Diagnostic Reference Levels in Interventional Procedures

Wednesday 5 December, 2012
14:35 – 15:00

Eliseo Vano
Radiology Department
COMPLUTENSE UNIVERSITY MADRID
1. Introduction.
2. Diagnostic Reference Levels (DRLs) as recommended by ICRP for IR.
3. Widening the use of DRLs and individual patient dose values to help in optimization. Future?
1. Still a lack of knowledge on the concept of Diagnostic Reference Levels (DRLs) in the medical community.
2. Sometimes DRLs are used as limits and applied to individual patients.
3. The name “diagnostic RLs” may be confusing when applied to interventional procedures.
4. Potential to improve and expand the use of DRLs in interventional procedures.
ICRP and DRLs (5 years periods)

- ICRP Publication 60 [1991] proposed some recommendations on Diagnostic Reference Levels (DRLs) that were later expanded in ICRP Publication 73 [1996].
- “These levels, which are a form of investigation level, apply to an easily measured quantity, usually the absorbed dose in air, or in a tissue-equivalent material at the surface of a simple standard phantom or representative patient”
ICRP and Interventional Radiology

- ICRP published in 2001 “additional advice” on the application of DRLs in diagnostic and interventional radiology, and in 2007, included a summary of these recommendations in Publication-105.
For fluoroscopically guided interventional procedures, DRLs, in principle, could be used to promote the management of patient doses with regard to avoiding unnecessary stochastic radiation risks.

However, the observed distribution of patient doses is very wide, even for a specified protocol, because the duration and complexity of the fluoroscopic exposure for each conduct of a procedure is strongly dependent on the individual clinical circumstances.
More than one quantity (i.e., multiple diagnostic reference levels) may be needed to evaluate patient dose and stochastic risk adequately.

DRLs are not applicable to the management of deterministic radiation risks (i.e., radiation-induced skin injuries) from fluoroscopically guided interventional procedures.
Preliminary reference levels in interventional cardiology

Table 3  Preliminary reference levels proposed

<table>
<thead>
<tr>
<th></th>
<th>PTCA</th>
<th>CA</th>
</tr>
</thead>
<tbody>
<tr>
<td>DAP (Gy×cm²)</td>
<td>94</td>
<td>57</td>
</tr>
<tr>
<td>FT (min)</td>
<td>16</td>
<td>6</td>
</tr>
<tr>
<td>No. of frames</td>
<td>1355</td>
<td>1270</td>
</tr>
</tbody>
</table>
### Radiation Doses in Interventional Radiology Procedures: The RAD-IR Study

**Part I: Overall Measures of Dose**

Donald L. Miller, MD, Stephen Balter, PhD, Patricia E. Cole, PhD, MD, Hollington T. Lu, MS, MA, Beth A. Schueler, PhD, Michael Geisinger, MD, Alejandro Berenstein, MD, Robin Albert, MD, Jeffrey D. Georgia, MD, Patrick T. Noonan, MD, John F. Cardella, MD, James St. George, MD, Eric J. Russell, MD, Tim W. Malisch, MD, Robert L. Vogelzang, MD, George L. Miller III, MD, and Jon Anderson, PhD

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Cases</th>
<th>Mean fluoroscopy time (min)</th>
<th>Mean number of images</th>
<th>Mean DAP Gy.cm²</th>
<th>Mean cumulative dose Gy</th>
</tr>
</thead>
<tbody>
<tr>
<td>TIPS</td>
<td>135</td>
<td>38.7</td>
<td>231</td>
<td>335.4</td>
<td>2.00</td>
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<tr>
<td>Biliary drainage</td>
<td>123</td>
<td>23.6</td>
<td>15</td>
<td>70.6</td>
<td>0.91</td>
</tr>
<tr>
<td>Renal stent</td>
<td>103</td>
<td>21.6</td>
<td>159</td>
<td>190.0</td>
<td>1.61</td>
</tr>
<tr>
<td>Iliac stent</td>
<td>93</td>
<td>18.4</td>
<td>241</td>
<td>212.8</td>
<td>1.34</td>
</tr>
<tr>
<td>Hepatic chemoembol.</td>
<td>126</td>
<td>16.8</td>
<td>216</td>
<td>282.3</td>
<td>1.41</td>
</tr>
<tr>
<td>Pelvic fibroid embol.</td>
<td>90</td>
<td>29.5</td>
<td>305</td>
<td>298.2</td>
<td>2.46</td>
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<tr>
<td>Vertebroplasty</td>
<td>98</td>
<td>16.2</td>
<td>77</td>
<td>78.1</td>
<td>1.25</td>
</tr>
</tbody>
</table>

Seven academic medical centers; 2142 procedures

In Europe, a similar survey (SENTINEL) has been finished
A pilot study exploring the possibility of establishing guidance levels in x-ray directed interventional procedures

S. Balter
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International Atomic Energy Agency, P. O. Box 100, Wagramer Strasse 5, Vienna, Austria A-1400

**TABLE V. Suggested guidance levels (75th percentile).**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>$P_{KA}$ (KAP) (Gy cm$^2$)</th>
<th>Fluoroscopy time (min)</th>
<th>No. of images</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA</td>
<td>50</td>
<td>9</td>
<td>1000</td>
</tr>
<tr>
<td>(PCI)—moderate complexity</td>
<td>125</td>
<td>22</td>
<td>1700</td>
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</tbody>
</table>
REFERENCE LEVELS AT EUROPEAN LEVEL FOR CARDIAC INTERVENTIONAL PROCEDURES

R. Padovani¹,², E. Vano², A. Trianni¹, C. Bokou³, H. Bosmans⁴, D. Bor⁵, J. Jankowski⁶, P. Torbica⁷, K. Kepler⁸, A. Dowling⁹, C. Milu¹⁰, V. Tsapaki¹¹, D. Salat¹², J. Vassileva¹³ and K. Faulkner¹⁴

PATIENT DOSE IN INTERVENTIONAL RADIOLOGY: A EUROPEAN SURVEY

Doses to Patients from Radiographic and Fluoroscopic X-ray Imaging Procedures in the UK – 2010 Review

D Hart, M C Hillier and P C Shrimpton

Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States

Recommendations of the NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS

September 30, 2012

National Council on Radiation Protection and Measurements
7910 Woodmont Avenue, Suite 400 / Bethesda, MD 20814-3095
ICRP-103 (2007): In emergency or existing controllable exposure situations, the reference levels represent the level of dose or risk, above which it is judged to be inappropriate to plan to allow exposures to occur and for which therefore protective actions should be planned and optimised.
• Need to expand the application of the DRL concept to interventional procedures, nuclear medicine procedures, and other procedures that use more than one imaging modality.
• The discussion suggested using not only a percentile (e.g., 75th percentile) of the patient dose distributions but a more complete use of the full distribution to help in optimization.
• Based on the initial discussions at its next meeting, C3 will consider setting up a Task Group

ICRP created in 2012, a Working Party to revisit DRL for diagnostic and interventional imaging
1. The use of **phantoms versus patient dose values** needs some refinement.

Phantom based approach only deals (in general) with equipment issues, whilst patient dose metric approach also deals with **procedure and operator variation**.
Differences between x-ray systems in the entrance dose rate for the routine setting for a phantom equivalent to a medium size patient (SERVEI-SENTINEL Spanish survey)

Factor 4.6
2. DRLs should be linked to image quality or diagnostic information for different clinical tasks.

New imaging acquisition modalities (rotational, cone beam CT, etc) versus conventional cine or digital subtraction angiography (DSA) series should be considered during optimization.
Patient dose report: CT mode versus cine run

<p>| | | | | | | | | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1</td>
<td>DR</td>
<td>FIXED</td>
<td>Testbolus</td>
<td>8s</td>
<td>3F/s</td>
<td>15-Feb-10 10:44:45</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>81kV 211mA</td>
<td>3.5ms 0.0CL small</td>
<td>42cm</td>
<td>77.5μGy.m²</td>
<td>3.3mGy</td>
<td>OLAO</td>
<td>OCRA 24F</td>
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<tr>
<td>2</td>
<td>DR</td>
<td>FIXED</td>
<td>Testbolus</td>
<td>3s</td>
<td>3F/s</td>
<td>15-Feb-10 10:47:14</td>
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<tr>
<td>A</td>
<td>81kV 201mA</td>
<td>3.5ms 0.0CL small</td>
<td>42cm</td>
<td>28.2μGy.m²</td>
<td>1.2mGy</td>
<td>OLAO</td>
<td>OCRA 9F</td>
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<tr>
<td>3</td>
<td>DR</td>
<td>FIXED</td>
<td>Testbolus</td>
<td>20s</td>
<td>3F/s</td>
<td>15-Feb-10 10:47:21</td>
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<td></td>
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<tr>
<td>A</td>
<td>81kV 225mA</td>
<td>3.4ms 0.0CL small</td>
<td>42cm</td>
<td>206.8μGy.m²</td>
<td>8.7mGy</td>
<td>OLAO</td>
<td>OCRA 61F</td>
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<tr>
<td>4</td>
<td>3D</td>
<td>DYNAAUT</td>
<td>5sDRc</td>
<td>5s</td>
<td>30F/s</td>
<td>15-Feb-10 10:56:58</td>
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<tr>
<td>A</td>
<td>90kV 465mA</td>
<td>3.5ms 0.0CL large</td>
<td>48cm</td>
<td>1447.6μGy.m²</td>
<td>52.8mGy</td>
<td>99RAO</td>
<td>OCRA 133F</td>
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<td>6</td>
<td>CARD</td>
<td>FIXED</td>
<td>LV 3040</td>
<td>5s</td>
<td>30F/s</td>
<td>15-Feb-10 11:31:19</td>
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<tr>
<td>A</td>
<td>73kV 370mA</td>
<td>3.5ms 0.1CL small</td>
<td>42cm</td>
<td>405.1μGy.m²</td>
<td>26.7mGy</td>
<td>56RAO</td>
<td>24CRA 141F</td>
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<tr>
<td>7</td>
<td>CARD</td>
<td>FIXED</td>
<td>LV 3040</td>
<td>5s</td>
<td>30F/s</td>
<td>15-Feb-10 11:47:10</td>
<td></td>
<td></td>
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<tr>
<td>A</td>
<td>73kV 404mA</td>
<td>3.5ms 0.0CL small</td>
<td>42cm</td>
<td>419.9μGy.m²</td>
<td>27.6mGy</td>
<td>56RAO</td>
<td>24CRA 134F</td>
<td></td>
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</tbody>
</table>

CT mode: 133 frames; 11 μGy.m²/fr and 0.4 mGy/fr  
Cine run: 134 frames; 3.1 μGy.m²/fr and 0.2 mGy/fr  
CT mode run requires 4 times more KAP and 2 times more skin dose/fr (these factors also apply to the total run)
For a typical paediatric cardiac procedure:
CT mode represents: 12% of the total KAP
CT mode represents: 6% of the total cumulative skin dose
3. Standardization and consensus on the levels of complexity for some common procedures and the impact on DRLs.

- Some attempts in cardiology.
- Very few in interventional radiology.
- Medical societies should be involved
Clinical and Technical Determinants of the Complexity of Percutaneous Transluminal Coronary Angioplasty Procedures: Analysis in Relation to Radiation Exposure Parameters

Guglielmo Bernardi,1 MD, Renato Padovani,2 PhD, Giorgio Morocutti,1 MD, Eliseo Vaño,3 PhD, Maria Rosa Malisan,2 PhD, Massimo Rinuncini,1 MD, Leonardo Spedicato,1 MD, and Paolo M. Fioretti,1 MD

Approx.

Medium = 1.5 x simple

Complex = 2.0 x simple
A pilot study exploring the possibility of establishing guidance levels in x-ray directed interventional procedures

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Approx. Medium = 1.5 x simple

Complex = 2.0 x simple
4. Possibility of deriving trigger (alarm) levels from DRLs (values 2 or 3 times higher than DRLs?) to investigate individual cases of high dose values.

4. Exploitation of the full individual patient dose distributions in addition to DRLs, to help with optimization.
CIRSE 2007. Establishment of procedure specific dose trigger levels in interventional radiology to be used for clinical follow up.
All cardiac procedures

3rd quartile

More than twice 3rd quartile: 4.6%

twice 3rd quartile

<table>
<thead>
<tr>
<th>Sample</th>
<th>Median</th>
<th>Mean</th>
<th>SD</th>
<th>Min</th>
<th>Max</th>
<th>3rd quartile</th>
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<tr>
<td>6558</td>
<td>70</td>
<td>86</td>
<td>68</td>
<td>1</td>
<td>924</td>
<td>106</td>
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</table>
Coronary Angiography (all complexities)

More than twice 3rd quartile: 0.5%

<table>
<thead>
<tr>
<th>Sample</th>
<th>Median</th>
<th>Mean</th>
<th>SD</th>
<th>Min</th>
<th>Max</th>
<th>3rd quartile</th>
</tr>
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<tr>
<td>2407</td>
<td>46</td>
<td>48</td>
<td>26</td>
<td>1</td>
<td>536</td>
<td>56</td>
</tr>
</tbody>
</table>
PTCA (all complexities)

More than twice 3rd quartile: 2.9%

Sample 3237  Median  98  Mean  118  SD  63  Min  26  Max  764  3rd quartile  139
All cardiac procedures

More than twice 3rd quartile (3324 mGy): 4.5%
More than 5000 mGy: 1.3%

Cumulative Air Kerma (mGy)

Sample  Median  Mean  SD  Min  Max  3rd quartile
6557      1079   1325  1039  1    12683  1662
<table>
<thead>
<tr>
<th>Sample</th>
<th>Gy cm²</th>
<th>Gy cm²</th>
<th>Gy cm²</th>
<th>Gy cm²</th>
<th>% of median</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac diagnostic</td>
<td>2377</td>
<td>46</td>
<td>56</td>
<td>10</td>
<td>22</td>
</tr>
<tr>
<td>Cardiac therapeutic</td>
<td>3409</td>
<td>97</td>
<td>138</td>
<td>41</td>
<td>42</td>
</tr>
<tr>
<td>Electrophysiology (cardiac)</td>
<td>563</td>
<td>24</td>
<td>48</td>
<td>24</td>
<td>101</td>
</tr>
<tr>
<td>Vascular total</td>
<td>1270</td>
<td>47</td>
<td>111</td>
<td>64</td>
<td>136</td>
</tr>
<tr>
<td>Cerebral total</td>
<td>695</td>
<td>87</td>
<td>190</td>
<td>102</td>
<td>118</td>
</tr>
</tbody>
</table>

Sample of 8,314 procedures (San Carlos University Hospital Madrid)

For UK, Ref. HPA-CRCE-034 (2010) 31,324 patients for CA and 5,805 for PTCA

Interquartile (% median)
6. Deriving DRLs from different sample sizes (number of procedures per centre) and from centres with very different workloads.

7. Balancing the relevance of two or more dose related quantities used to set DRLs (e.g. KAP, cumulative Air Kerma, number of images, fluoroscopy time, etc).

8. Recommended periodicity to update DRLs, and factors to be considered to establish such periodicity.
Diagnostic Reference Levels are already being used for fluoroscopy guided interventional procedures and they have proved to be a very useful tool to help with optimization (in the setting of X-ray systems, in the protocols used and in the operational procedures).

More advice from ICRP is still needed to clarify some aspects of optimization strategies that would take into account for stochastic effects but also help to avoid (when possible) tissue reactions (deterministic effects).
When the full patient individual doses distribution is available, **other optimization options could be considered and implemented** (such as decreasing high dose tails in the distributions and discriminating individual high dose values for clinical follow-up).