IAEA activities on RP in interventional procedures

Ola Holmberg, Ph.D.
Head, Radiation Protection of Patients Unit
International Atomic Energy Agency, Vienna, Austria
Image guided interventional procedures

Number of procedures is growing fast

• According to the UNSCEAR 2008 Report, approximately 3.6 million interventional radiology procedures were undertaken annually worldwide.

• According to the UNSCEAR 2020/2021 Report, the estimated total annual number of interventional radiology procedures is about 24 million.

• This is more than a sixfold increase!
**Table 1: National Cancer Institute (NCI)**

<table>
<thead>
<tr>
<th>Band</th>
<th>Skin-Dose Range (Gy)</th>
<th>Grade</th>
<th>NCI Skin Reaction</th>
<th>Prompt</th>
<th>Early</th>
<th>Midterm</th>
<th>Long Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1</td>
<td>0–2</td>
<td>NA</td>
<td>No observable effects</td>
<td>No observable effects</td>
<td>No observable effects</td>
<td>No observable effects</td>
<td>No observable effects</td>
</tr>
<tr>
<td>A2</td>
<td>2–5</td>
<td>1</td>
<td>Transient erythema</td>
<td>Epilation</td>
<td>Recovery from hair loss</td>
<td>No observable effects</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>5–10</td>
<td>1–2</td>
<td>Transient erythema</td>
<td>Erythema, epilation</td>
<td>Recovery at higher doses; prolonged erythema; permanent partial epilation</td>
<td>Recovery at higher doses; dermal atrophy or induration</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>10–15</td>
<td>2–3</td>
<td>Transient erythema</td>
<td>Erythema, epilation; possible dry or moist desquamation; recovery from desquamation</td>
<td>Prolonged erythema; permanent epilation</td>
<td>Telangiectasia; dermal atrophy or induration; skin likely to be weak</td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>&gt;15</td>
<td>3–4</td>
<td>Transient erythema; after very high doses, edema and acute ulceration; long-term surgical intervention likely to be required</td>
<td>Erythema, epilation; moist desquamation</td>
<td>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</td>
<td>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</td>
<td></td>
</tr>
</tbody>
</table>

Most advice currently available on skin reactions is based on data from animal studies, and subsequent to recommendations are presented in tabular form. The variability of injury to skin and tissues is based on data from animal studies and animals are prone to develop a chronic scarring caused by the National Cancer Institute (NCI) in interventional fluoroscopy. For a single patient, noticeable scarring may be noted up to 2 months after a single treatment. The degree of the reaction increases with radiation dose.
Figure A1: NCI skin toxicity grade 1. TAx

Figure 5: NCI skin toxicity grade 2 (see Appendix).

Figure A5: NCI skin toxicity grade 3. Increased severity

Figure A8: NCI skin toxicity grade 4. (a) Central area of deep necrosis surrounded by indurated and
How often do injuries happen?

The frequency of major radiation injuries is estimated to be between 1:10,000 and 1:100,000 procedures.
Facilities at which image guided interventional procedures are performed should have systems in place for identifying patients who may be at risk of late radiation injuries, typically based on estimates of peak skin dose, cumulative reference air kerma or air kerma–area product, which take account of the fact that patients have different sensitivities to radiation.

For these patients, information should be added to their medical records so that appropriate observation and follow-up is ensured.
SAFRAD (SAFety in RADiological procedures)

- International web-based voluntary and anonymized reporting system for FGI procedures
- Developed 2009-2011; Piloted 2011-2012
- Improvements 2012
- Additional modifications 2015-2017
- Promotion through IAEA meetings and TC events, and during relevant meeting and congresses
SAFRAD (SAFety in RADiological procedures)

• The primary objective of SAFRAD event reporting system is educational in nature
  – Identify patients at risk for deterministic effects
  – Encourage follow-up examinations for adverse side effects
  – Educate physicians/other medical personnel
  – Encourage physicians to educate patients at risk
  – Minimize adverse side effects based on awareness
  – Lessons can be learned and shared

• Confidentiality is maintained by the IAEA
SAFRAD (SAFety in RADiological procedures)

SAFRAD (SAFety in RADiological procedures) is a voluntary reporting system aiming to sustain a database of comprehensive data such as patient’s dose report and other relevant data when these patients are submitted to defined trigger levels or events in fluoroscopically-guided diagnostic and interventional procedures. The primary objective of the system is educational. It is believed that going through the process of SAFRAD itself results in safety and quality of service.

All data furnished by participants (hospitals, regulators) will remain accessible to the participant. The participant will have access periodically to analysed results. The IAEA will publish overall summary reports of SAFRAD data from time to time. SAFRAD will not supply identifiable data to any governmental authority or other third party.

How to use SAFRAD

Overview
SAFRAD website provides you with on-line forms to be filled in order to

Guidelines and forms
Download:
- Guidelines for the interventionalist
- Guidelines for the treating physician
- Instructions for the coordinator
- Patient information leaflet
- Patient data collection form

https://www.iaea.org/resources/rpop/resources/databases-and-learning-systems/safrad
SAFRAD triggers for reporting (initial set)

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Fluoroscopy time</td>
<td>&gt; 60 minutes</td>
</tr>
</tbody>
</table>
| 2 | KAP (DAP) values                                                            | > 300 Gy.cm\(^2\) (cardiac and neuro)  
                                | > 500 Gy.cm\(^2\) (other procedures) |
| 3 | \(K_{a,r}\) (total air kerma at the interventional reference point)         | > 5000 mGy (5 Gy)     |
| 4 | Measured skin dose                                                          | > 3 Gy                |
| 5 | Number of series or cine runs                                               | > 20                  |
| 6 | Multiple procedures within 12 months                                        |                       |

[https://rpop.iaea.org/safrad/](https://rpop.iaea.org/safrad/)
SAFRAD status (March 2023)

319 events reported to date from 25 hospitals

- 19 recognized tissue reactions
- 2 severe erythema; 2 ulceration; 9 skin erythema (transient); 6 epilation
- 11 PCI; 3 CTO, 3 neuroembolizations head; 1 Arteriovenous malformations (embolization); 1 ICD implantation
- In 6 patients 4 triggers exceeded, in 3 patients 3 triggers exceeded
  - **CD**: known in 11: in 10 with >5 Gy; in 1 < trigger
  - **KAP**: known in 15: in 12 with > 300 Gy.cm² and 10 with >500 Gy.cm²; in 3 < trigger
  - **FT**: known in all; 10 with > 60 min, 10 < trigger
Future of SAFRAD

• Many more reports needed to define more realistic trigger dose indicators for different types of interventional procedures
• SAFRAD database needs upgrade to simplify reporting and provide analyses of reported events
• Update of trigger level values needed based on evidence

• The Meeting of consultants in May 2021 advised the IAEA to design an international study
International study of patient doses and tissue reactions from FGI procedures

Objectives:

• Improve the information about the frequency of occurrence of tissue reactions in patients from different type of FGI procedures (cardiac, neuro, and body) performed in different parts of the world.

• Study the relationship between the tissue reactions and the radiation exposure metrics, procedure factors and patient related factors.

• Use the results of the study to update trigger level values for patient follow up for skin reactions.

• Update recommendations for improving radiation protection of patients.

• Provide feedback for the needed development of SAFRAD.

Expert panel:
D. Miller, S. Balter, K. Jones, R. Sánchez, M. Mahesh, A. Rogers; IAEA staff
Study coordinator: J. Vassileva
Current status (May 2023)

- Midterm report (6 months)
- Total 55,849 procedures, out of them:
  - 33,691 cardiac
  - 8,828 non-cardiac vascular
  - 6,658 non-vascular
  - 3,716 neurovascular
  - 632 FG-tumor therapy
- 7 facilities reported 12 cases of tissue reactions (3% of all patients followed)
- Results under analysis

<table>
<thead>
<tr>
<th></th>
<th>Total number of procedures</th>
<th>Patients followed-up for tissue reactions</th>
<th>Tissue reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac</td>
<td>34,691</td>
<td>234 (0.7%)</td>
<td>1</td>
</tr>
<tr>
<td>Non-cardiac vascular</td>
<td>8,828</td>
<td>62 (0.7%)</td>
<td>0</td>
</tr>
<tr>
<td>Non-vascular</td>
<td>6,658</td>
<td>9 (0.1%)</td>
<td>0</td>
</tr>
<tr>
<td>Neurovascular</td>
<td>3,716</td>
<td>83 (2.2%)</td>
<td>10</td>
</tr>
<tr>
<td>FG-tumor therapy</td>
<td>632</td>
<td>18 (2.8%)</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>54,525</strong></td>
<td><strong>406 (0.7%)</strong></td>
<td><strong>12</strong></td>
</tr>
</tbody>
</table>
Public website http://rpop.iaea.org

Annually: 1 million pageviews

- Contains useful information and FAQs for health professionals, patients and public
- Links to resources: training material, posters, webinars, videos, etc.
Public website http://rpop.iaea.org

2 entries – 2 different audiences
Public website http://rpop.iaea.org

Patients and public

Patients can read about what to expect during their upcoming medical examinations using ionizing radiation. Information from the RPOP website helps not only to patients but also to their carers, and anyone interested in this subject.

- X-rays
- Computed Tomography (CT)
- Interventional procedures
- Nuclear medicine
- Radiotherapy
- Brachytherapy
- RPOP Home
- About radiation
- X-rays
- Computed Tomography (CT)
- Interventional procedures
- Nuclear medicine
- Radiotherapy
- Brachytherapy
- Pregnant women
- Children

Frequently asked questions by the health professionals

- Which procedures are associated with higher radiation doses?
- What are the possible effects of radiation exposure from Interventional procedures?
- Should I be concerned about radiation if my child has been prescribed an Interventional procedure?

Interventional procedures - what patients need to know

Interventional procedures - angiography, cardiac catheterisation and Computed tomography (CT) can be associated with higher doses of radiation with doses that are about 100 to 1000 times higher than that delivered during a chest X-ray.

Related resources

% Children and radiation - what patients need to know
Public website http://rpop.iaea.org

Interventional procedures

https://www.iaea.org/resources/rpop/health-professionals/interventional-procedures
Posters on radiation protection topics

Available in 31 languages

https://www.iaea.org/resources/rpop/resources/posters-and-leaflets
Posters on radiation protection topics

Available in 30 languages

https://www.iaea.org/resources/rpop/resources/posters-and-leaflets
Posters on radiation protection topics

Available in 26 languages

10 Pearls: Radiation protection for children in interventional procedures

1. Remember: Some tissues of a growing child are more sensitive to radiation than adult
Children have longer life span to manifest radiation effects

2. Discuss with parents before the procedure
- Ask about previous exposures
- Answer their concerns about radiation safety

3. Increase awareness among your team members through the use of a pre-procedure safety checklist

4. Plan the procedures in detail and in advance to avoid improper or aborted runs or other repeated exposures

5. Protect the patient's thyroid, breast, eyes and gonads where possible

6. Use optimal technique:
- Lower frame rates. Decrease from 7.6 to 3 pulses per second when possible
- Remove grids from machine if possible for infants under 20 kg
  Use air-gap technique instead
- Minimize imaging time
- Minimize field overlap in repeated acquisitions
- Use tighter collimation
- Minimize magnification usage

7. Use “last image hold” rather than additional exposures, where appropriate

8. Increase distance between patient and the X-ray tube and decrease distance between patient and image receptor

9. Use dose recording and dose reduction technologies in equipment

10. Review and record radiation dose after the procedure

https://www.iaea.org/resources/rpop/resources/posters-and-leaflets
Posters on radiation protection topics

Available in 30 languages

https://www.iaea.org/resources/rpop/resources/posters-and-leaflets
IAEA free training resources

https://www.iaea.org/resources/rpop/resources/training-material

Diagnostic and interventional radiology

Cardiology

Lectures:
01. Why talk about radiation protection in cardiology?
02. Talking about radiation dose
03. What radiation effects are possible? (besides skin injuries)
04. X-ray production and angiography equipment
05. Patient dose management: Part 1-2
06. Standards and guidance
07. Occupational exposure and protective devices
08. Image quality in cardiac angiography
09. Optimization of radiation protection in cardiology
10. Radiation protection in paediatric interventional cardiology
11. Cardiac CT - radiation doses, dose management and practical issues

Doctors using fluoroscopy outside radiology

Lectures:
01. Overview of radiation protection
02. Understanding radiation units
03. What can radiation do?
04. Anatomy of fluoroscopy & CT Fluoroscopy Equipment
05. How do I reduce my radiation risk?
06A. Radiation protection for patients in orthopaedic surgery
06B. Radiation Exposure in Gastroenterology
06C. Other medical specialties that use fluoroscopy
07. International standards and recommendations

Paediatric radiology

Lectures (in Spanish) →

Lectures (in Russian) →
Providing training

Training courses and workshops under TC regional and national projects

- Regional training courses
- National training courses
- Main target audience: health professionals in hospitals
RPOP webinars

- Online lectures on topics in radiation protection of patients and staff
- In English, Spanish, Portuguese, Russian
- Held in cooperation with Image Gently, ESR (EuroSafe Imaging), LatinSafe, EFRS, IOMP, CIRSE
- Free registration and attendance
- Recording available for viewing

https://www.iaea.org/resources/rpop/resources/webinars
RPOP webinars (2016-2019)
https://www.iaea.org/resources/rpop/resources/webinars
RPOP webinars (2020-)
https://www.iaea.org/resources/rpop/resources/webinars
E-learning with certification

Radiation Protection in interventional radiology (2019)

- Based on the 6 webinars
- Final quiz
- Certificate of completion if >80% correct answers
- Available from the e-learning platform of the IAEA

https://www.iaea.org/resources/rpop/resources/online-training
E-learning with certification

Radiation Protection in Interventional Procedures
Practical Tutorials

- 13 short practical tutorials, 4-8 minutes each with interactive videos
- To learn effect of various factors on patient and staff dose
- Available also for viewing without registration and for free download and use by trainers

https://www.iaea.org/resources/rpop/resources/online-training