people

**Risk**: ~50,000 cases of radiation induced cancer (0.03%)
   ~40,000 cases of moderate skin damage
   (0.25% of interventional procedures)

Dose Management ✈✈✈ Reduced Risk
Defining Radiation Exposure
Terminology can be confusing.

- (m) Sievert
- Roentgen
- Air Kerma
- rad
- Dose Area
- (m) Gray
- Product
- Effective Dose
- Peak Skin dose
The “Education” Problem

“Our patient has radiation illness!!”
Google: “symptoms of radiation illness”
   Fatigue, fever, nausea, vomiting, weakness, bruising …
Google: “Dose for radiation illness”
   1 sievert
Google: “conversion gray to sievert”
   1 gray = 1 sievert
Patient received 5,400 mGy (5.5Gy) cumulative air kerma and has nausea and vomiting
   ➔ “Our patient has radiation illness”
Radiation - Terms

Exposure / energy produced
- The amount of ionizing radiation a person is exposed to
- Measured in coulomb/kg (C/kg) or roentgens (R)

Absorbed dose
- The amount of energy deposited in any material, or the amount of radiation needed to transfer a certain amount of energy (1 joule/kg).
- Measured in gray (Gy) or rad (1 Gy = 100 rad)

Dose equivalent
- The absorbed dose multiplied a quality factor allowing for different tissue sensitivities, or the equivalent dose of radiation having the same damaging effect as an equal dose of gamma rays (accounting for different biological effects of radiation).
- Measured in sievert (Sv) or rem (1 Sv = 100 rem)
What is Dose?

- Detector Exposure - $R$
- Organ Dose / Effective Dose - $mSv$
- Peak Skin Dose (PSD) - $mGy$
- Incident Dose* [Air Kerma (AK) at Reference Point] - $mGy$
- Dose Area Product (DAP) - $Gy \, cm^2$

Measuring Dose: Fluoroscopy Time
What do we ‘measure’? Terminology.

Total Air Kerma (mGy):
- Procedural cumulative dose (delivered to air) at the interventional reference point (Usually along central ray of x-ray beam 15cm back from isocenter)
- Measured and displayed on all fluoroscopic equipment sold in USA after 2006
- Can be used to monitor thresholds for deterministic effects of radiation exposure

Peak Skin Dose (mGy):
- Maximum dose received by any local area of the skin
- Not measured directly ➔ derived from total air kerma using a variety of calculations, taking into account angles / projections of x-Ray beams
- Less than total air kerma for most (but not all) procedures
- Determines deterministic effects of radiation exposure
Dose Tracking System (PSD)

Dose Tracking System (DTS) can display the cumulative Entrance Skin Dose to the patient with color segmentation in real time.
What do we ‘measure’? Terminology.

Dose Area Product (mGy cm\(^{-2}\)):
- Cumulative sum of product of instantenous air kerma and X-Ray field area
- Good measure for total energy delivered to patient
- Provided by most modern fluoroscopic equipment
- Important as a marker of stochastic risk (but not deterministic)

Effective Dose (mSv):
- Used in radiation protection to express detriment to whole body if only part of the body is exposed
- Important as a marker of stochastic risk (but not deterministic)
Effective Dose Examples

Low levels of radiation (<100 mSv):

- Annual background radiation: 3 mSv
- Chest X-Ray: 0.1 mSv
- Whole body CT Scan: 10 mSv
- Pediatric cardiac catheterization:
  - Most procedures: <20 mSv
  - Diagnostic /simple interventions: <5 mSv
How much radiation is used in paediatric radiology examinations compared to other exposures?

<table>
<thead>
<tr>
<th></th>
<th>Estimated dose</th>
<th>Days of background radiation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Natural background</td>
<td>3 mSv/year</td>
<td>1 day</td>
</tr>
<tr>
<td>Airline passenger</td>
<td>0.04 mSv</td>
<td>4 days</td>
</tr>
<tr>
<td>Chest X-ray</td>
<td>0.01 mSv</td>
<td>1 day</td>
</tr>
<tr>
<td>Head CT</td>
<td>2 mSv</td>
<td>8 months</td>
</tr>
<tr>
<td>Chest CT</td>
<td>3 mSv</td>
<td>12 months</td>
</tr>
<tr>
<td>Abdominal CT</td>
<td>5 mSv</td>
<td>20 months</td>
</tr>
<tr>
<td>Angiography or venography</td>
<td>11-33 mSv</td>
<td>4-11 years</td>
</tr>
<tr>
<td>CT guided intervention</td>
<td>11-17 mSv</td>
<td>4-6 years</td>
</tr>
</tbody>
</table>

www.imagegently.org
Pre-requisites for Effective Dose Management
Attitude / Awareness

- Staff and physician attitude towards capturing and recording data related to radiation exposure not always perfect
- Vano et al, Health Physics, 2011
  - 10 pediatric interventional cardiac centers from 9 countries (Latin America)
  - Only 64% of cardiologists used dosimeters regularly
  - Only 36% of cardiologists were aware of personal values
  - Patient dose data available only in a few centers and not analyzed on a regular basis
Increasing awareness as the key ingredient to quality improvement efforts

Characterization of Radiation Exposure and Effect of a Radiation Monitoring Policy in a Large Volume Pediatric Cardiac Catheterization Lab

George R. Verghese, MD, MBA, Doff B. McElhinney, MD, Keith J. Strauss, MSc, and Lisa Bergersen, MD, MPH

Objectives: This study aimed to characterize radiation dose during cardiac catheterization in congenital heart disease and to assess changes in dose after the introduction of a radiation monitoring policy. Background: Minimizing radiation exposure is an important patient safety initiative and relatively few data are available characterizing radiation dose for the broad spectrum of congenital cardiac catheter-based procedures. Results: Between 7/1/05 and 12/10/08, 3,355 cases were identified for inclusion. Radiation dose increased with age and procedural complexity. Patients were characterized into low, medium, and high dose categories relative to each other. “Low” dose cases included isolated pulmonary or aortic valvotomy, pre-Fontan assessment, and ASD closure. “High” dose cases involved multiple procedures in pul-

CCI 2012

“… After the introduction of a radiation threshold monitoring and notification policy, there was a statistically significant decrease in radiation dose …”
Dose Awareness and Regulation Continues to Increase

This Month in the News:

- Less than one-third of providers understand dose risks
- Predict Cancer Risk to Curb Unnecessary Diagnostic Procedures
- Dialing in on Dose, Radiation Dose Backlash
- Disease burden linked w/ higher rad exposure
- Court Convicts Doctors in Radiation Overdose Case

Recommendations, Guidelines, Regulations:

Organizational - Professional - Societal - Local - State - National - Federal - International
Importance of Dose Management [ALARA]

Regulatory (Hospital)  
TJC, JCI

Recommendations / Guidelines  
NCRP, IAEA, ACR

Hospital Programs  
Image Gently

Public  
Dose Registries, IAEA SmartCard

Economic  
Reimbursement, Accreditation, Licensure, Choice

Regulatory (Manufacturer)  
FDA, IEC

PATIENT SAFETY!
Since January 2014: 33 publications !!
Use of a Dose-dependent Follow-up Protocol and Mechanisms to Reduce Patients and Staff Radiation Exposure in Congenital and Structural Interventions

Jacyln M. Sawday, RT, Tanya Maria Kempton, RN, Vincent Oshovo, CCR, CCT
Mark Goch, RT, Joanne L. Chisolm, RN, Sharon L. Hill, MEd, RT, ACR, Amy Kirk, ACR
John P. Chestam, MD, and Raf J. Holzer, MD, MS

Background: Increasingly complex structural congenital cardiac interventions require efforts at reducing patients/staff radiation exposure. Standard follow-up protocols are often inadequate in detecting all patients who may have sustained radiation burns. Methods: Single-center retrospective chart review divided into four intervals. Phase 1 (07/07-08/08, 413 procedures) protocol: follow-up based on fluoroscopy time only; fluoro rate for digital acquisition (DA) 30 fps, and fluoroscopy (F) 30 fps. Dose-based follow-up was used for phase 3-4. Phase 2 (08/07-09/08, 458 procedures; DA 30 fps, FL 15 fps). Phase 3 (09/08-06/10, 303 procedures; DA: 15-30 fps, FL: 15 fps, use of added radiation protection devices). Phase 4 (07/10-01/12, 09 procedures; DA: 15-30 fps, FL: 15 fps, superior make reduction filter (SMRF) with high-quality fluoroscopy capabilities). Results: There was a significant reduction in the median cumulative air kerma between the four study periods (716 mGy vs. 566 mGy vs. 486 mGy vs. 241 mGy; P < 0.001), even though the overall fluoroscopy times remained very similar (25 min vs. 32 min vs. 26 min vs. 20 min, P = 0.002). There was a trend towards lower physician radiation exposure over the four study periods (127 mGy vs. 152 mGy vs. 106 mGy vs. 59 mGy, P = 0.15). Fifteen patients with radiation burns were identified during the study period. When changing to a dose-based follow-up protocol (phase 1 vs. phase 4), there was a significant increase in the incidence of detached radiation burns (9.5% vs. 2%, P = 0.04).

Conclusions: Dose-based follow-up protocols are superior in detecting radiation burns when compared to fluoroscopy time-based protocols. Frame rate reduction of fluoroscopy and cine acquisition and use of modified imaging equipment can reduce a significant reduction to patient/staff exposure.

Key words: congenital heart disease; structural heart disease; radiation exposure; radiation protection fluoroscopy

INTRODUCTION

Radiation protection and patient/staff dose monitoring are essential quality and safety tools within the cardiac catheterization laboratory. Patients with congenital heart disease frequently undergo numerous diagnostic and therapeutic catheterization procedures, in addition to other imaging studies such as CT scans [1]. The frequency and duration of these procedures has increased notably over the last two decades as a result of advances made in transcatheter techniques and instrumentation available to the interventional cardiologist. Although the long-term effects of this exposure are not known and difficult to estimate, there is significant concern especially about long-term stochastic effects of this “friendly fire” [2], such as solid tumors and leukemia. This is especially true in children [3], as growing tissue is much more sensitive to the biological effects of radiation. Furthermore, children have much more time to survive long enough through the latent period that often occurs before malignancies develop and therefore are more likely to eventually manifest late effects of radiation exposure.

The Heart Center, Nationwide Children’s Hospital, Columbus, Ohio.

Conflict of Interest: John Chestam is a consultant for Toshiba Medical Systems.

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### TABLE IV. Radiation Dose by Case Type in Age Strata

<table>
<thead>
<tr>
<th>Age groups</th>
<th>Procedure type</th>
<th>$n$</th>
<th>Weight (kg)</th>
<th>Fluoroscopy time (min)</th>
<th>Air KERMA (mGy) median [IQR]</th>
<th>DAP (μGy m$^2$) median [IQR]</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1</td>
<td>Pulmonary valvotomy (isolated)</td>
<td>86</td>
<td>4.3</td>
<td>28</td>
<td>233 [129, 388]</td>
<td>797 [459, 1,355]</td>
</tr>
<tr>
<td></td>
<td>Aortic valvotomy (isolated)</td>
<td>43</td>
<td>4.4</td>
<td>30</td>
<td>307 [200, 447]</td>
<td>957 [629, 1,524]</td>
</tr>
<tr>
<td></td>
<td>Pre-Glenn Evaluation</td>
<td>128</td>
<td>5.2</td>
<td>41</td>
<td>412 [266, 686]</td>
<td>1378 [954, 2,040]</td>
</tr>
<tr>
<td></td>
<td>Aorta dilation and or stent</td>
<td>42</td>
<td>5.3</td>
<td>34</td>
<td>452 [252, 766]</td>
<td>1298 [827, 2,292]</td>
</tr>
<tr>
<td></td>
<td>Prox R or L angioplasty and or stent only</td>
<td>43</td>
<td>4.7</td>
<td>53</td>
<td>571 [396, 913]</td>
<td>1852 [1,415, 2,824]</td>
</tr>
<tr>
<td></td>
<td>≥2 prox or distal R or L angioplasty or stent</td>
<td>75</td>
<td>5.5</td>
<td>73</td>
<td>892 [491, 1,265]</td>
<td>2744 [1,868, 4,154]</td>
</tr>
<tr>
<td></td>
<td>Pulmonary vein dilation</td>
<td>52</td>
<td>5.5</td>
<td>90</td>
<td>968 [597, 1,420]</td>
<td>3504 [2,333, 5,039]</td>
</tr>
<tr>
<td>1–4</td>
<td>PDA device or coil closure</td>
<td>61</td>
<td>13.0</td>
<td>17</td>
<td>240 [139, 321]</td>
<td>800 [558, 1,430]</td>
</tr>
<tr>
<td></td>
<td>Pre-Fontan Assessment</td>
<td>128</td>
<td>12.6</td>
<td>45</td>
<td>464 [286, 734]</td>
<td>2,395 [1,413, 3,880]</td>
</tr>
<tr>
<td></td>
<td>ASD or PFO closure (isolated)</td>
<td>29</td>
<td>14.7</td>
<td>30</td>
<td>540 [361, 753]</td>
<td>2,197 [1,614, 3,048]</td>
</tr>
<tr>
<td></td>
<td>RVOT dilation and or stent</td>
<td>27</td>
<td>11.5</td>
<td>42</td>
<td>788 [318, 1,418]</td>
<td>3,007 [1,457, 4,486]</td>
</tr>
<tr>
<td></td>
<td>Prox R or L angioplasty and or stent only</td>
<td>44</td>
<td>11.9</td>
<td>53</td>
<td>827 [551, 1,313]</td>
<td>3,513 [2,717, 4,706]</td>
</tr>
<tr>
<td></td>
<td>Pulmonary vein dilation</td>
<td>34</td>
<td>10.1</td>
<td>86</td>
<td>973 [620, 1,504]</td>
<td>4,769 [3,012, 6,499]</td>
</tr>
<tr>
<td>5–9</td>
<td>ASD or PFO closure (isolated)</td>
<td>40</td>
<td>22.0</td>
<td>31</td>
<td>522 [331, 862]</td>
<td>2,816 [1,431, 3,978]</td>
</tr>
<tr>
<td></td>
<td>RVOT dilation and or stent</td>
<td>23</td>
<td>25.9</td>
<td>36</td>
<td>852 [434, 1,360]</td>
<td>4,348 [2,548, 6,211]</td>
</tr>
<tr>
<td></td>
<td>Prox R or L angioplasty and or stent only</td>
<td>22</td>
<td>22.0</td>
<td>52</td>
<td>931 [668, 1,733]</td>
<td>5,303 [4,396, 6,615]</td>
</tr>
<tr>
<td></td>
<td>Fenestration device and other intervention</td>
<td>28</td>
<td>20.4</td>
<td>56</td>
<td>1,034 [795, 1,865]</td>
<td>5,330 [3,033, 7,608]</td>
</tr>
<tr>
<td></td>
<td>≥2 prox or distal R or L angioplasty or stent</td>
<td>51</td>
<td>20.6</td>
<td>73</td>
<td>1,776 [1,088, 2,793]</td>
<td>6,420 [3,882, 10,930]</td>
</tr>
<tr>
<td>10–15</td>
<td>ASD or PFO closure (isolated)</td>
<td>27</td>
<td>49.7</td>
<td>34</td>
<td>1,459 [814, 2,324]</td>
<td>7,492 [4,419, 10,582]</td>
</tr>
<tr>
<td></td>
<td>RVOT dilation and or stent</td>
<td>25</td>
<td>45.7</td>
<td>52</td>
<td>2,019 [977, 3,065]</td>
<td>9,449 [5,917, 18,958]</td>
</tr>
<tr>
<td></td>
<td>≥2 prox or distal R or L angioplasty or stent</td>
<td>37</td>
<td>44.2</td>
<td>78</td>
<td>3,612 [2,211, 6,206]</td>
<td>18,497 [11,440, 24,072]</td>
</tr>
<tr>
<td>≥16</td>
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<td>9,871 [6,097, 15,341]</td>
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Verghese et al, CCI, 2012
Patient Radiation Exposure in a Modern, Large-Volume, Pediatric Cardiac Catheterization Laboratory

Andrew C. Glatz • Akash Patel • Xiaowei Zhu • Yoav Dori • Brian D. Hanna • Matthew J. Gillespie • Jonathan J. Rome

Table 5: Radiation exposure measures by type of interventional cases stratified by patient weight category. Values >10 observations available.

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<tr>
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<th>Area (m²)</th>
<th>mAs (mGy·cm)</th>
<th>mAs/m²</th>
<th>mAs/m²</th>
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<td>2,560 (1,624-7,209)</td>
<td>97 (93-95)</td>
<td>29 (11-70)</td>
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<td>675 (225-1,125)</td>
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<td>2,560 (1,624-7,209)</td>
<td>97 (93-95)</td>
<td>29 (11-70)</td>
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<tr>
<td>1.25</td>
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<td>335 (135-1,249)</td>
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<td>PDA (mean kg)</td>
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<td>352 (220-709)</td>
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<td>77 (71-87)</td>
<td>26.4 (14-37)</td>
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</table>

Data reported as median (IQR) or % of total; data only reported for interventional procedures with >10 observations. Significant differences exist at ≤ 0.05 levels of radiation exposure across procedural types (p ≤ 0.0001 by Kruskal-Wallis or p < 0.0001 by Pearson Chi-square) ASD, atrial septal defect; PDA, patent ductus arteriosus; BMI, body mass index; PA, pulmonary artery; PDA, patent ductus arteriosus; RVOT, right ventricular outflow tract; ORC, systemic-pulmonary artery shunt.
Radiation dose benchmarks during cardiac catheterization for congenital heart disease in the United States.


Abstract

OBJECTIVES: The aim of this study was to define age-stratified, procedure-specific benchmark radiation dose levels during interventional catheterization for congenital heart disease.

BACKGROUND: There is a paucity of published literature with regard to radiation dose levels during catheterization for congenital heart disease. Obtaining benchmark radiation data is essential for assessing the impact of quality improvement initiatives for radiation safety.

METHODS: Data were obtained retrospectively from 7 laboratories participating in the Congenital Cardiac Catheterization Project on Outcomes collaborative. Total air kerma, dose area product, and total fluoroscopy time were obtained for the following procedures: 1) patent ductus arteriosus closure; 2) atrial septal defect closure; 3) pulmonary valvuloplasty; 4) aortic valvuloplasty; 5) treatment of coarctation of aorta; and 6) transcatheter pulmonary valve placement.

RESULTS: Between January 2009 and July 2013, 2,713 cases were identified. Radiation dose benchmarks are presented including median, 75th percentile, and 95th percentile. Radiation doses varied widely between age groups and procedure types. Radiation exposure was lowest in patent ductus arteriosus closure and highest in transcatheter pulmonary valve placement. Total fluoroscopy time was a poor marker of radiation exposure and did not correlate well with total air kerma and dose area product.

CONCLUSIONS: This study presents age-stratified radiation dose values for 6 common congenital heart interventional catheterization procedures. Fluoroscopy time alone is not an adequate measure for monitoring radiation exposure. These values will be used as baseline for measuring the effectiveness of future quality improvement activities by the Congenital Cardiac Catheterization Project on Outcomes collaborative.
Local QI: Reduction in patient dose

- Collect important data for every procedure
  - Dose (Total Air Kerma and DAP)
  - Fluoroscopy time
  - Age and weight
  - Procedure type
- Have a named member of staff responsible for radiation safety and all radiation-related QI efforts
- Collected data needs to be readily accessible (either spreadsheet or DBMS)
- ➔ Implement change
- ➔ Analyze your data
Fluoro frame rates from 30 to 15 fps
Acquisition frame rates from 30 to 15 fps

Increased use of Fluoro Record (SNRF)

Reduction in patient dose
- Look at your results (QI Example) -
Reduction in patient dose
- Compare Your Data -

- Compare median radiation dose (by procedure type and age) to data reported from other centers
- Metrics established by the QMWG can be used to compare your data to that of other centers
- Where/when available use data from registries to compare performance to other centers
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## C3PO-QI: Radiation Dose Benchmarks

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<td>45</td>
<td>62</td>
<td>179</td>
<td>303</td>
<td>933</td>
</tr>
</tbody>
</table>

**Total Air Kerma (mGy)**

**Dose Artea Product (GCm2)**
Cath related (Pediatric)
Quality Improvement Initiatives

IMPACT
CCISC
C3PO-QI
Radiation Safety
Quality Improvement Toolkit for the Pediatric Cath Lab

Radiation Program Best Practice
SCAI Webinar

Save the date:
SCAI QIT Radiation Webinar
March 18th 2015
Objective:
Prevalently, the multi-center Congenital Cardiac Catheterization Outcomes Project (CCPO) established baseline adverse event rates and methods to adjust for case mix, allowing equitable comparison of outcomes between physicians and institutions. In this project we plan to initiate improvements in the quality of care we deliver to patients undergoing catheterization for congenital heart disease by reducing radiation exposure. Collaboratively, we will work to identify and implement interventions to improve physician and equipment performance while measuring the impact of our efforts using action and learning cycles. We intend to achieve these improvements by utilizing a mobile web-based data reporting platform which will support our multi-center project.

Methods to Reduce Radiation Exposure:

PDSA Methodology:
- Plan: Proposing changes based on hypotheses and theories.
- Do: Implementing the change.
- Study: Measuring or describing the effect.
- Act: Revise and updating the process based on what is learned.

Key Driver Diagram:
A common QI design tool, which summarizes the key factors thought to have a potential impact on our goal, and strategies or changes for improvement.

For more information, please visit our website at: https://c3po-gi.chboston.org/Home
What do we need to do?
Core Curriculum

Radiation Safety Program for the Cardiac Catheterization Laboratory

Charles E. Chambers, MD, Kenneth A. Fetterly, PhD, Ralf Holzer, MD, Pei-Jan Paul Lin, PhD, James C. Blankenship, MD, Stephen Balter, PhD, and Warren K. Laskey, MD

The Society of Cardiovascular Angiography and Interventions present a practical approach to assist cardiac catheterization laboratories in establishing a radiation safety program. The importance of this program is emphasized by the appropriate concerns for the increasing use of ionizing radiation in medical imaging, and its potential adverse effects. An overview of the assessment of radiation dose is provided with a review of basic terminology for dose management. The components of a radiation safety program include essential personnel, radiation monitoring, protective shielding, imaging equipment, and training/education. A procedure based review of radiation dose management is described including pre-procedure, procedure and post-procedure best practice recommendations. Specific radiation safety considerations are discussed including women and fluoroscopic procedures as well as patients with congenital and structural heart disease. © 2011 Wiley-Liss, Inc.

Key words: radiation physics; angiography coronary; diagnostic cardiac catheterization; complications adult cath/intervention; percutaneous coronary intervention
ALARA

- “As low as reasonably achievable”
- General principle guiding radiation exposure
- Keep radiation dose exposure to patient as low as reasonable for each procedure, given clinical need and patient factors
Guiding Principles

- Approach Radiation protection
  - patient and staff

- Patient: Radiation dose is optimized when imaging is performed with the least amount of radiation required to provide adequate image quality and image guidance.
Guiding Principle

- Staff: Scattered radiation in the room is directly proportional to the patient dose; if patient dose is reduced, so too is the dose to the operator and team.

**GOAL**

- To optimize radiation for the patient and minimize radiation for staff
In Practice

How many times have we:

- left our hands in the beam?
- expediency over personal safety?
- our backs to the X-ray source?
- unaware of our foot on the pedal?
- pushed away a protective barrier?
Proper Radiological Positioning*

- Maximize distance between x-ray tube & patient.
- Minimize distance between patient & Image Intensifier.
- Stand on side of the Image Intensifier
- Inverse square law – make use of it!

* Rad Techs play crucial role
Control Fluoroscopy

- Collimate
- Limit use to necessary evaluation of moving structures.
- Employ last-image-hold to review findings
- Unnecessary/Inadvertent fluoro – Make Aware!
- Time bell warning
- Reduce fluoroscopy pulses/sec to as low as possible/suitable (30/sec, 15/sec, 7.5/sec, 3.5/sec)
- System in the room – increases dose awareness
- IG Checklist
Reduce Dose

- Reduce field size (collimate)
- Minimize field overlap.
- Use low frame rate
  Avoid unnecessary runs
Personal Protection - Hands

- Keep hands out of the beam
- Finger /ring badges
- Angle of beam off hands
- Collimation
- Care
Control Images

- Limit acquisition to what is essential for diagnostic and documentation purposes.
  - Last image hold
  - Think - Plan each run
  - Think - # frames / second
  - Think - magnification
Personal Protection - Shields

- Lead table skirt / drape
- Over head shields
- Mobile Devices
- Radioprotective non-lead patient drapes
Personal Protection –
Awareness of Geometry

- Maintain awareness of body position relative to the x-ray beam
- Horizontal x-ray beam: operator and staff should stand on the side of the image receptor (I.I.)
- Vertical x-ray beam: the image receptor should be above the table.
- Angle beam where possible
Personal Protection - Wear

- Well fitted lead apron (knees)
- Leaded glasses (with sides)
- Thyroid shield
- Lead gloves – anesthetist
  - operator
Team Ergonomics*

- Train operators and staff in ergonomics of the room - good positioning when using fluoroscopy equipment; periodically assess their practice.
- Inverse Square Law
- Front or Back lead
- Identify and provide the best personal protective gear for operators and staff.

• Acknowledge expertise & vigilance of our technologists
Where do we go from here?
The Future of Dose Management

- Detailed dose information/documentation commonplace
- Patient dose data recorded in the patients medical record
- Dose reference levels further established and used for FGI procedures (national registries)
- Interventionalists responsible for patient radiation levels: Justification / patient follow up needed above threshold

No Other As Well-Defined Quantifiable Metric Exists
The Future is Now ...

**FDA to provide $2M to fund radiation protection**

*Feb 4, 2013*

The FDA will provide grant funds totaling an estimated $2 million for the support of a Center for Devices and Radiological Health (CDRH) radiation protection program. The goal of the program, dubbed 2013 Assuring Radiation Protection, will be to coordinate...

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**Federal**

**State**

**Professional**

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**Radiation Safety Training**

**Document Dose Information**

**Establish Reference Levels / Dose Limits**

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“Radiation exposure will become utmost crucial for any center participating in the care of children with CHD.”
Measuring Dose: Dose Displays-Real-Time Feedback

Dose Alert Feature

Procedural radiation monitoring, notification, and recording of patient dosing information.

- Staff members who assist during fluoroscopy will provide verbal alerts to the physician using fluoroscopy.
- For units with reference point air kerma capability initial notification is given at 3000 mGy and every 1000 mGy after or its measurement equivalent according to the specific equipment capabilities.

*Note: Dose readings do not include backscatter from the patient and are not a representation of the patient’s actual absorbed dose. Many factors outside the knowledge of the Infinix system are involved in that determination.
Dose Recording/Reporting Capabilities

1. Dose Recording
2. Dose Reporting
3. Database Output

HIS/RIS

Patient Information
- Patient Name: Unknown
- Birth Date: 1873-01-01
- Patient ID: Unknown

Exam Information
- Study Date: 2011-05-10
- Study ID: XA20110510114650
- Referring Physician: Name

Report Status
- Completion Flag: COMPLETE
- Verification Flag: VERIFIED
- Verifying Observer: 2011-05-10 - Observer Name: TOSHIBA

Report
- Procedure: Projection X-Ray
- Has Intent: Therapeutic Intent
- Observer Type: Device
- Device Observer UID: 1.2.820.0.16.5.3.1.1000000010
- Device Observer Manufacturer: TOSHIBA_MEC
- Device Observer Model Name: DFP-8000D
- Device Observer Serial Number: 000000010
- Irradiation Event Type: Fluoroscopy
- Irradiation Event Type: Fluoroscopy
- Irradiation Event Type: Fluoroscopy

Patinet Size(cm)
- 66

Patinet Weight(kg)
- 5.9

Entrance Dose(mG)
- 108.08

Area Dose Product
- 729.73

Exposed Area
- 0

Dose Comment
- Total Time Of Fluor
- Total Time Of Fluor
- Total Number Of E:
- Performed Station: INFINIX

TOSHIBA
Leading Innovation
The Power of SNRF ➔ Towards “Acquisition-less” Imaging

- Near Diagnostic IQ with Fluoro
- Fluoro 80% Less Dose
- Fluoro recording ability is an important reduction technique
Patients Typically Receive Radiation Exposure from Multiple Exams and Modalities Over the Course of Treatment

A Centralized Solution is a Better Solution
Real-Time Staff Dose Monitoring

- Real-time Staff Dose
- Easy to Interpret
- Empowers User to Adjust Working Behavior
“We are heading towards era of significant public reporting... and increased regulation”
Conclusions

• Times are changing: Increasing awareness of need to reduce radiation exposure
• Pediatric patients are at particular risk of the stochastic effects of radiation exposure (life expectancy, vulnerability, multiple procedures)
• Regulatory requirements and reimbursement make dose management an integral procedural component
• Manufacturers have identified the need for more sophisticated dose management
• Local and national QI initiatives are focusing on need to reduce radiation exposure
• Data gained from larger registries and QI initiatives is crucial to allow comparison of results between different institutions and operators
• More coherence is required in what is captured and recorded in registries relating to radiation exposure