Topical Session III.3.2

(Thursday 23 October 2008; 14:00-14:25)

Radiation Protection in Interventional Radiology

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Content

- Introduction.
- UNSCEAR data on Interventional Radiology.
- ICRP recommendations and other international actions on IR.
- Radiation risks for patients and staff.
- Conclusions.

Interventional Radiology

- Doctors with expertise in imaging techniques enabling them to guide small catheters and guide-wires through blood vessels or other pathways in the body to treat diseases without surgery.
- Patient and staff safety was incorporated into the IR practice. Training in RP is a key aspect.

Interventional Radiology advantages

- **IR techniques can replace some open surgical procedures, allowing patients to be treated with less risk and minimizing hospital stay.**
- **The advantages to patients are obvious:**
  - **General anaesthesia is usually not required and**
  - **Risk, pain and recovery time are often significantly reduced.**

Many medical specialities involved…

- The speciality of IR overlaps other fields.
- Specialists performing IR procedures today include not only radiologists but also other types of physicians such as general surgeons, vascular surgeons, cardiologists, gastroenterologists, gynaecologists, and urologists.

UNSCEAR data on Interventional Radiology

- The combination of prolonged localized fluoroscopy, multiple radiographic exposures, and repeated procedures can cause patient doses to reach levels producing radiation injury.
- There may be underreporting of skin injuries.

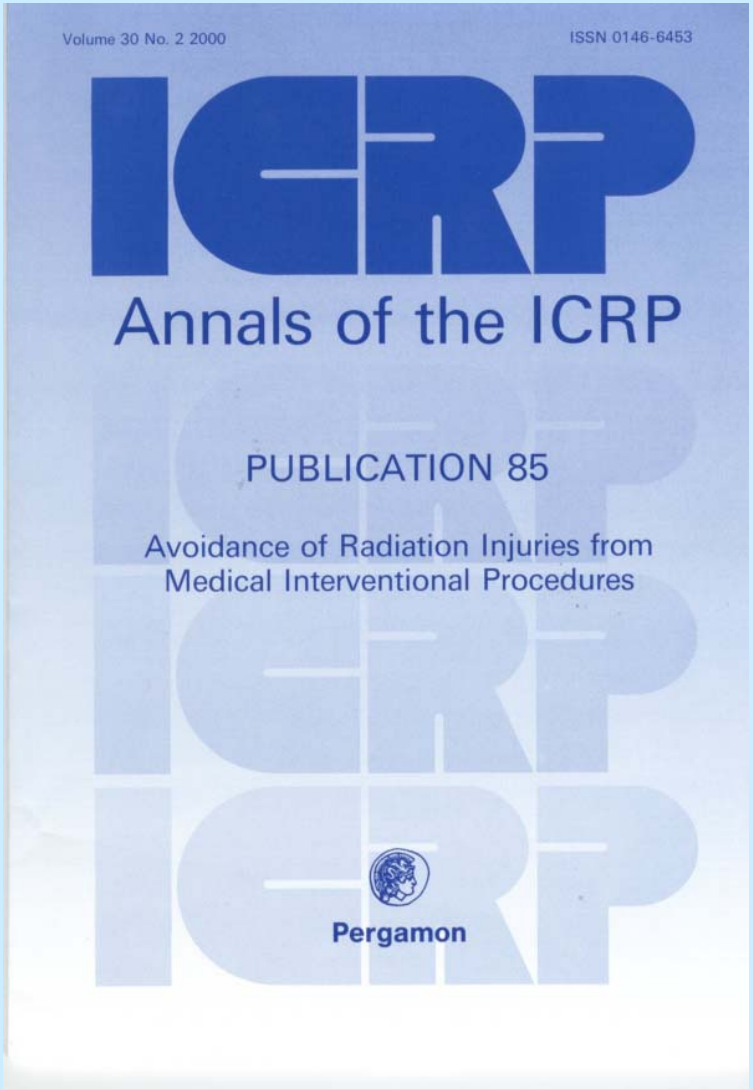
UNSCEAR data on Interventional Radiology

- During the 2008 annual UNSCEAR meeting it was reported that around half of the collective effective dose due to diagnostic (and interventional) imaging originated from: CT, angiography examinations and IR.

UNSCEAR data on Interventional Radiology

- **The two main causes for radiation injuries were:**
  - **the use of suboptimal equipment, and**
  - **procedures performed by individuals inadequately trained in radiation protection.**

ICRP and Interventional Radiology



- **In addition to ICRP-85 (2000), the new 2007 ICRP Recommendations addressed different aspects especially relevant for IR.**
- **ICRP recognized three kinds of medical exposure of patients: diagnostic, interventional and therapeutic procedures.**

ICRP 2007 and Interventional Radiology

- **Justification and staff doses:**
  - **“The principal aim of medical exposures is to do more good than harm to the patient, subsidiary account *being taken of the radiation detriment from the exposure of the radiological staff* and of other individuals”.**

ICRP 2007 and Interventional Radiology

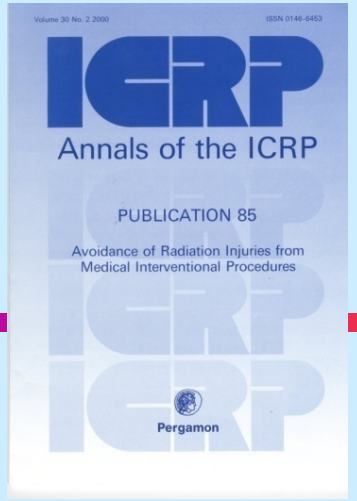
- **Diagnostic reference levels (DRL)**
  - **ICRP Publication 105 says: For fluoroscopically guided interventional procedures, DRL, in principle, could be used to promote the management of patient doses with regard to avoiding unnecessary stochastic radiation risks.**
  - **However … the relative 'complexity' of the procedure should be taken into account.**

ICRP 2007 and risk to the eyes

- **ICRP stated that dose limits (to the eyes) remain unchanged. However, new data on the radiosensitivity of the eye with regard to visual impairment are expected.**

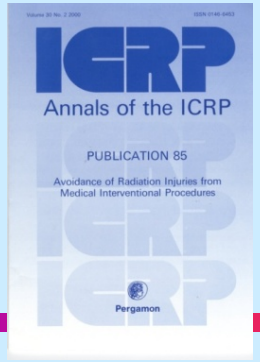
ICRP 2007 and risk to the eyes

- **The Commission will consider these data and their possible significance for the equivalent dose limit for the lens of the eye when they become available. Because of the uncertainty concerning this risk, there should be particular emphasis on optimisation in situations of exposure of the eyes.**



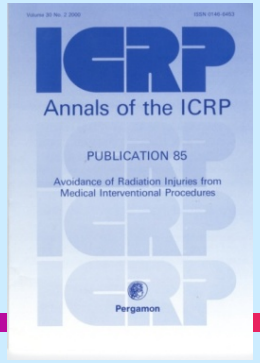
ICRP specific recommendations for IR

- The clinical protocol for each type of interventional procedure should include information on radiographic images (projections, number, and technique factors), fluoroscopy times, air kerma rates etc.
- Each interventional physician should be trained to use this information, displayed at the operator's position.



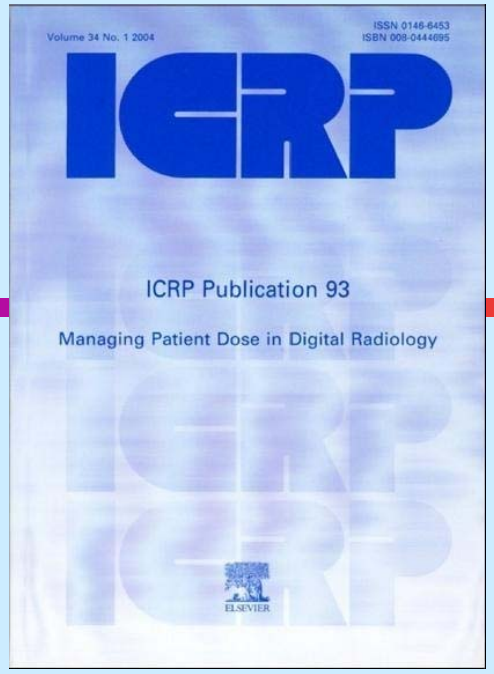
ICRP specific recommendations for IR

- **ICRP recommends that all patients should be informed of the likelihood of radiation effects as part of informed consent.**
- **The Commission states that a *second specific level of training in radiation protection, additional to that undertaken for diagnostic radiology, is desirable.***
- **Specific additional training should be planned when new x-ray systems or techniques are implemented in a centre.**



ICRP specific recommendations for IR

- **It is recommended that some RP tools be supplied by the manufacturers when installing the x-ray systems.**
- ***It is recommended that interventional radiology departments develop a policy that staff should wear two dosimeters.*** **Doses in departments should be analysed and high doses and outliers should be investigated".**



ICRP recommendations on digital radiology influencing IR

- **ICRP recommends that the industry should promote tools to inform radiologists, radiographers, and medical physicists about the exposure parameters and the resultant patient doses.**
- **The exposure parameters and the resultant patient doses should be standardised, displayed, and recorded.**

ICRP on going documents (IR)

- **The ICRP is presently preparing two other documents concerning RP aspects for IR :**
  - **Cardiology and**
  - **Education and Training of RP aspects.**
- **A third document has been considered to be (probably) started in 2009:**
  - **Widening the use of reference levels for interventional radiology, digital radiology and new technology .**

Other international organizations

- **FDA 1994: Serious X-ray-induced skin injuries to patients during fluoroscopically guided procedures.**
- **WHO: Joint WHO/ISH/CE Workshop on Efficacy and Radiation Safety in Interventional Radiology (1995) and later, in 2000, published a booklet entitled “Efficacy and radiation safety in interventional radiology”.**

Other international organizations

- **IEC published in 2000 a standard entitled ‘‘Particular requirements for the safety of X-ray equipment for interventional procedures’’ and in 2007 a standard on “Radiation dose documentation”.**
- **IRPA: IR has also been a relevant topic through all its congresses and publications.**
- **EC has funded several research actions dealing with IR (DIMOND and SENTINEL) and produced an interactive CD-ROM free available.**

FDA Advise (1994)

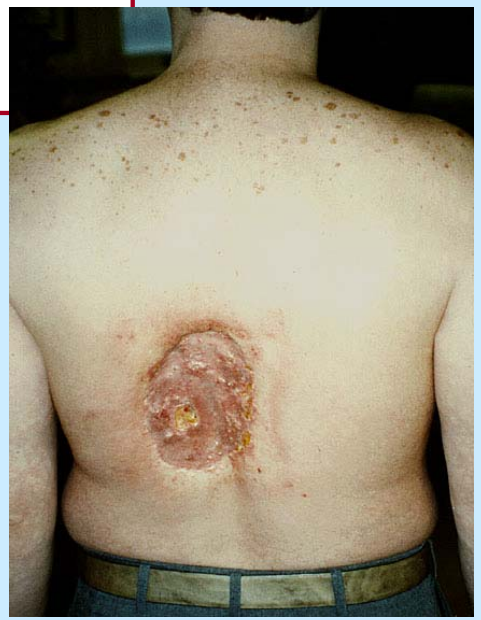
FOOD AND DRUG ADMINISTRATION

IMPORTANT INFORMATION FOR PHYSICIANS
AND OTHER HEALTH CARE PROFESSIONALS
September 9, 1994

AVOIDANCE OF SERIOUS X-RAY-INDUCED SKIN INJURIES TO PATIENTS DURING FLUOROSCOPICALLY-GUIDED PROCEDURES

WARNING - FDA has reports of occasional but at times severe radiation-induced burns to patients from fluoroscopically-guided, invasive procedures. This communication describes the nature of these injuries and provides recommendations for avoiding them.

T. Shope, Radiographics
1996; 16: 1195-99



BfS Bundesamt für Strahlenschutz

Fachbereich Strahlenhygiene
Institut für Strahlenhygiene (ISH)

Joint WHO / ISH Workshop on Efficacy and Radiation Safety in Interventional Radiology

Munich-Neuherberg, Germany, October 9-13, 1995

Herausgeber:
Alfred Bäuml
Burkhard Bauer
Jürgen-Helmut Bernhardt
Friedrich-Ernst Stieve
Richard Veit
Ingeborg Zeitlberger

BfS-ISH-178/97

1995

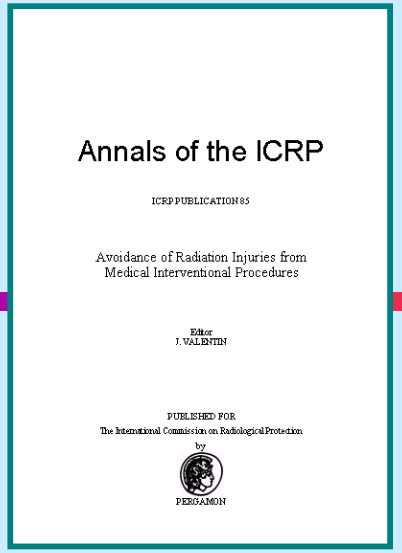
BfS-ISH-Berichte

Efficacy and radiation safety in interventional radiology

2000

World Health Organization
Geneva

ICRP report 85 (2001): Avoidance of Radiation Injuries from Interventional Procedures


Annals of the ICRP

ICRP PUBLICATION 85

Avoidance of Radiation Injuries from Medical Interventional Procedures

Editor
J. VALENTIN

PUBLISHED FOR
The International Commission on Radiological Protection
by

PERGAMON

21 months after a CA and two PTCA's (15 - 20 Gy) (Courtesy of F. Mettler).


ICRP Publication 85

Avoidance of Radiation Injuries from Medical Interventional Procedures

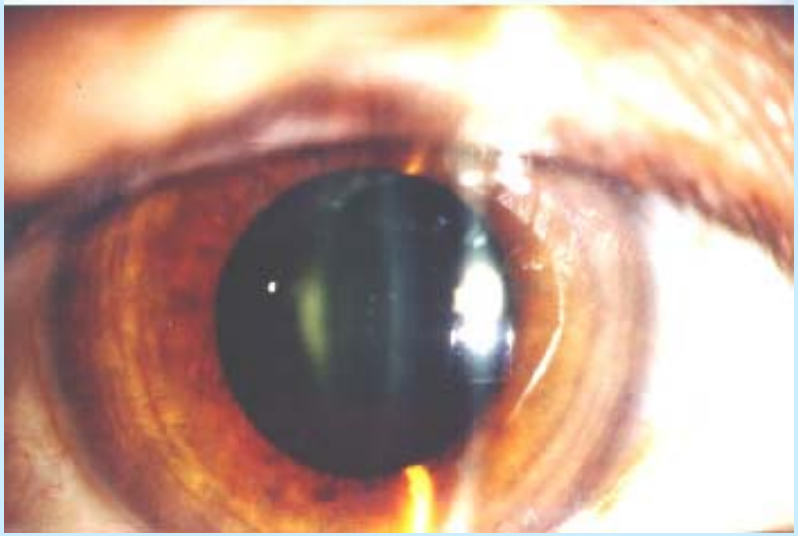
Above Photograph of the patient's back after a coronary angiography and two angioplasty procedures within three days, assessed cumulative dose 15,000 to 20,000 mGy. The patient has consistently refused skin grafting after excision of necrotic tissue. (Photograph courtesy of F. Mettler).

Below Cataract in the eye of an interventionalist after repeated use of old x-ray systems and improper working conditions related to high levels of scattered radiation. (Photograph courtesy of E. Vañó).

An information publication for the medical profession from the

ICRP
INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

Cataract in eye of interventionalist after repeated use of old x ray systems and improper working conditions.



IAEA and Interventional Radiology

- **IAEA is leading an International Action Plan on the RP of patients and IR is one of its priorities.**
- **Training interventional cardiologists to RP has represented an important effort over the last years. The training material is freely available on CD from the IAEA and on the website (http://rpop.iaea.org/RPoP/RPoP/Content/index.htm).**
- **Cooperation with SOLACI in a survey to evaluate lens injuries.**

Medical IR Societies

- **The Society of Interventional Radiology (SIR) in US, provides a specific position statement on radiation safety (http://www.sirweb.org/patients/radiationSafetyStatements.shtml).**
- **The Cardiovascular and Interventional Radiological Society of Europe (CIRSE) offers a webpage for patients and public on radiation safety (http://www.cirse.org/index.php?pid=153) and its Standards of Practice Committee is considering including more aspects on radiation protection in its documents.**

Radiation risks in interventional radiology

- **Interventional procedures are the medical imaging exposures imparting the highest radiation doses to the patients and staff.**
- **Measured dose rates to the staff range from 1 to more than 100 mSv/h and some cases of radiation injuries (mainly cataracts) have been reported among professionals.**

Radiation risks in interventional radiology

- **According to UNSCEAR data for maximum effective doses for patients during procedures ranging from 13 mSv for PTA to 180 mSv for TIPS, some organ doses may be higher than 100 Gy.**
- **Skin doses over several tens of Gy have also been reported with important radiation injuries.**

Radiation risks in interventional radiology

- **Stochastic risks for most of the patients (of advanced age) are lower than for other imaging procedures but a certain percentage of IR (between a 5 to 20% depending on the procedures) is carried out on patients under 40.**

Dose and dose-rate effectiveness factor (DDREF)

- **ICRP has adopted the LNT (linear non threshold) model combined with a value of 2 for the DDREF.**
- **Publication 99 states that: “The ICRP recommended a DDREF of 2 for radiation protection purposes ... the chosen DDREF should be applied to chronic exposures at dose rates less than 6 mGy/h averaged over the first few hours, and to acute exposures at total doses less than 0.2 Gy”, quoting UNSCEAR data.**

Dose and dose-rate effectiveness factor (DDREF)

- **ICRP refers that: “When dose rates are lower than around 0.1 Gy/hour there is repair of cellular radiation injury during the irradiation”.**
- **For some IR procedures, dose and dose rates can be much higher than the quoted values. During an interventional cardiology procedure, a cine frame may involve a skin dose of 1 mGy imparted in 10 ms. This means an instantaneous dose rate of 360 Gy/h.**

Patient and staff dose values

- **A large number of publications have appeared over the last years on patient and staff doses in IR: the European Commission research programmes, national surveys of some IR societies (SIR at USA, and several European countries).**
- **The IAEA and the International Action Plan of Protection of Patients.**
- **Today, thanks to these studies, patient dose reference levels are available for IR and interventional cardiology.**

Patient and staff dose values

- It has been recognised that some of the official data published for staff doses in IR and cardiology could underestimate the real occupational risk deriving from the lack of a regular use of personal dosimeters and the use of a single dosimeter under the apron. Dose values to the non- protected organ or tissues (e.g. lens of the eyes) are unknown to most of the IR professionals.

Conclusions

- **Today IR is safe and highly beneficial to patients, but the levels of radiation are among the highest used in medical imaging.**
- **Medical doctors employing fluoroscopically-guided procedures need to be trained and certified in RP for this practice.**
- **X-ray systems used for IR should be submitted to a strict acceptance and commissioning process.**

Conclusions

- **Industry should continue to implement dose saving options for the interventional systems and aim at standardizing the patient dose reports, at archiving and processing them automatically.**
- **Occupational dosimetry should be improved.**
- **Patient dose surveys and the use of reference levels should be extended.**