Implications in medical imaging of the new ICRP thresholds for tissue reactions

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Abstract–The International Commission on Radiological Protection (ICRP) statement on tissue reactions, issued by the Commission in April 2011, reviewed epidemiological evidence and suggested that there are some tissue reactions where threshold doses are or may be lower than those previously considered. For the lens of the eye, the threshold is now considered to be 0.5 Gy. The absorbed dose threshold for circulatory disease in the heart and brain may be as low as 0.5 Gy. These values can be reached in some patients during interventional cardiology or neuroradiology procedures. They may also be of concern for repeated computed tomography examinations of the head. The new thresholds should be considered in optimisation strategies for clinical procedures, especially in patients likely to require repeated interventions. The new dose thresholds also affect occupational protection for operators and staff. Some operators do not protect their eyes or their brain adequately. After several years of work without proper protection, the absorbed doses to the lens of the eye and the brain of staff can exceed 0.5 Gy. More research is needed to understand the biological effects of cumulative incident air kerma and the instantaneous air kerma rates currently used in medical imaging. The new thresholds, and the need for specific occupational dosimetry related to lens doses, should be considered in radiation protection programmes, and should be included in the education and training of professionals involved in fluoroscopy guided procedures and computed tomography.

Keywords: Radiological protection; Tissue reactions; Interventional radiology; Interventional cardiology; Neuroradiology; Deterministic effects

1. INTRODUCTION

The International Commission on Radiological Protection (ICRP) statement on tissue reactions, issued by the Commission in April 2011, (ICRP, 2012) reviewed available epidemiological evidence and suggested that there are some tissue reactions where threshold doses are or may be lower than those previously considered.

For the lens of the eye, the threshold is now considered to be 0.5 Gy. The absorbed dose threshold for circulatory disease in the heart and brain may be as low as 0.5 Gy. These values can be reached in some patients during interventional cardiology or neuroradiology procedures (Thierry-Chef et al., 2008; Vañó et al., 2013a; Sánchez et al., 2014). They can also be reached in some staff involved in interventional procedures if radiation protection tools are not used properly (Dauer et al., 2010; Vañó et al., 2010, 2013c; Ciraj-Bjelac et al., 2012).

The new thresholds should be considered during the justification process and especially in optimisation strategies for clinical procedures. This is particularly important for patients who are likely to require repeated interventions, and for staff in interventional laboratories who have a high workload (Picano, 2012; Miller, 2013; Bartal et al., 2014).

This paper presents some examples of organ dose values (heart, brain, and lens of the eye) in patients who have undergone cardiology or neuroradiology interventional procedures or head computed tomography (CT), and in staff working in interventional laboratories.

2. HEART DOSES IN INTERVENTIONAL CARDIOLOGY AND CARDIAC CT

Organ doses can be estimated with PCXMC 2.0 software, which uses Monte Carlo-derived calculations (Tapiovaara and Siiskonen, 2008). In interventional cardiology procedures, the absorbed dose to the heart can be estimated from the cumulative air kerma (CAK) at the 'patient entrance reference point' defined by the International Electrotechnical Commission (IEC, 2010). The estimated absorbed dose to the heart from CAK of 1 Gy, delivered from a posterior–anterior projection with the typical x-ray beam quality and field size used in cardiology, is 250 mGy. When collimation is not used – as is usually the case in interventional cardiology – the estimated absorbed dose to the heart is approximately 20–25% of CAK. For cardiac interventions, CAK > 2.0–2.5 Gy therefore implies an absorbed dose to the heart greater than the 0.5 Gy threshold proposed by the Commission (ICRP, 2012). In order to ensure that organ doses that may exceed the threshold are detected and these patients are followed appropriately, patient dose metrics should be recorded and reported for every patient and every examination.

In a sample of 6557 diagnostic and therapeutic cardiac interventional procedures performed at the San Carlos University Hospital in Madrid (Spain) in 2010 and 2011, the median CAK was 1079 mGy and the third quartile CAK was 1662 mGy. In 17% of these procedures, CAK was >2.0 Gy, and in 10% of these procedures, CAK was >2.5 Gy (Fig. 1). This implies that the organ dose to the heart was

All cardiac procedures (SCUH 2010-2011)

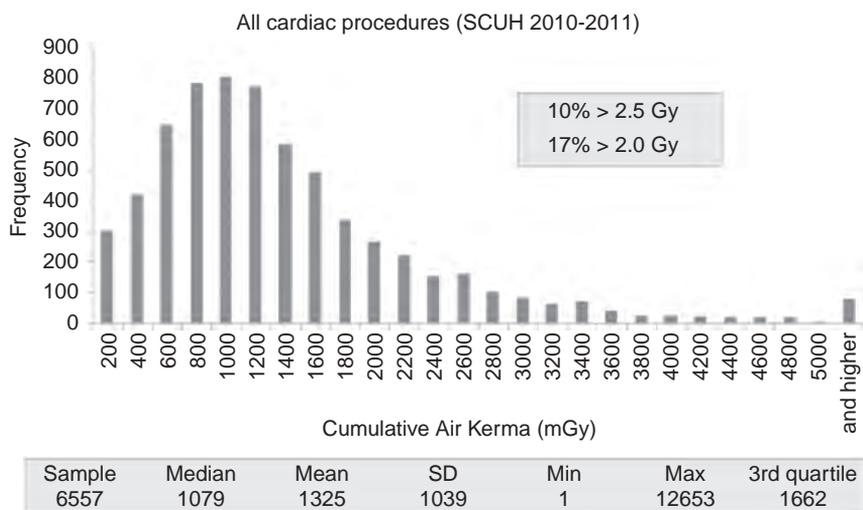| Sample	Median	Mean	SD	Min	Max	3rd quartile
6557	1079	1325	1039	1	12653	1662

Fig. 1. Cumulative air kerma (CAK) at the patient entrance reference point for interventional (diagnostic and therapeutic) cardiac procedures at the San Carlos University Hospital (SCUH) in Madrid, Spain.

approximately 0.5 Gy or greater in 10–17% of these procedures. In a sample of 4128 therapeutic interventional cardiac procedures performed in the same hospital, the median CAK was 1435 mGy and the third quartile CAK was 2076 mGy. Of these procedures, 27% resulted in CAK > 2.0 Gy (i.e. with estimated organ dose to the heart of approximately 0.5 Gy) and 16% resulted in CAK > 2.5 Gy.

Data from the 2008–2009 US nationwide evaluation of x-ray trends (NEXT) survey of cardiac catheterisation have been reported (Miller et al., 2012b). These data were acquired from 171 hospitals in 30 US states. Radiation dose metrics were recorded for diagnostic cardiac catheterisations ($n = 1038$), percutaneous coronary interventions (PCI) ($n = 117$), and combined diagnostic and PCI procedures ($n = 390$). For diagnostic catheterisations, 5.1% resulted in CAK > 2.0 Gy and 3.5% in CAK > 2.5 Gy. For PCI, these percentages were 32.5% and 26.5%, respectively, and for combined procedures, the percentages were 35.2% and 24.9%, respectively.

Absorbed dose to the heart from CT coronary angiography may also be substantial, especially when the patient undergoes multiple examinations. Different acquisition techniques and heart rates determine heart dose in these cases. Matsubara et al. (2011) reported absorbed doses to the heart using a 64 detector-row CT. When helical acquisitions using electrocardiogram modulation of tube current were performed at simulated heart rates of 40, 60, and 90 beats min^{-1}, the absorbed doses to the heart were 178.6, 139.1, and 159.3 mGy, respectively.
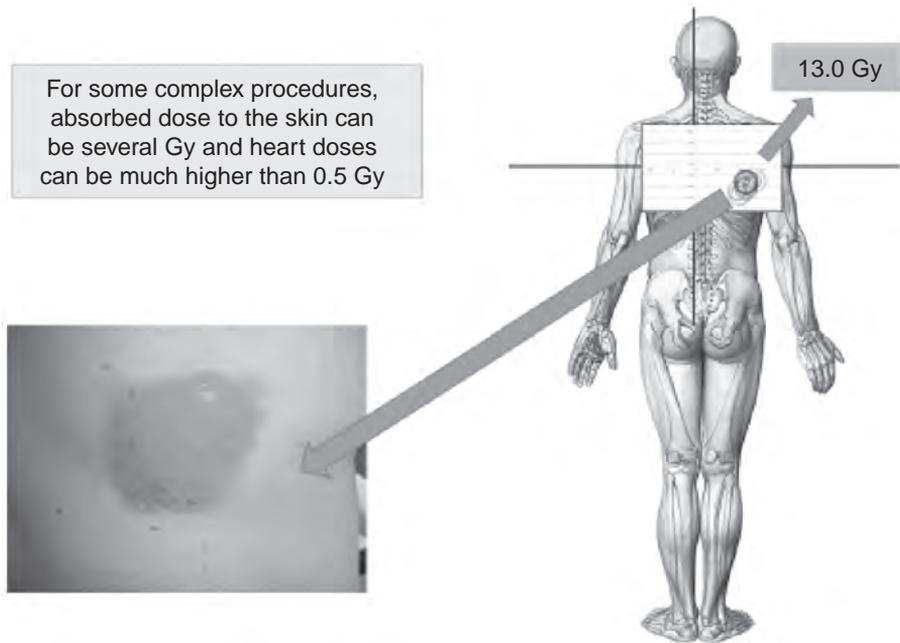
Fig. 2. Example of a skin injury during a complex cardiology procedure (treatment of a chronic total occlusion) (Vañó et al., 2013a). The estimated peak skin dose was 13 Gy.

When skin injuries occur after a cardiac interventional procedure (Fig. 2) (Vañó et al., 2013a), tissue reactions in the cardiovascular system should also be considered as part of the clinical follow-up.

3. BRAIN AND LENS OF THE EYE DOSES IN INTERVENTIONAL NEURORADIOLOGY AND HEAD CT PROCEDURES

Absorbed doses to the brain and cerebrovascular system (including the carotid artery in the neck) delivered to patients during interventional neuroradiology procedures may also be substantial. Clinicians should consider the new threshold for tissue reactions in the cerebrovascular system when they develop optimisation strategies.

In a recent survey at the San Carlos University Hospital in Madrid (Sánchez et al., 2014) the absorbed dose to the brain was estimated using PCXMC 2.0 software (Tapiovaara and Siiskonen, 2008) for 99 diagnostic and therapeutic neuroradiology procedures. In total, 9031 beam projections were processed. Brain doses ≥0.5 Gy were observed in 34% of cerebral embolisation procedures. For these procedures, if collimation is not used, CAK of 1000 mGy will result in an estimated absorbed dose to the brain of approximately 250 mGy.

Thierry-Chef et al. (2008) published absorbed doses to the brain for 49 paediatric patients undergoing intracranial embolisation. The average dose to the whole brain was calculated using Monte Carlo software. They noted that the distribution of the absorbed dose within the brain can vary substantially depending on field size and field motion during procedures. The median absorbed dose, averaged over the entire brain, was 440 mGy (range 50–2700 mGy) assuming large uniform frontal and lateral fields. If collimated frontal and lateral fields focused near the centre of the brain were assumed, the median dose was estimated to be 60 mGy (range 8–310 mGy). Average absorbed doses to the brain, when exposed to large uniform fields, were >500 mGy in 21 of the 49 cases (43%). Brain dose is dramatically reduced if the brain is irradiated with narrow non-uniform fields that vary in location, as compared with irradiation by large uniform frontal and lateral fields. If this optimisation strategy was used, all the analysed procedures could be performed with brain doses <0.5 Gy. Collimation and limiting fluoroscopy time and dose rate were the most effective means to minimise dose.

During some CT procedures, especially brain perfusion examinations, brain and lens absorbed doses may approach or exceed the new threshold of 0.5 Gy. Zhang et al. (2012) reported eye doses of 81 to 348 mGy from brain perfusion CT using Monte Carlo simulations. The wide range is due to the different CT scanners and protocols used.

Using Monte Carlo simulation software designed for patient CT dosimetry, Perisinakis et al. (2013) studied the effect of head size and shape, miscentring, and bowtie filter size on peak patient tissue doses from modern brain perfusion 256-slice CT in 106 individual-specific adult head phantoms. The mean peak doses to the lens of the eye, skin, brain, and red bone marrow were 124, 120, 95, and 163 mGy, respectively. They concluded that doses to these tissues from a standard low-dose brain perfusion 256-slice CT protocol are well below the thresholds for the induction of erythema, cataract, cerebrovascular disease, and depression of haematopoiesis. Nonetheless, every effort should be made to optimise the procedure and minimise the dose received by these tissues.

Estimation of brain doses and evaluation of dose-sparing techniques should be part of the optimisation process, particularly for patients who have or will undergo multiple procedures and for paediatric patients. This implies that patient dose metrics should be recorded and reported for every patient and every such examination. If cumulative absorbed brain dose is expected to be >0.5 Gy, the possibility of a tissue reaction in the cerebrovascular system should be considered as part of the informed consent process in addition to the risk of a tissue reaction in the skin or a stochastic effect.

4. OCCUPATIONAL LENS DOSES IN INTERVENTIONAL STAFF

As a consequence of the new threshold for lens effects, the Commission provided a new recommendation for the occupational dose limit to the lens of the eye. The recommended equivalent dose limit for the lens of the eye was reduced from 150 mSv year^{-1}

to 20 mSv year^{-1}, averaged over a 5-year period, with no year's dose exceeding 50 mSv (ICRP, 2012). The new International and European Basic Safety Standards incorporate this new occupational limit (European Commission, 2012; IAEA, 2014). The UK Health Protection Agency (HPA) endorses the conclusion reached by the Commission in its 2011 statement (Bouffler et al., 2012). The Health Protection Agency is now part of Public Health England, an executive agency of the Department of Health. The HPA believes that further work is desirable to better quantify the risk at low doses and following protracted exposures, as is research into the mechanistic basis for radiation cataractogenesis. This research will help to inform selection of risk projection models.

The new dose thresholds, especially the 0.5 Gy threshold for the lens of the eye, affect occupational protection for operators and other involved staff. This is particularly important for fluoroscopically guided procedures. Some operators do not protect their eyes or their brain adequately during interventional procedures. After several years of work without proper protection, cumulative absorbed doses to the lens can exceed 0.5 Gy (Vañó et al., 2010, 2013c; Ciraj-Bjelac et al., 2012). During most of the IAEA.RELID (Retrospective Evaluation of Lens Injuries and Dose) (see: https://rpop.iaea.org/rpop/rpop/content/news/relid-cataract-study.htm, accessed on 13 January 2015) surveys of radiation-related lens opacities in interventionalists and staff (Vañó et al., 2010, 2013c; Ciraj-Bjelac et al., 2012), 40–50% of the professionals involved in interventional cardiology procedures who volunteered to be examined had lens opacities (posterior subcapsular opacities). Only 10% of the members of the control groups had such opacities. It should be noted that most of the detected lens opacities were in professionals who had worked for several years without any eye protection.

Many medical specialties outside the imaging departments (e.g. vascular surgery, urology, orthopaedics, gastroenterology, and anaesthetics and pain management) are starting to use or increase their use of fluoroscopically guided procedures in surgical theatres without the radiation protection tools available in standard interventional laboratories (ICRP, 2010; Burns et al., 2013). This may result in occupational doses in these physicians that are higher than the typical values recorded in interventional radiology and cardiology services where protection tools are used regularly. Also, because of the growing use of positron-emission tomography (PET)-CT, and the high workload for PET-CT staff, occupational protection is becoming the focus of greater attention in nuclear medicine installations (Ryan et al., 2013).

Lack of compliance with the regular use of personal dosimetry has been a problem for many years in many countries (Kim et al., 2012; Durán et al., 2013; Bartal et al., 2014). This is one of the reasons for the lack of accurate occupational dose data (and reliable radiation risk estimations) in relevant professional groups. Several investigators are working on Monte Carlo calculations and detection of staff location in the catheterisation laboratory to estimate staff doses during clinical procedures through the use of radiographic and geometric data (Badal et al., 2013). Other authors (Vañó et al., 2013b) used a different method to develop a realistic approach to estimate lens doses in interventional cardiology when personal dosimeters are not used regularly. They concluded that for around 2000 diagnostic, PCI, and valvular procedures, the

median scatter dose value per procedure at the C-arm was 0.78, 1.07, and 1.45 mSv, respectively. Lens doses are approximately 50–60% of these values when radiation protection tools are not used. For all of these procedures, the ratio between the scatter dose at the C-arm and the kerma-area product was 10.3–11.3 μSv(Gy cm^2)$^{-1}$.

Newer active personal dosimeters display occupational dose rates in real time inside the interventional fluoroscopy suite, and allow subsequent detailed analyses of staff and patient doses by recording dose at very short intervals. These data permit the development of new optimisation strategies to improve occupational protection (Sánchez et al., 2010). Several medical societies have published or endorsed documents on occupational protection that are also expected to improve radiation safety (Miller et al., 2010, 2012a; Durán et al., 2013). Some users have urged that scatter doses be included in patient dose reports. New ethical issues are emerging in situations where reducing patient dose involves increasing staff doses and vice versa.

Occupational radiological protection is still a challenge in several clinical situations. The Commission has included specific recommendations and advice for occupational protection in most of its publications in recent years (ICRP, 2000, 2007a,b,c, 2009, 2010, 2013a,b).

5. DOSE RATES FOR PATIENTS AND STAFF

One area where more research is needed is an understanding of the biological effects of cumulative incident air kerma and the instantaneous air kerma rates used currently in medical imaging. In *Publication 99* (ICRP, 2005), the Commission stated that its radiation protection philosophy is based on the linear no-threshold theory. According to this theory, total radiation-related cancer risk is proportional to dose at low and moderately low doses (of the order of 200 mGy or less) and dose rates (less than 6 mGy h^{-1}, averaged over the first few hours).

Table 1. Ranges of photon energy, dose per procedure and dose rate (incident air kerma) in medical imaging procedures for patients and staff.

Patients	Range
Photon energy	20–130 keV
Dose (incident air kerma)	1–5000 mGy
Dose rate (from fluoroscopy and radiography)	5–5000 mGy min^{-1}
Staff, if radiation protection tools not used	
Photon energy	20–130 keV
Dose (incident air kerma)	1–5000 μGy
Dose rate (patient/1000)	5–5000 μGy min^{-1}
ICRP (2005), DDREF of 2, if:	
Dose rates less than 6 mGy h^{-1} (0.1 mGy min^{-1})	
Acute exposures of total doses less than 0.2 Gy	

DDREF, dose and dose-rate effectiveness factor.

In medical imaging, patient doses may exceed these values (Table 1). Some interventional procedures may result in CAK of several Gy (Fig. 2). Incident air kerma values of 4–8 mGy at the patient entrance reference point may result from some abdominal digital subtraction angiography images obtained with radiation pulses of 40–80 ms. This is equivalent to instantaneous dose rates of 5 Gy min^{-1}. Operator dose (incident air kerma) at the typical working position is around 1/1000 of incident air kerma at the patient's skin, so the instantaneous dose rate to an unprotected operator may reach approximately 5 mGy min^{-1}. During interventional cardiology procedures, air kerma at the patient's skin of 0.5 mGy frame^{-1} can be reached during cineradiography runs, with radiation pulses of 5 ms. This results in an air kerma rate of 100 mGy s^{-1} (6 Gy min^{-1}) at the patient's skin. This dose rate is much higher than the 6 mGy h^{-1} reported in *Publication 99* (ICRP, 2005).

6. CONCLUSIONS

Radiation protection programmes and optimisation strategies for medical imaging should take into account the new thresholds for tissue reactions. Optimisation strategies should attempt to minimise the possibility of exceeding the thresholds for the heart, brain, and lens of the eye in patients, both for individual high-dose exposures (e.g. complex interventional fluoroscopy procedures) and for multiple moderate-dose exposures (e.g. a patient who has or will undergo repeated brain perfusion CT examinations or interventional fluoroscopy procedures). This implies that patient dose metrics should be recorded and reported for every patient and every such examination. Also, if the dose to the brain, heart, or lens of the eye is predicted to exceed 0.5 Gy, tissue reactions in these organs should be considered in the follow-up of these patients.

These concepts should be included in the education and training of professionals involved in fluoroscopy guided procedures and CT. Attention should also be paid to the proper use of protection tools by staff in interventional fluoroscopy, as absorbed dose to the lens of the eye >0.5 Gy and an increased prevalence of lens opacities has been observed when protection tools are not used or not used properly.

Several Commission documents provide additional advice. These include *Publication 85*, 'Avoidance of radiation injuries from medical interventional procedures' (ICRP, 2000); *Publication 105*, 'Radiological protection in medicine' (ICRP, 2007c); *Publication 113*, 'Education and training in radiological protection for diagnostic and interventional procedures' (ICRP, 2009); *Publication 117*, 'Radiological protection in fluoroscopically guided procedures performed outside the imaging department' (ICRP, 2010); *Publication 120*, 'Radiological protection in cardiology' (ICRP, 2013a); and *Publication 121*, 'Radiological protection in paediatric diagnostic and interventional radiology' (ICRP, 2013b).

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