

Ask EuroSafe Imaging Tips & Tricks

Interventional Radiology Working Group

Management of high radiation doses to patients in IR – follow up procedures

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Background

- Interventional procedures within cardiology and radiology often involve high doses to patients and, in particular, to patients' skin.
- To prevent this risk, the evaluation of maximum local skin dose (MSD) in interventional procedures is of paramount importance, but it is very difficult to undertake it in the daily work.

(Padovani et al, 2005)

Background

- Technological advances relating to imaging equipment coupled with greater procedural complexity have resulted in the potential for substantial radiation exposure risks for both patients and operators.

(Panuccio et al, 2010)

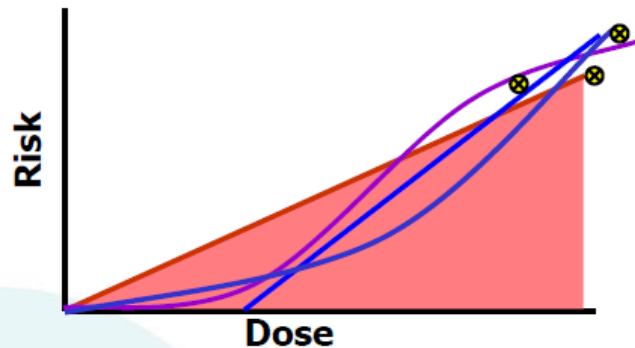
- The informed consent process should include information on radiation risk (ICRP 120)
- When the patient's radiation dose from interventional procedures exceeds the institution's trigger level, clinical follow-up should be performed for early detection and management of skin injuries (ICRP 120)
- For most patients, clinically important skin reactions only occur when the absorbed skin dose is above 5 Gy. But the lowest dose that may produce a noticeable skin change is conventionally considered to be 2 Gy (ICRP 120)

- Suggested values for the trigger level are a skin dose of 3 Gy:
 - DAP (Dose Area Product) of 500 Gy cm^2 or an AK (Air Kerma) at the patient entrance reference point of 5 Gy (ICRP 120)
 - For cardiac procedures, a DAP of 125 - 250 Gy cm^2 may be more appropriate, depending on radiation field size and the specific protocols (ICRP 120)

Dose and possible effects

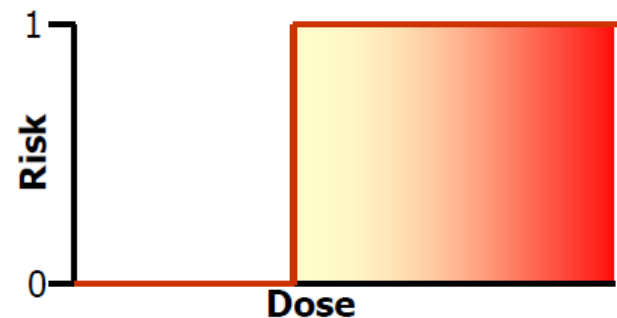
STOCHASTIC EFFECTS

- Linear - No threshold
- Other models (non linear)
- Severity independent from the dose
- Examples: cancer, genetic disease



DETERMINISTIC EFFECTS

- Threshold
- Severity depends on dose
- Examples: skin injuries



Deterministic effects

The threshold can vary with:

- Genetic conditions
- Previous exposure
- Simultaneous treatments

Fluoroscopically Guided Interventional Procedures: A Review of Radiation Effects on Patients' Skin and Hair¹

Stephen Balter, PhD
John W. Hopewell, DSc
Donald L. Miller, MD
Louis K. Wagner, PhD
Michael J. Zelefsky, MD

Most advice currently available with regard to fluoroscopic skin reactions is based on a table published in 1994. Most caveats in that report were not included in later reproductions, and subsequent research has yielded additional insights. This review is a consensus report of current scientific data. Expected skin reactions for an average patient are presented in tabular form as a function of peak skin dose and time after irradiation. The text and table in

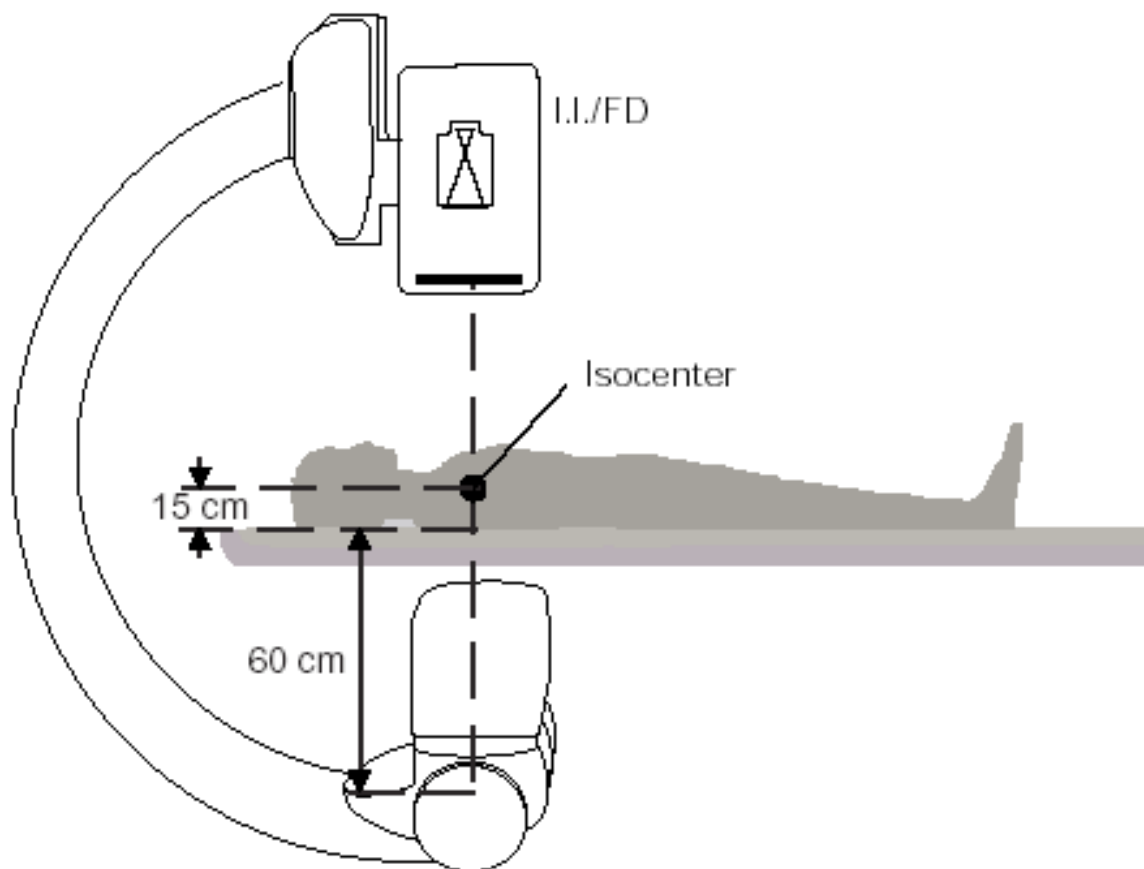
ESR
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1. How to identify patient doses in real time?
 - Can we use the parameters we have access to?
2. Establish follow up trigger levels for typical high dose procedures within interventional radiology (IR)
3. Develop informed consent document with information on radiation risk and information documents if doses above trigger levels are reached
4. Make the follow-up procedure and the trigger levels well known within the IR department
 - Will increase patient safety
 - Will increase dose awareness among IR staff
 - Indirectly decrease radiation doses to patients and staff over time

Real time dose indicators available

- Fluoroscopic time - not an adequate measure for patient dose
- DAP or KAP (Kerma Air Product)
 - DAP or KAP is a surrogate measurement for the entire amount of energy delivered to the patient by the beam
 - Unit - Gycm^2 (ICRP, 2013)
- AK
 - Patient entrance reference point (IEC standard 2010)
 - For isocentric fluoroscopic systems such as C – arm fluoroscopes, the patient entrance reference point is located along the central x – ray beam at a distance of 15 cm from the isocenter in the direction of the focal spot
 - Unit – Gy (ICRP, 2013)

PERP – Patient Entrance Reference Point

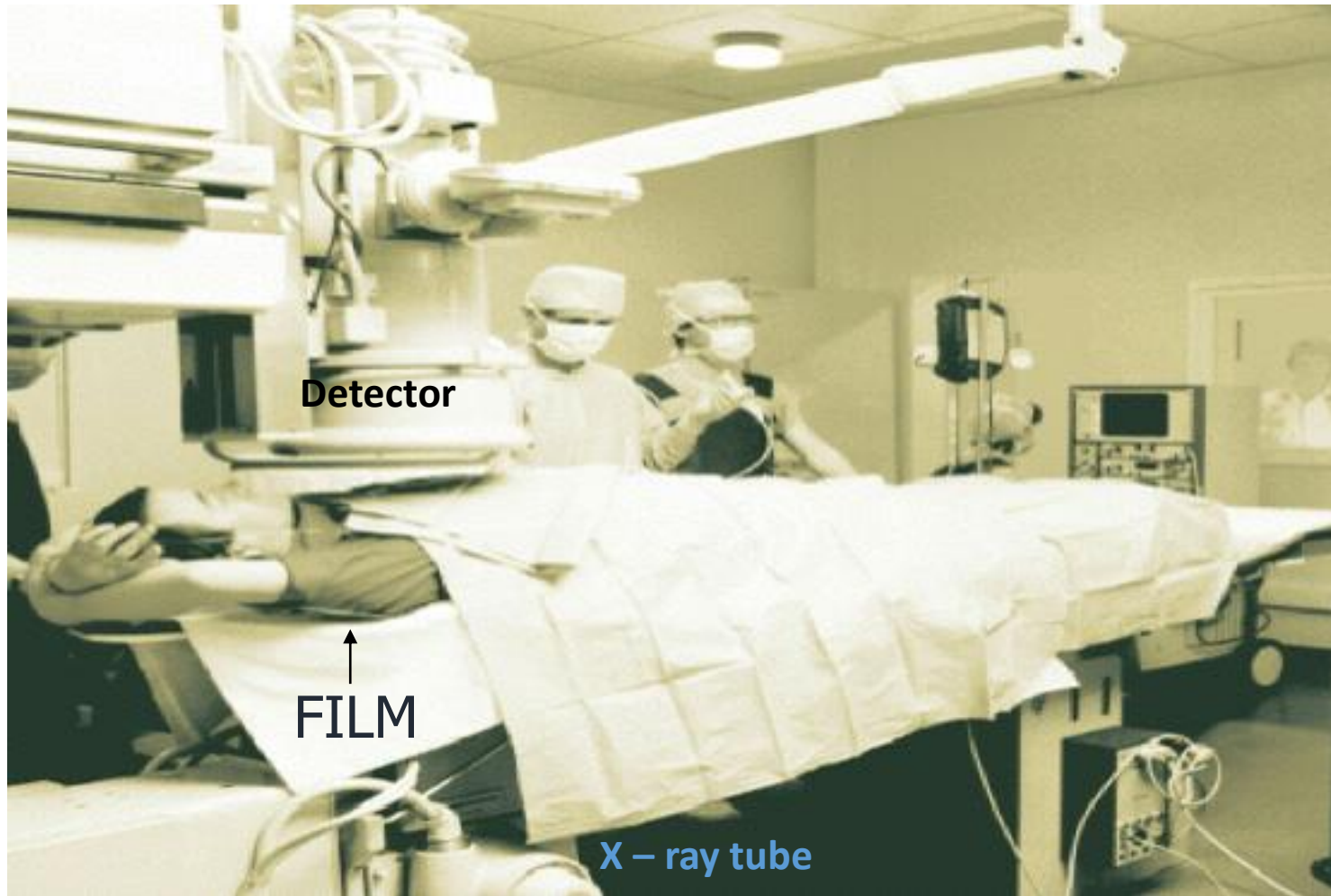


Can these parameters be used to find the actual patient dose?

- You can do a comparison between these parameters and actual dose, using radiochromic film
- The radiochromic film is placed so it covers the area on the patient that is exposed to radiation during an interventional procedure
- Shown to have acceptable precision and accuracy for clinical measurements of skin dose
- Range Gafchromic® XR – RV3
 - 10 mGy – 30 Gy

(McCabe et al, 2011)

Collecting patient data using radiochromic film – set up example



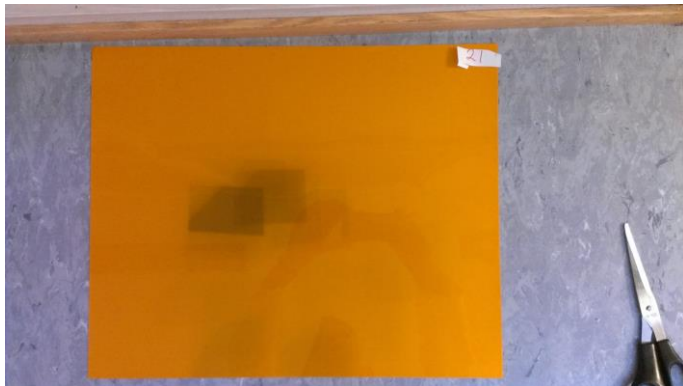
Radiochromic film - change in density when hit by radiation



- Small radiation fields, many projections
- Give a "low" threshold value using DAP



- Larger radiation fields, fewer projections
- Give a higher threshold value using DAP



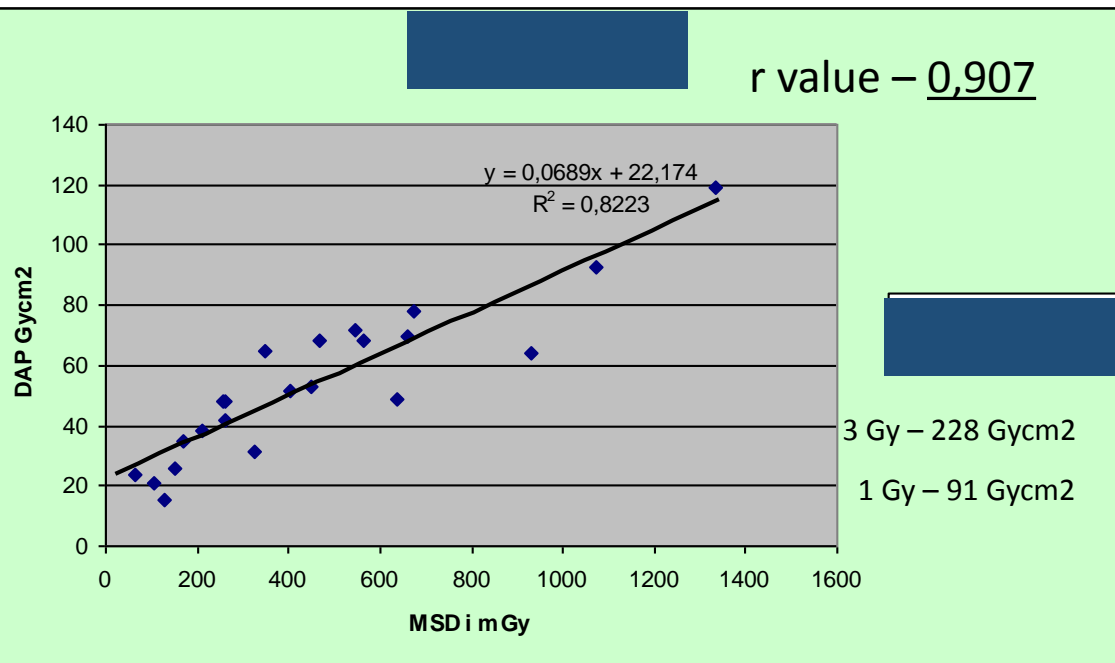
Examples of the work on preparing follow-up procedures at St. Olav's University Hospital in Norway -

Looking for correlation between DAP or AK and MSD

Correlation between MSD and DAP from PCI procedures – 22 patients

(Percutaneous Coronary Intervention)

Good correlation → DAP can be used for establishing a trigger value



Threshold value for follow up:

3 Gy

DAP – 230 Gycm²

1 Gy

DAP – 100 Gycm²

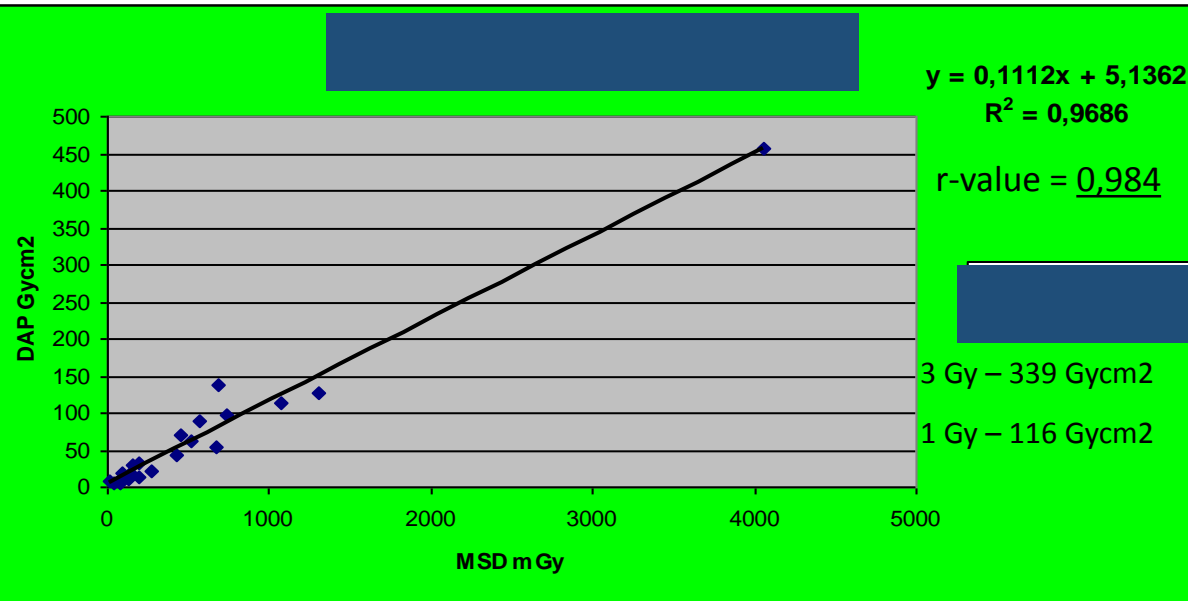
r = 0,91

R² = 0,82

Correlation between MSD and DAP from RFA procedures – 21 patients

(Radiofrequency Ablation)

Very good correlation → DAP can be used for establishing a trigger value



Threshold value for follow up :

3 Gy

DAP - **340 Gycm²**

1 Gy

DAP – 120 Gycm²

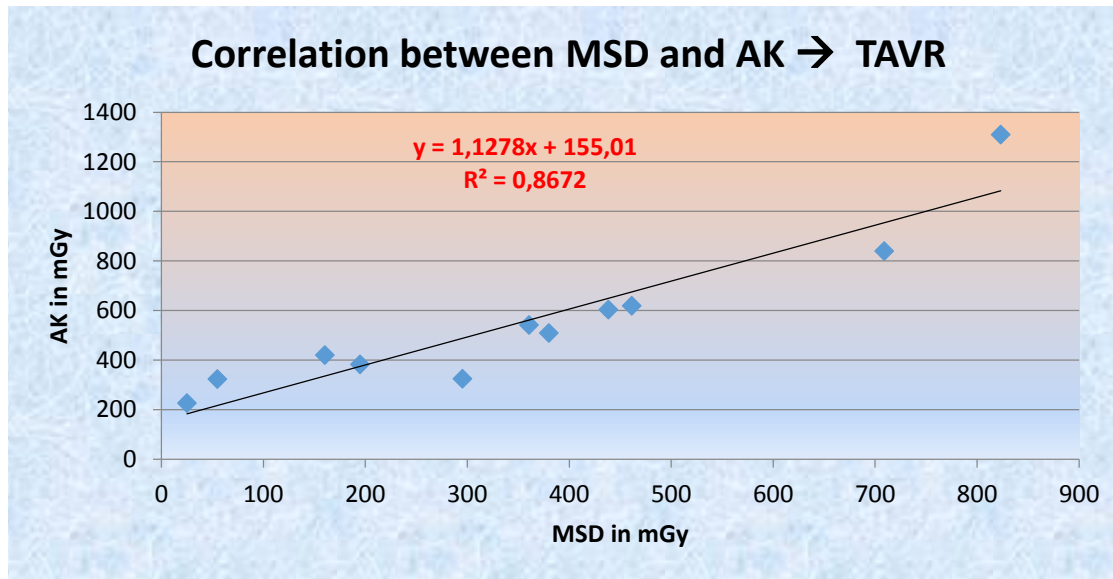
$r = 0,98$

$R^2 = 0,97$

Correlation between MSD and AK from TAVR

(Trans Aortic Valve Replacement) procedures – 11 patients

Good correlation → AK can be used for establishing a trigger value



Threshold value for follow up :

3 Gy

AK – 3500 mGy

1 Gy

AK – 1300 mGy

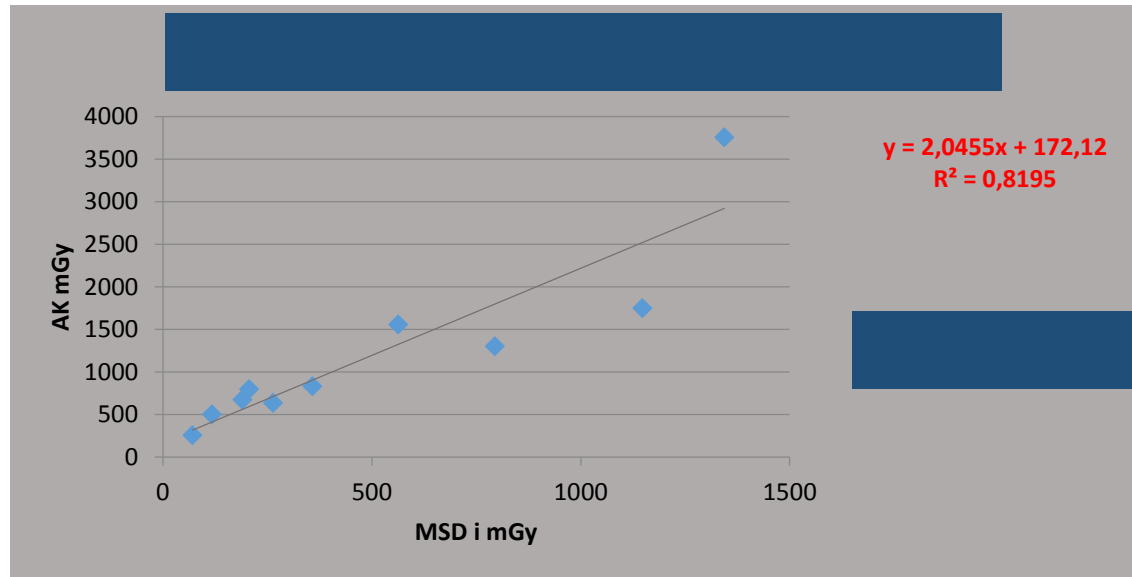
$r = 0,93$

$R^2 = 0,87$

Correlation between MSD and AK from EVAR

(Endovascular Aneurysm Repair) procedures – 11 patients

Good correlation → AK can be used for establishing a trigger value



Threshold value for follow up :

3 Gy: AK → 6308,6 mGy

→ **6 000 mGy**

1 Gy: Ak → 2217,6

→ **2 000 mGy**

$r = 0,91$
 $R^2 = 0,82$

Example – Informed consent document with information on radiation risk – before procedure at the cardiac interventional department St. Olav`s University Hospital



- During examination and any blocking of the coronary arteries and during treatment of certain types of cardiac arrhythmia, x-ray is used
- A known risk after being exposed to radiation is a local skin reaction in the irradiated area on your back. Such reactions appear very rarely and the risk depends on the individual`s sensitivity to irradiation and the radiation dose received
- If the radiation dose you receive is high, you will be informed and followed up after the procedure

After a high radiation dose procedure

(Balter et al, 2010)



- 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!**
- Some facilities place a follow-up call to the patient during this time to query about any skin irritation and 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.

Example of post procedure patient discharge instructions (Stecker et al, 2009)

APPENDIX: C

Example of Postprocedure Patient Discharge Instructions for High-dose Procedures

X-Ray Usage - one of these two boxes is checked as part of the discharge instruction process:

☐ Your procedure was completed without the use of substantial amounts of x-rays. No special follow-up is needed because radiation side effects are highly unlikely.

☐ Your procedure required the use of substantial amounts of x-rays. Radiation side-effects are unlikely but possible. Please have a family member inspect your _____, for signs of redness or rash two weeks from today. Please call (###) ### - #### and tell us whether or not anything is seen.

Example – Information document to patients involving high radiation dose procedure at the cardiac interventional department St. Olav`s University Hospital



- The examination and treatment of the coronary arteries were performed with x-ray radiation guidance. Side effects of this radiation dose are unlikely but may occur rarely. For example, one may experience irritation or burning in the skin on the back.
- We do therefor recommend that you get a family member, or other person, to check the skin on your back for redness or rash about 2 weeks after this procedure.
- If these changes have occurred, contact your GP for inspection. The GP will then inform the interventional department at the hospital about this.

Summary

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Managing high patient doses in IR

- Establishing local follow-up procedures regarding high patient doses in IR are preferred
- It is possible to identify trigger levels from available parameters from the IR equipment
 - Radiochromic films are a good option for achieving this
 - Other more advanced real time dose mapping options exists
- This will most likely increase the general awareness of radiation protection and radiation doses for patients and staff
- Before establishing local follow-up trigger levels, it is recommended that you use ICRP`s guidelines and thresholds for the follow up procedure

References

- Balter, S., Hopewell, J.E., Miller, D.L., Wagner, L.K. og Zelefsky, M.J. (2010). Fluoroscopically guided interventional procedures: A review of radiation effects on patients skin and hair. Radiology: Volume 254: Number 2 – February 2010
- ICRP, 2013. Radiological Protection in Cardiology. ICRP publication 120. Ann. ICRP 42(1)
- Padovani, R., Bernardi, G., Quai, E., Signor, M., Toh, H.S., Morocutti, G. and Spedicato, L. (2005). Retrospective evaluation of occurrence of skin injuries in interventional cardiac procedures. Radiation Protection Dosimetry (2005), Vol. 117, No. 1-3, pp. 247-250
- Panuccio, G., Greenberg, R.K., Wunderle, K., Mastracci, T.M., Eagleton, M.G. and Davros, W. (2010) Comparison with indirect radiation dose estimates with directly measured radiation dose for patient and operators during complex endovascular procedures. Journal of Vascular Surgery 2011; 53 : 885-94
- McCabe, P. Bradley, Michael, A. Speidel and Pike, T.L. (2011). Calibration of Gafchromic XR-RV3 radiochromic film for skin dose measurement using standardized x-ray spectra and a commercial flatbed scanner. Med. Phys. 38 (4), April 2011
- Stecker, M.S., Balter, S., Towbin, R.B., Miller, D.L., Vano, E., Bartal, G., Angle, J.F., Chao, C.P., Cohen, A.M., Dixon, R.G., Gross, K., Hartnell, G.G., Schueler, B., Statler, J.D., de Baere, T. and Cardella J.F. (2009). Guidelines for patient radiation dose management. Journal of Vascular Interventional Radiology 2009; 20: s263-s273