

AAPM 2018 Annual Meeting

Adverse radiation effects in interventional cardiology

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Point 1

Radiation-induced tissue reactions are an uncommon side effect of FGI.

2

Point 2

They are usually self-limiting but can be catastrophic

3

Point 3

Based on court records, it is estimated that several catastrophic injuries occur in the United States each year

4

Point 4

Properly functioning fluoroscopes can deliver more radiation to a patient's skin during a complex interventional procedure than most radiation therapy systems deliver in a single treatment.

(a) A 42-year-old man.11 months after angioplasty. Painful ulcer, causing insomnia (right subscapular area). (b) Surgical debridement with the index of bleeding from the edge was performed. (c) 20 days after initial debridement, granulation was poor, and extension of tissue necrosis was observed. Insomnia with pain continued. (d) Further surgical debridement was done, and the adjacent skin flap was raised. (e) Into the wound floor and edges, bm-PRP was injected. (f) Eight months after the reconstructive surgery, there was no pain complaint.

The clinical benefits of IP are generally much higher than the radiation risk for patients

Radiation risk should be explicitly included in overall pre-procedure justification for:

- **Extremely large patients**
- **certain complex pathologies**
- **or repeated procedures in the same patient**

Which are the tissues at risk?

- Skin
 - Hair
 - Subcutaneous fat
 - Muscle
 - Eye lens
- Published / reported patient adverse effects in interventional cardiology focus on skin or underlying tissue
 - No publication on patient eyes

Higher risk patients:

- There are biologic factors, that increase sensitivity and hence potential for skin reactions:
 - *diabetes mellitus*
 - *systemic lupus erythematosus*
 - *Scleroderma*
 - *mixed connective tissue disease and homozygosity for ataxia telangiectasia.*
 - *Drug interactions*

Genetic disorders increasing radiosensitivity

- Bloom syndrome
- Gorlin syndrome
- Familial polyposis
- Gardner syndrome
- Hereditary melanoma
- Dysplastic nevus syndrome
- Xeroderma pigmentosum variant

- Ataxia teleangiectatica
- ATM-like disorder
- Nijmegen breakage syndrome
- Severe combined immune deficiency (SCID)
- Ligase IV syndrome
- Seckel syndrome
- Fanconi anemia

Drugs increasing radiosensitivity

- Actinomycin D
- Doxorubicin
- Bleomycin
- 5-FU
- Methotrexat
- NNRTI-based antiretroviral therapy in HIV patients
- Platinum containing chemotherapeutic drugs
- Antiangiogenic drugs
- BRAF inhibitors and others

Other patient related factors that increase radiation effects



- **Smoking**
- **Poor nutrition status**
- **Compromised skin integrity**

Several factors can lead to tissue reactions

- **complex clinical problem**
- **the type of procedure**
- **operator experience**
- **X-ray equipment that is not optimal for the procedure**
- **long fluoroscopy times**
- **large number of images**
- **operating with non-optimized technical parameters (beam rotation, position of X-ray tube and image detector, magnification, fluoroscopy mode, use of filter, etc)**

**Are doses so high?
Are we exaggerating the issue?**

- Recent literature reports skin doses of up to 59 Gy in interventional procedures

Biggest problem is that:

- patients generally do not seek consultation for their skin lesions from the cardiologist who performed the fluoroscopy-guided procedure
- Also, these physicians do not routinely screen their patients prospectively for long-term dermatologic adverse effects.

Table 1**Tissue Reactions from Single-Delivery Radiation Dose to Skin of the Neck, Torso, Pelvis, Buttocks, or Arms**

| Band | Single-Site Acute Skin-Dose Range (Gy)* | NCI Skin Reaction Grade [†] | Approximate Time of Onset of Effects | | | |
|------|---|--------------------------------------|--|---|---|--|
| | | | Prompt | Early | Midterm | Long Term |
| A1 | 0–2 | NA | No observable effects expected | No observable effects expected | No observable effects expected | No observable effects expected |
| A2 | 2–5 | 1 | Transient erythema | Epilation | Recovery from hair loss | No observable results expected |
| B | 5–10 | 1–2 | Transient erythema | Erythema, epilation | Recovery; at higher doses, prolonged erythema, permanent partial epilation | Recovery; at higher doses, dermal atrophy or induration |
| C | 10–15 | 2–3 | Transient erythema | Erythema, epilation; possible dry or moist desquamation; recovery from desquamation | Prolonged erythema; permanent epilation | Telangiectasia [‡] ; dermal atrophy or induration; skin likely to be weak |
| D | >15 | 3–4 | Transient erythema; after very high doses, edema and acute ulceration; long-term surgical intervention likely to be required | Erythema, epilation; moist desquamation | 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 | 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 |

Note. — Applicable to normal range of patient radiosensitivities in absence of mitigating or aggravating physical or clinical factors. Data do not apply to the skin of the scalp. Dose and time bands are not rigid boundaries. Signs and symptoms are expected to appear earlier as skin dose increases. Prompt is <2 weeks; early, 2–8 weeks; midterm, 6–52 weeks; long term, >40 weeks.

* Skin dose refers to actual skin dose (including backscatter). This quantity is not the reference point air kerma described by Food and Drug Administration (21 CFR § 1020.32 [2008]) or International Electrotechnical Commission (57). Skin dosimetry is unlikely to be more accurate than $\pm 50\%$. NA = not applicable.

[†] NCI = National Cancer Institute

[‡] Refers to radiation-induced telangiectasia. Telangiectasia associated with area of initial moist desquamation or healing of ulceration may be present earlier.



Frequency of major radiation injuries

1

Miller DL et al.
Clinical radiation
management for
fluoroscopically
guided
interventional
procedures.
Radiology 2010;
257(2): 321-332.

2

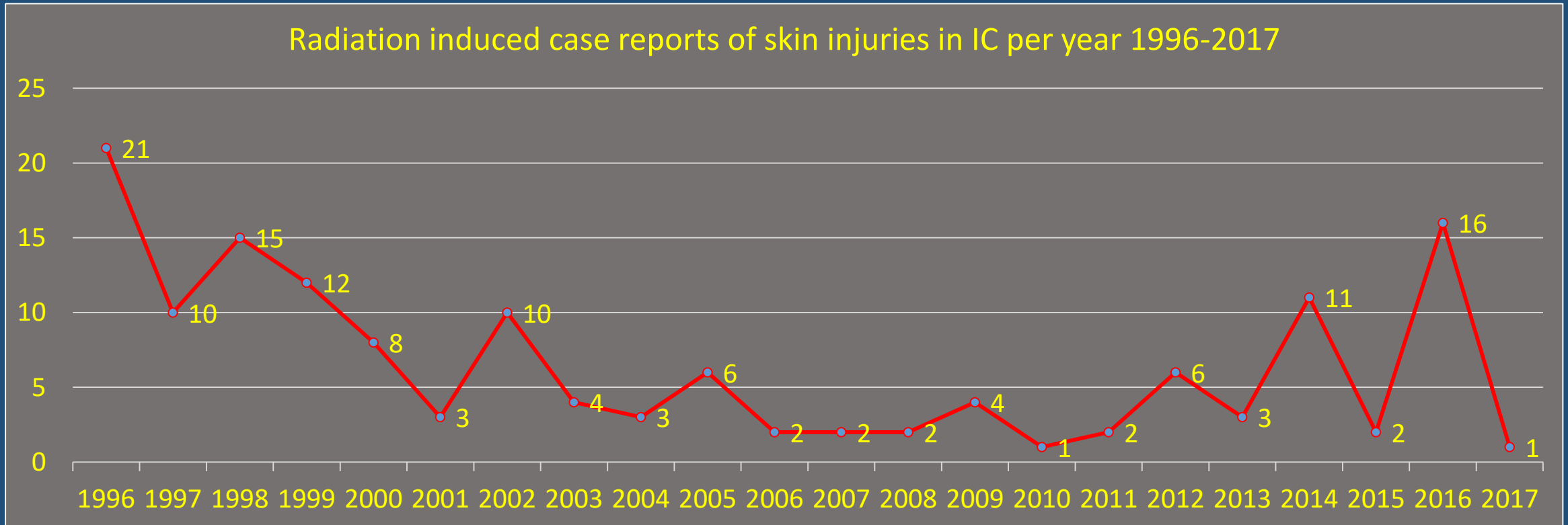
Based on 10
injuries reported
every year in the
USA from nearly
10 million
interventions:

3

1:10,000 to
1:100,000
procedures

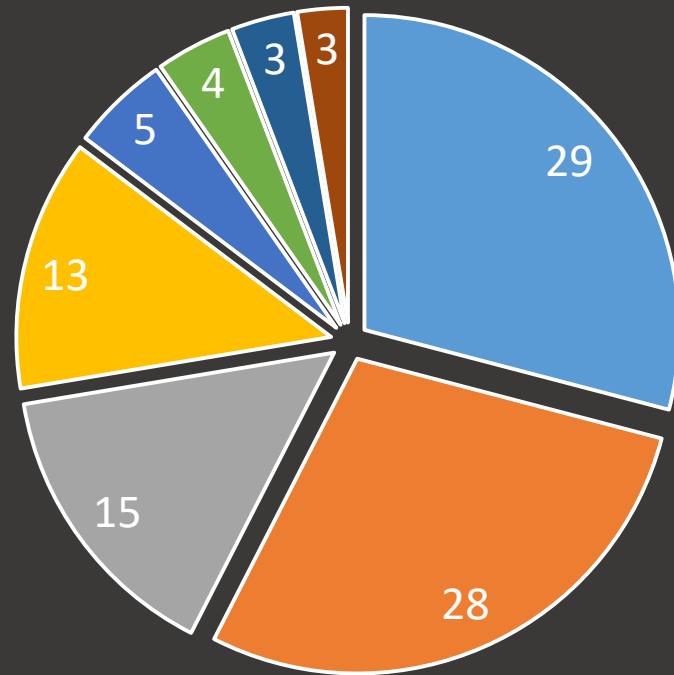
true risk is not known, mainly because these injuries are not reported around the world

Literature review 1996-2017



- Published literature has 155 patient skin injuries between 1996-2017

% of Country distribution of published 155 skin injuries

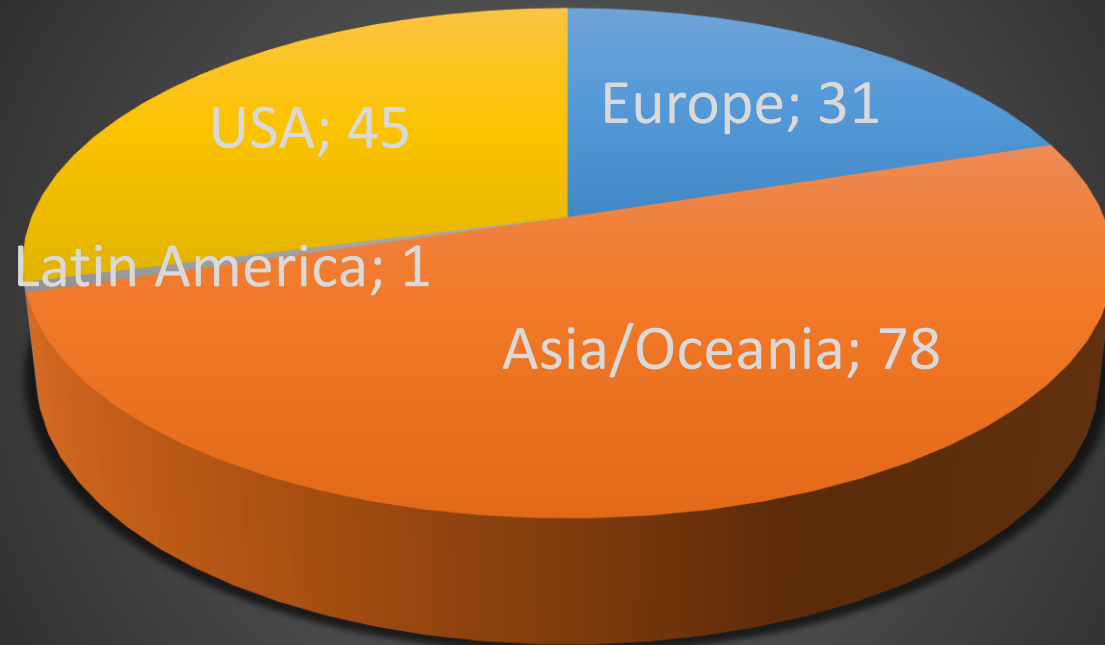


■ USA ■ Japan ■ Taiwan ■ France
■ Rest ■ Istrael ■ Spain ■ Thailand

Rest of countries include:

- Australia
- Austria
- Mexico
- Norway
- Portugal
- Switzerland
- Belgium

Geographical distribution



- Asia/Oceania mostly in:
 - ✓ Japan: 44
 - ✓ Taiwan: 23
- Europe:
 - ✓ France: 20
- USA: 45
- Africa/Middle East: 0

International advice



International bodies have issued special advice in the area of interventional radiology

- NCRP
- ICRP
- NCI
- FDA
- Various radiology societies
- Medical physics societies
- Campaigns



A**ICRP reports**

Report 85
 Report 113
 Report 117
 Report 118
 Report 120
 Report 121, 2013
 Report 139, 2018

Recommendations**B****NCRP 168, 2010**

TABLE 4.7—Suggested values for first and subsequent notifications and the SRDL.

| Dose Metric | First Notification | Subsequent Notifications (increments) | SRDL |
|-----------------------|-------------------------|---------------------------------------|-------------------------|
| $D_{\text{skin,max}}$ | 2 Gy | 0.5 Gy | 3 Gy |
| $K_{a,r}$ | 3 Gy | 1 Gy | 5 Gy ^a |
| P_{KA} | 300 Gy cm ^{2b} | 100 Gy cm ^{2b} | 500 Gy cm ^{2b} |
| Fluoroscopy time | 30 min | 15 min | 60 min |

SRDL values

SRDL: It is a selected threshold value that is used to trigger additional dose management actions.

Radiation Protection of Patients (RPOP)

Bonn Call for Action platform

Resources

[RPOP Home](#)[International Safety Standards](#)[Publications](#)[Posters and leaflets](#)[Bonn Call for Action platform](#)[Activities related to Bonn Call for Action](#)[Smart Card](#)

The Bonn Call for Action seeks to foster coordinated work to address issues arising in radiation protection in medicine. It was issued at an IAEA-organized 2012 international conference held in Bonn, Germany, and strengthened at the follow-up conference in Vienna, Austria in 2017. The 2012 conference aimed to:

- indicate gaps in current approaches to radiation protection in medicine;
- identify tools for improving radiation protection in medicine;
- review advances, challenges and opportunities in the field of radiation protection in medicine;

Related Stories



IAEA Conference Identifies Challenges in Radiation Protection in Medicine



Director General's Remarks at Conclusion of International Conference on Radiation Protection in Medicine

Related resources

Balter S IAEA Conference December 2017

| Bonn Action Item | Recommendation for effective risk management of skin injuries in IP |
|-----------------------------------|--|
| Clinical Audit | Strengthen the application of clinical audit in relation to justification, ensuring that justification becomes an effective, transparent and accountable part of normal radiological practice. |
| Quality Assurance | Strengthen the establishment of quality assurance programs for medical exposures, as part of the application of comprehensive quality management systems. |
| Exposure Record Technology | Develop and apply technological solutions for patient exposure records, harmonize the dose data formats provided by imaging equipment, and increase utilization of electronic health records. |
| Technical Solutions | Support development of technical solutions for reduction of radiation exposure of patients, while maintaining clinical outcome, as well as of health of workers. |
| Prioritize Education | Prioritize radiation protection education and training for health professionals globally, targeting professionals using radiation in all medical and dental areas. |
| Prospective Risk Analysis | Implement prospective risk analysis methods to enhance safety in clinical practice |

<https://www.sciencedirect.com/science/article/pii/S1120179718311165>



ELSEVIER

Physica Medica

Volume 52, August 2018, Pages 56-64



Review paper

The International Atomic Energy Agency action plan on radiation protection of patients and staff in interventional procedures: Achieving change in practice

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<https://doi.org/10.1016/j.ejmp.2018.06.634>

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- Manufacturers play an important role in making patients safer.
- Low dose technologies are still expensive and manufacturers should make these affordable in less resourced countries.
- Automatic patient dose reporting and real-time skin dose map are important for dose optimization.
- Clinical audit and better QA processes together with more studies on the impact of lens opacities in clinical practice and on paediatric patients are needed.



Practical tips in clinical every day routine

Apply the 3, 6, 9 rule

- Some facilities use a 3, 6, 9 rule to help manage radiation delivery during difficult procedures.
- The physician is advised when the reference air kerma reaches 3 Gy.
- This first alert is just for the **physician's** information. The purpose is to help the physician gauge the pace of the procedure and to project just how much radiation might be necessary for its completion.
- The physician might wish to re-orient the beam.

At 6 Gy, the second alert is provided

- At 6 Gy the physician must be again notified.
- He should know that there is a risk of erythema or more severe effects if the beam has not been rotated to a new orientation.
- This gives the physician a chance to consider options for dose abatement.

At 9 Gy, the third alert is issued.

At 9 Gy, the third alert is issued.

The degree of risk to the patient will depend on whether previous dose abatement actions have been implemented.

This does represent a potentially serious dose level and a benefit-risk decision is necessary, just as a physician would make a benefit-risk decision about whether or not the iodine burden from the contrast agent is too great

After the 9 Gy:

- Further warnings at 3 Gy intervals would be provided
- The physician must make commensurate decisions about benefit versus risk.

After a high radiation dose procedure:

- the patient should be advised about the areas on the skin of the back where erythema or other skin reaction might develop.
- The patient should be asked to examine himself or herself until about 2 to 4 weeks after the procedure for any skin changes in those areas.
- In case of a reaction:
 - ✓ *do not itch*
 - ✓ *do not scratch*
 - ✓ *Report finding to physician*

After a high radiation dose procedure:

- ✓ Some facilities place a follow-up call to the patient during this time to query about any skin irritation
- ✓ This is found to be effective in ensuring that a patient who develops skin irritation does not seek medical help at a place where there may be a chance of missing the correct diagnosis.

In case of erythema:

- The patient can be advised to see a dermatologist.
- The dermatologist should be contacted, advising him or her on the particular details of the patient's complaint.
- Depending on the clinical situation the dermatologists takes on action without delaying.



Major injury What is next?

Can be Very Complex

- **Combined skills of:**
 - Wound care specialist
 - Dermatologist
 - Plastic surgeon and others
- **Best guidance: Refer patients to experienced providers with all information on radiogenic origin**

Big trouble if:

- Punch biopsy
- Secondary complications



Have paediatric patients high risk of injury?

- No studies have reported radiation skin injury in paediatric patients.
- Maximum PSD reported was 481 mGy for children younger than 10 years.
- However, these patients undergo often a substantial number of interventional procedures so PSD should be monitored.

What are the responsibilities of the medical physicist?

- The qualified medical physicist should evaluate all positive patient reports regarding the dosimetric aspects of the procedure
- He should discuss findings with each operator, separately
- The physicist could assist in facilitating clinical follow-up as determined by the operator.
- There may be other recommendations and/or requirements pertaining to patient follow-up according to a **particular institution's policies**.

Conclusions

- Identify and “flag” the patient
- Inform patient
- Patient instructions for either positive or negative incidents
(to perform self examination 4 weeks after the procedure)
- In case of a reaction:
 - ✓ **do not itch**
 - ✓ **do not scratch**
- Telephone patient in 3-4 weeks time
- Print dose report and archive



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*Thank you for your
attention*

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