The Identification and Evaluation of Likely High-Dose Electrophysiology (EP) Procedures at a Large Teaching Hospital

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October 18, 2007
NCHPS
Agenda

- Introduction
Introduction

- **Rationale**
  - Fluoroscopy procedures
  - Interventional procedures
  - FDA September 1994 Advisory
  - 1995 Advisory
  - December 2005 JCAHO action
Introduction

- Study Purpose
  - Evaluate radiation dose to adult patients undergoing EP procedures
Agenda

- Specific Goals
- Background
- Review of EP Fluoroscopy Log
- Dose Monitoring
- Results
- Conclusions and Future Direction
Introduction

- Specific goals
  - Retrospective evaluation of fluoroscopy time
  - Identify lengthy/high-dose procedures
  - Measure peak skin dose using film
  - Evaluate the relationship between dose, time, weight, BMI
    - Which variables are best predictors of dose?
Background

- Biological effects of radiation exposure
  - Sufficiently high doses
    - Cannot repair
    - Cellular death
    - Tissue breakdown
Background

- Biological effects of radiation exposure (Wagner 1996)

<table>
<thead>
<tr>
<th>Effect</th>
<th>Single-dose Threshold (rad)</th>
<th>Onset</th>
<th>Peak</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early Transient Erythema</td>
<td>200</td>
<td>Hours</td>
<td>~24 hours</td>
</tr>
<tr>
<td>Main Erythema</td>
<td>600</td>
<td>~10 days</td>
<td>~2 weeks</td>
</tr>
<tr>
<td>Temporary Epilation</td>
<td>300</td>
<td>~3 weeks</td>
<td>NA</td>
</tr>
<tr>
<td>Permanent Epilation</td>
<td>700</td>
<td>~3 weeks</td>
<td>NA</td>
</tr>
<tr>
<td>Dry Desquamation</td>
<td>1000</td>
<td>~4 weeks</td>
<td>~5 weeks</td>
</tr>
<tr>
<td>Moist Desquamation</td>
<td>1500</td>
<td>~4 weeks</td>
<td>~5 weeks</td>
</tr>
<tr>
<td>Secondary Ulceration</td>
<td>2000</td>
<td>&gt;6 weeks</td>
<td>--</td>
</tr>
<tr>
<td>Late Erythema</td>
<td>1500</td>
<td>~6-10 weeks</td>
<td>--</td>
</tr>
<tr>
<td>Dermal Necrosis (1st phase)</td>
<td>1800</td>
<td>&gt;10 weeks</td>
<td>--</td>
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<tr>
<td>Dermal Atrophy (1st phase)</td>
<td>1000</td>
<td>&gt;14 weeks</td>
<td>--</td>
</tr>
<tr>
<td>Dermal Atrophy (2nd phase)</td>
<td>1000</td>
<td>&gt;1 year</td>
<td>--</td>
</tr>
</tbody>
</table>
Background

- Physics of fluoroscopic imaging
- Image-intensifier technology
Background

- Physics of fluoroscopic imaging
  - Typical ESE rates = 0.5 – 20 R/minute (Giles 2002)

- Automatic Brightness System (ABS)
- Equipment configuration
- Continuous vs. pulsed
- Magnification
- Patient size/pathology
Background

- How the heart works
Diagnose and treat arrhythmia

Overview of EP procedures

- Electrophysiology study (ESP)
- Catheter ablation (ABL)
- Implantable cardioverter defibrillator (ICD)
- Pacemaker (PM)
- Biventricular devices (BIV)
- Change out (CO)
Review of EP Fluoroscopy Log

- Procedure date
- Procedure type
- Physician
- Total fluoroscopy time

- 247 properly documented adult EP procedures
  - March 27, 2003 – March 30, 2005
Review of EP Fluoroscopy Log

- Ablation 62±48 min  BIV Implant 51±28 min
## Review of EP Fluoroscopy Log

<table>
<thead>
<tr>
<th>Type of Procedure</th>
<th>Total Procedures</th>
<th># Procedures &gt;60 min. (%)</th>
<th># Procedures &gt;90 min. (%)</th>
<th># Procedures &gt;120 min. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABL</td>
<td>33</td>
<td>12 (36)</td>
<td>8 (24)</td>
<td>5 (15)</td>
</tr>
<tr>
<td>BIV</td>
<td>28</td>
<td>7 (25)</td>
<td>2 (7)</td>
<td>2 (7)</td>
</tr>
<tr>
<td>EPS</td>
<td>13</td>
<td>1 (2)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>PM</td>
<td>71</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>CO</td>
<td>46</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>
Dose Monitoring for ABL and BIV

- Radiochromic dosimetry film
  - Gafchromic XR Type R
  - Manufactured by ISP
  - Designed for fluoroscopy-guided procedures
Dose Monitoring for ABL and BIV

- Characteristics:
  - Diacetylene - Solid state polymerization
  - Self-developing (simple color change)
  - Measures low-energy photons (<200 keV)
  - Energy independent in the diagnostic range
  - Dose rate and dose fractionation independent
  - Dynamic range of 10 – 1500 rad
  - Large format (14”x17”)
  - Unaffected by light and water
  - Relatively inexpensive ($20/sheet)
Dose Monitoring for ABL and BIV

- Determining dose
  - Ordinary flatbed scanner (Epson Model 1680)
    - Coefficient of variation reported ~1.8% (Thomas 2005)
  - Photoshop software with RGB capability
  - Analyze mean red channel pixel values ($C$)
  - Film response = $C_{ni}/C_i$
  - Response of film increases over time (Dini et al 2003)
    - ~16% in 24 hours, ~4% in next 24 hours, ~2% over next 300 hours (12.5 days)
Dose Monitoring for ABL and BIV

- Determining dose
  - Create a calibration tablet
  - Scanning protocols
Dose Monitoring for ABL and BIV

- **Scanner performance**
  - Developed daily test pattern
    - Evaluate scanner operation
    - Coefficient of variation 2.1%
  - Dye sublimation process
    - Lab-quality printing
    - Very stable
    - Less vulnerable to fading
Dose Monitoring for ABL and BIV

- Needed to generate a calibration tablet and calibration curve
  - Necessary for each lot
  - Expose film to known dose rate for known time
  - Dose rate determined with a Rad Cal MDH Model 1515
    - Electronic dosimeter with a 6 cc ionization chamber
Dose Monitoring for ABL and BIV

- MDH and x-ray tube orientation
  - 90 kVp, 100 mA, 10 ms, 15 p/s
  - Mean exposure rate of 47.2 R/minute (Tablet 1)
Dose Monitoring for ABL and BIV

- Expose a 2”x2” piece of film
- Expose up to three films at once

Film Supporting Device
Radiochromic Film
# Dose Monitoring for ABL and BIV

## Calibration Tablet 1

<table>
<thead>
<tr>
<th>Film Number</th>
<th>Date of Exposure</th>
<th>Minutes Exposed</th>
<th>Total Dose (rad)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>N/A</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>2</td>
<td>09/02/2005</td>
<td>1.1</td>
<td>51.0</td>
</tr>
<tr>
<td>3</td>
<td>09/02/2005</td>
<td>2.2</td>
<td>102.0</td>
</tr>
<tr>
<td>4</td>
<td>09/02/2005</td>
<td>4.3</td>
<td>199.3</td>
</tr>
<tr>
<td>5</td>
<td>09/02/2005</td>
<td>6.5</td>
<td>301.3</td>
</tr>
<tr>
<td>6</td>
<td>09/02/2005</td>
<td>8.7</td>
<td>403.2</td>
</tr>
<tr>
<td>7</td>
<td>09/02/2005</td>
<td>10.7</td>
<td>495.9</td>
</tr>
<tr>
<td>8</td>
<td>09/02/2005</td>
<td>12.9</td>
<td>597.9</td>
</tr>
<tr>
<td>9</td>
<td>09/02/2005</td>
<td>15.0</td>
<td>695.3</td>
</tr>
<tr>
<td>10</td>
<td>08/25/2005</td>
<td>17.8</td>
<td>825.0</td>
</tr>
<tr>
<td>11</td>
<td>08/25/2005</td>
<td>20.0</td>
<td>927.0</td>
</tr>
<tr>
<td>12</td>
<td>08/25/2005</td>
<td>22.5</td>
<td>1042.9</td>
</tr>
</tbody>
</table>
Dose Monitoring for ABL and BIV

- Calibration tablet 1 (final scan)
Dose Monitoring for ABL and BIV

- Combined calibration curve for tablets 1 and 2

\[ y = 0.0063x + 1 \]

\[ R^2 = 0.9937 \]
Dose Monitoring for ABL and BIV

- Dose monitoring
  - September 9, 2005–June 8, 2006
  - Research described to each subject
    - Subject Information Sheet
    - Oral approval
  - Film placed underneath the subject
  - Protective plastic sleeve
  - Centered roughly to the heart area
Dose Monitoring for ABL and BIV

- Dose determination
  - Subject films scanned at same post-irradiation time as calibration tablet
  - Visually identify darkest area
  - Scan in centering template
  - Lowest pixel value used to determine dose
    - Equation of line for calibration curve
    - $y=0.0063x+1$
      - $x=$dose
      - $y=$film response ($\frac{C_{r}}{C_{i}}$)
Dose Monitoring for ABL and BIV

- Subject 27 with and without centering template
Results

- 33 subjects
  - 30 with accurate time and measurable dose
  - Determined mean, SD, maximum, minimum values for patient weight, BMI, fluoro time, peak skin dose
Results

- Descriptive statistics for all procedures

<table>
<thead>
<tr>
<th>All Procedures</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Maximum</th>
<th>Minimum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (lbs)</td>
<td>204.0</td>
<td>57.7</td>
<td>331.0</td>
<td>116.0</td>
</tr>
<tr>
<td>Body Mass Index (BMI)</td>
<td>30.0</td>
<td>7.0</td>
<td>43.7</td>
<td>19.3</td>
</tr>
<tr>
<td>Fluoroscopy time (min)</td>
<td>46.2</td>
<td>24.5</td>
<td>94.0</td>
<td>12.5</td>
</tr>
<tr>
<td>Peak skin dose (rad)</td>
<td>149.9</td>
<td>142.1</td>
<td>764.4</td>
<td>31.8</td>
</tr>
<tr>
<td>Number of Procedures</td>
<td>30</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>
## Results

### Descriptive statistics by procedure type

<table>
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<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ablation Only</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight (lbs)</td>
<td>181.4</td>
<td>40.2</td>
<td>240.0</td>
<td>116.0</td>
<td>223.8</td>
<td>64.4</td>
<td>331.0</td>
<td>146.0</td>
</tr>
<tr>
<td>Body Mass Index (BMI)</td>
<td>27.4</td>
<td>5.3</td>
<td>37.8</td>
<td>19.3</td>
<td>32.4</td>
<td>7.6</td>
<td>43.7</td>
<td>21.1</td>
</tr>
<tr>
<td>Fluoroscopy time (min)</td>
<td>57.4</td>
<td>27.8</td>
<td>94.0</td>
<td>12.5</td>
<td>36.4</td>
<td>16.5</td>
<td>71.4</td>
<td>19.3</td>
</tr>
<tr>
<td>Peak skin dose (rad)</td>
<td>133.2</td>
<td>94.0</td>
<td>366.9</td>
<td>31.8</td>
<td>164.5</td>
<td>175.8</td>
<td>764.4</td>
<td>38.6</td>
</tr>
<tr>
<td>Number of Procedures</td>
<td>14</td>
<td></td>
<td></td>
<td></td>
<td>16</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


## Results

- **Descriptive statistics of dose by BMI weight class**

<table>
<thead>
<tr>
<th></th>
<th>Normal BMI of 18.5-24.9</th>
<th>Overweight BMI of 25-29.9</th>
<th>Obese BMI of 30 and greater</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Subjects</td>
<td>9</td>
<td>9</td>
<td>12</td>
</tr>
<tr>
<td>% of Total Subjects</td>
<td>30%</td>
<td>30%</td>
<td>40%</td>
</tr>
<tr>
<td>Mean Dose (rad)</td>
<td>72.4</td>
<td>119.1</td>
<td>231.1</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>30.3</td>
<td>75.4</td>
<td>188.6</td>
</tr>
<tr>
<td>Minimum</td>
<td>31.8</td>
<td>38.6</td>
<td>71.6</td>
</tr>
<tr>
<td>Maximum</td>
<td>111.0</td>
<td>264.7</td>
<td>764.4</td>
</tr>
<tr>
<td>Subjects (%) in BMI Class &gt; 200 rad</td>
<td>0 (0)</td>
<td>2 (25)</td>
<td>5 (38)</td>
</tr>
</tbody>
</table>
Results

- Differences between the sexes
  - Males received mean skin doses double that of women
  - No female subjects exceeded 200 rad

- Overall mean entrance skin dose rate was 3.4 rad/minute
  - Consistent with IAEA and Wall-1996
Results

- Scatter plots
- Linear regression analysis
- $r^{-2}$ values determined
  - Describe the linear least squares fit
Results

$r^2 = 0.12$
Results

\[ r^2 = 0.41 \]
Results

\[ r^2 = 0.36 \]
Results

- Subject 1 as an outlier
Results

- **Discussion**
  - Developed simple, accurate and reproducible procedures
  - Positive correlation between variables compared
  - Strength of linear correlation consistent with literature
  - Mean fluoroscopy times are consistent with literature
Results

Discussion

- Fluoroscopy time is a poor predictor
- **Weight x time** and BMI x time correlated best
- Overall individual predictive strength
- Sentinel event from single procedure not likely
Conclusions and Future Direction

- Concerns with overweight and obese patients
- Concerns with additional/repeat procedures
- Routine monitoring
  - Complicated but important consideration
  - Overweight and obese at greatest risk
Acknowledgements

- Dr. Don Fox
- Drs. Ivanovic and Watson
- Drs. Sanders and Selzman and the staff of the EP Lab
- Environment, Health and Safety
The End...Thank You
### Results

<table>
<thead>
<tr>
<th></th>
<th>Dose vs. Weight</th>
<th>Dose vs. Weight x Time</th>
<th>Dose vs. BMI</th>
<th>Dose vs. BMI x Time</th>
<th>Dose vs. Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ablation Only</td>
<td>0.23</td>
<td>0.68</td>
<td>0.13</td>
<td>0.61</td>
<td>0.37</td>
</tr>
<tr>
<td>BIV Only</td>
<td>0.43</td>
<td>0.44</td>
<td>0.37</td>
<td>0.44</td>
<td>0.18</td>
</tr>
<tr>
<td>BIV (No Subject 1)</td>
<td>0.45</td>
<td>0.60</td>
<td>0.42</td>
<td>0.65</td>
<td>0.37</td>
</tr>
<tr>
<td>All Procedures</td>
<td>0.37</td>
<td>0.41</td>
<td>0.30</td>
<td>0.36</td>
<td>0.12</td>
</tr>
<tr>
<td>All Procedures (No Subject 1)</td>
<td>0.26</td>
<td>0.63</td>
<td>0.21</td>
<td>0.59</td>
<td>0.32</td>
</tr>
</tbody>
</table>
Results

\[ r^2 = 0.37 \]
Results

![Graph showing the relationship between BMI and Peak Skin Dose (Rad). The correlation coefficient is r²=0.30.](image)
Dose Monitoring for ABL and BIV

- Subject 2 (Ablation) and Subject 27 (BIV)
# Literature Review - Ablation 62±48 min

<table>
<thead>
<tr>
<th>Author</th>
<th>Study Size</th>
<th>Procedure</th>
<th>Diagnosis</th>
<th>Fluoroscopy Time (minutes)</th>
<th>Skin Dose (rad)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manolis</td>
<td>132</td>
<td>Ablation</td>
<td>Multiple Accessory Pathways</td>
<td>Mean of 89±54</td>
<td>Not Reported</td>
</tr>
<tr>
<td>Rosenthal</td>
<td>799</td>
<td>Ablation</td>
<td>Not Specified</td>
<td>Mean of 58±55</td>
<td>130 (estimate)</td>
</tr>
<tr>
<td>Macle</td>
<td>43</td>
<td>Ablation</td>
<td>Paroxysmal Atrial Fibrillation</td>
<td>Mean of 57±30</td>
<td>Not Reported</td>
</tr>
<tr>
<td>Lindsay</td>
<td>108</td>
<td>Ablation</td>
<td>Supraventricular Tachycardia</td>
<td>Mean of 50±31</td>
<td>Not Reported</td>
</tr>
<tr>
<td>Park</td>
<td>500</td>
<td>Ablation</td>
<td>Not Specified</td>
<td>Mean of 47±31</td>
<td>93+/−62 (estimate)</td>
</tr>
<tr>
<td>Manolis</td>
<td>24</td>
<td>Ablation</td>
<td>Atrial Tachycardia</td>
<td>Mean of 46±35</td>
<td>Not Reported</td>
</tr>
<tr>
<td>Manolis</td>
<td>29</td>
<td>Ablation</td>
<td>Ventricular Tachycardia</td>
<td>Mean of 45±28</td>
<td>Not Reported</td>
</tr>
<tr>
<td>Manolis</td>
<td>119</td>
<td>Ablation</td>
<td>AV Nodal Pathway</td>
<td>Mean of 27±24</td>
<td>Not Reported</td>
</tr>
<tr>
<td>Author</td>
<td>Study Size</td>
<td>Procedure</td>
<td>Diagnosis</td>
<td>Fluoroscopy Time (minutes)</td>
<td>Skin Dose (rad)</td>
</tr>
<tr>
<td>----------</td>
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<td>--------------</td>
<td>---------------</td>
<td>----------------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>Paisey</td>
<td>10</td>
<td>Biventricular</td>
<td>Not Specified</td>
<td>4.9-40.1</td>
<td>5-93</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Median of 21.5</td>
<td>Median of 23</td>
</tr>
<tr>
<td>Kostas</td>
<td>14</td>
<td>Biventricular</td>
<td>Not Specified</td>
<td>Mean of 35±22</td>
<td>Not Reported</td>
</tr>
<tr>
<td>Romeyer</td>
<td>103</td>
<td>Biventricular</td>
<td>Not Specified</td>
<td>Mean of 23±19</td>
<td>Not Reported</td>
</tr>
<tr>
<td>AAPM</td>
<td>13</td>
<td>Biventricular</td>
<td>Not Specified</td>
<td>30-200</td>
<td>80-600</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Median of 90</td>
<td>Median of 250</td>
</tr>
</tbody>
</table>
Background

- Backscatter radiation
  - Significant contribution to skin dose
  - 20-40%
    - X-ray energy
    - Field size
    - Patient thickness
  - Typical ESE 2.5-3 R/min (Mahesh/IAEA)
  - Backscatter factor
  - Observable effects after less than 1 hour
Background

- **Body Mass Index (CDC 2005)**
  - $\text{BMI} = \frac{\text{Weight in Pounds}}{(\text{Height in inches}) \times (\text{Height in inches})} \times 703$
  - 18.5-24.9 is normal
  - 25-29.9 is overweight
  - 30 and above is obese
Dose Monitoring for ABL and BIV

- Dose monitoring
  - Procedure information sheet completed

- Film and fluoroscopy time collected upon completion of the procedure
Background

- **Toshiba Model XTP-8100 G**
  - ESE depending upon patient size and mode

![Graph](image-url)
Dose Monitoring for ABL and BIV

**Calibration Tablet 2**

<table>
<thead>
<tr>
<th>Film Number</th>
<th>Date of Exposure</th>
<th>Minutes Exposed</th>
<th>Total Dose (R)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>N/A</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>2</td>
<td>02/13/2006</td>
<td>6.0</td>
<td>193.4</td>
</tr>
<tr>
<td>3</td>
<td>02/13/2006</td>
<td>12.0</td>
<td>386.8</td>
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<tr>
<td>4</td>
<td>02/13/2006</td>
<td>18.0</td>
<td>580.2</td>
</tr>
<tr>
<td>5</td>
<td>02/13/2006</td>
<td>24.0</td>
<td>773.6</td>
</tr>
<tr>
<td>6</td>
<td>02/13/2006</td>
<td>30.0</td>
<td>967.0</td>
</tr>
<tr>
<td>7</td>
<td>02/13/2006</td>
<td>38.0</td>
<td>1224.9</td>
</tr>
</tbody>
</table>
Project Approval Process

- Office of Human Research Ethics
  - Institutional Review Board
  - Phase 1
    - 5 page application
    - Retrospective review of the fluoroscopy log
Project Approval Process

- Office of Human Research Ethics
  - Institutional Review Board
  - Phase 2
    - 14 page application
    - Use of radiochromic film to evaluate skin dose
Project Approval Process

- Office of Human Research Ethics
  - Successfully complete Collaborative IRB Training Initiative
Future Directions

- Measure subject height/weight
- Measure chest thickness at landmark
- Record mode of operation (cont. vs. pulsed)