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Reduction of Exposure of Patients and Staff to Radiation During Fluoroscopically Guided Interventional Procedures

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Abstract The increase in the frequency of interventional procedures and in the number of medical specialties using fluoroscopically guided procedures together with the reevaluation of radiation risks by the International Commission on Radiological Protection (ICRP) and their impact on safety regulations has promoted several international research programs, guidelines produced by professional and scientific societies, and many valuable research articles during the last few years. This review summarizes the most important new findings and brings readers up to date on the subject of radiation safety in interventional radiology. Several key points are highlighted in the sections on guidelines of scientific and professional societies, national and regional patient and staff dose surveys, interventional procedures in pediatrics, automatic patient dose registry and analysis, occupational and lens dose evaluation, lens injury surveys, and patient dose follow-up and hybrid rooms. As a conclusion, the most relevant aspects are summarized as follows: the ICRP recommendation on the use of diagnostic reference levels for interventional procedures and new radiation thresholds for some tissue reactions; a new occupational dose limit for the lens and changes in regulation; guidelines of several medical societies on radiation safety for interventional procedures; relevant international research programs on the topic; advances in radiology systems offering standardized patient dose reports and optimized imaging protocols; more interest and actions in radiological protection training; more interest in patient dose management for pediatric procedures; concern with lens and skin radiation injuries and actions to avoid them; better postprocedural care as part of the quality programs and better clinical follow-up of patients and automatic collection and processing of individual patient doses to help in the optimization and contribute to the tracking of patient procedures and doses.

Keywords Interventional procedures · Staff dose · Patient dose · Fluoroscopy · Interventional radiology · Interventional cardiology · Optimization · Cataracts · Skin injuries · Radiation risk

Introduction

Since the last recommendations of the International Commission on Radiological Protection (ICRP) in 2007 [1] with a revision of the risk factors for stochastic effects and the statement on tissue reactions (deterministic effects) issued in April 2011 [2], several regulatory initiatives and scientific activities have been launched to improve patient and staff radiation safety and to foster optimization actions in interventional radiology. When we use the term "interventional radiology" in this article, we are referring to fluoroscopically guided procedures (FGPs).

In 2011, the ICRP alerted the radiological community to the epidemiological evidence suggesting that there are some tissue reaction effects where threshold doses are or might be lower than previously considered: 0.5 Gy for the lens of the eye (radiation-induced opacities) and also 0.5 Gy for circulatory disease of the heart or brain. Exposure of staff (lens of the eye) and patients to doses of this magnitude could be reached during some complex

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interventional procedures and the ICRP recommended particular emphasis be placed on dose optimization in these circumstances.

It appears that the rate of dose delivery does not modify the incidence of radiation-induced cataracts [3•]. The new proposed threshold dose for radiation-induced eye cataracts of 0.5 Gy is applicable for both short-term and fractionated exposures. Some experimental and animal data suggest that such preclinical radiation-induced lens opacities may progress with time to demonstrable visual disability. The latent period for radiation cataracts is inversely related to the dose.

For occupational exposure, the ICRP recommended an equivalent dose limit for the lens of the eye of 20 mSv/year, averaged over defined periods of 5 years, with the dose in a single year not exceeding 50 mSv [3•]. The immediate consequence was a change in the international basic safety standards (BSS) [4] and in the draft of the European BSS to adopt this new limit [5•].

Many medical specialties in addition to radiology and cardiology use fluoroscopy to guide interventional procedures as an alternative to more complex open surgery procedures that some elderly patients could have difficulty to support owing to the anesthesia or other clinical constraints. This increasing interest of many clinicians for these minimally invasive techniques together with the new international recommendations on radiation safety has promoted several international research activities on patient and staff dosimetry.

Some examples of these international actions are as follows: Retrospective Evaluation of Lens Injuries and Dose (RELID) [6•], Information System on Occupational Exposure in Medicine, Industry and Research (ISEMIR) [7], Safety in Radiological Procedures (SAFRAD) [8] launched by the International Atomic Energy Agency (IAEA), Safety and Efficacy for New Techniques and Imaging Using New Equipment to Support European Legislation (SENTINEL) [9], and Optimization of Radiation Protection for Medical Staff (ORAMED) [10] supported by the European Commission.

Within ISEMIR, the Working Group on Interventional Cardiology is assessing staff radiological protection levels and building an international database of occupational exposures. A survey of regulatory bodies has provided information at the country level on RP practices for staff in interventional cardiology [11•].

The evaluation of the radiation dose to the eye is not a straightforward issue. The current measurement techniques are still not adequately developed and are not available for routine use. Retrospective estimations are necessary to look for correlations with radiation lens opacities. The RELID program is using surveys for retrospective evaluation of staff doses. Participants are asked to provide information on the number of years of work in an interventional laboratory, use of protective screens and eyewear, workload with fluoroscopy time and cine acquisition details, and other information pertaining to the technique that may have a bearing on the radiation dose to the eye lens. The radiation dose is estimated on the basis of this information. The availability of personal monitoring badge data helps in correlation. The location of the staff in the interventional room is also taken into account [6•].

SAFRAD is a voluntary reporting system launched by the IAEA where the patient's dose report and relevant data are included in an international database when these patients are submitted to defined trigger levels or events with risk of skin radiation injuries in fluoroscopically guided diagnostic and interventional procedures [8].

The ICRP has produced three new documents containing recommendations for interventional procedures: publication 117 ("Radiological protection in fluoroscopically guided procedures performed outside the imaging department") [12••], publication 120 ("Radiological protection in cardiology") [13•], and publication 121 ("Radiological protection in paediatric diagnostic and interventional radiology") [14•].

A relevant success of the international cooperation on patient dosimetry with expected important impact on interventional radiology is the "Joint position statement on the IAEA patient radiation exposure tracking" [15•] supported by the European Society of Radiology, the US Food and Drug Administration, the IAEA, the International Organization for Medical Physics, the International Society of Radiographers and Radiological Technologists, the World Health Organization, and the Conference of Radiation Control Program Directors. The scope of patient radiation exposure tracking is to cover all imaging modalities which use ionizing radiation for interventional procedures and radiographic, fluoroscopic, computed tomography, and nuclear diagnostic examinations. The scope also includes radiation dose recording, reporting, and tracking.

This statement and other improvements in the upcoming European regulation [5•] will push the radiology industry and users to develop better strategies to evaluate patient doses, to transfer these values to patient reports (contributing to the patient dose tracking system), but also to make available software to process these dosimetric data and to do some automatic analysis with the results.

Finally, education and training in RP is a key aspect to reduce radiation doses to the staff and to maintain at the appropriate level radiation doses to the patients during interventional procedures. In April 2011, the ICRP published a set of recommendations entitled "Education and training in radiological protection for diagnostic and interventional procedures" [16•].

Some relevant clinicians are promoting radiation safety in their respective specialties. Picano [17•] is trying to attract the cardiology community to the issue. Cardiologists have a special mission to avoid unjustified or nonoptimized use of radiation, since they are responsible for 45 % of the entire cumulative effective dose of 3.0 mSv per head per year to the US population from all medical sources except radiotherapy. Interventional cardiologists have an occupational exposure per head per year two to three times higher than that of radiologists. The most active and experienced interventional cardiologists in high-volume catheterization laboratories have an annual exposure equivalent to around 5 mSv per head and a professional lifetime attributable to excess cancer risk on the order of one in 100. Cardiologists are the contemporary radiologists, but are sometimes imperfectly aware of the radiological dose for the examination they prescribe or practice, which can be in range of the equivalent of 1–60 mSv. A good cardiologist cannot be afraid of life-saving radiation, but must be afraid of radiation unawareness and negligence [17•].

Chambers [18•] recently highlighted the importance of radiation management and radiological protection training. He stated that managing radiation dose is an important component for all invasive cardiac procedures and necessitates accurate dose assessment to establish proper patient notification, education, and follow-up. To manage the radiation dose, it must be measured. Structural and congenital interventions often have longer procedure times, are performed on younger patients, and require further procedures. All physicians and staff involved with interventional fluoroscopy must be properly trained on the basic principles of radiation physics and safety. A qualified medical physicist must be involved with the physician in equipment selection and staff education. The best quality image with the most effective radiation dose provides the best patient care. Radiation dose management involves preprocedural, procedural, and postprocedural dose management. Adverse effects on skin from exposure to radiation occur weeks after the patient has been discharge and require follow-up protocols for detection [18•].

Purpose of This Review

The increase in the frequency of interventional procedures and in the number of medical specialties using FGPs together with the reevaluation of radiation risks by the ICRP and their impact on safety regulations has promoted several international research programs, guidelines produced by professional and scientific societies, and many valuable research articles during the last few years. This review summarizes the most important new findings and brings readers up to date on the subject of radiation safety in interventional radiology. Several key points are highlighted in the different sections as suggestion for work to be done in the coming years to maintain the clinical benefits of interventional radiology with the best level of radiation safety for patients and staff.

Guidelines of Scientific and Professional Societies

During the last few years, several scientific and professional societies have produced guidelines on radiation safety (including patient dosimetry) for interventional radiology [19••, 20••, 21••, 22••, 23•]. Some of these guidelines have been adopted simultaneously by American and European interventional radiology societies [19••, 20••, 21••] and others have been produced by groups of experts and later endorsed by professional societies [24••]. The role of the European Commission in producing some guidelines or final reports of research actions [9, 10, 25••] continues to be especially relevant to help in the optimization of the interventional practices.

Diagnostic reference levels (DRLs) are still a challenge for interventional radiology. The ICRP proposed their application in interventional radiology in 2001 and 2007 [26•], but it still is a long way to their effective application. The National Council on Radiation Protection and Measurements in the USA has published a document on this issue [27] and the ICRP launched a working party in 2012 to also give more specific advice on the use of DRLs in interventional procedures and new imaging techniques.

Key Points

- It is important to continue and support this work of producing guidelines and consensus documents on radiation safety by the scientific and professional societies.
- These documents should be presented and discussed during the scientific congresses of the societies and their application in routine clinical practice should be promoted.

National and Regional Patient and Staff Dose Surveys

Since the European SENTINEL [9] and DOSE DATAMED [25••] programs, very few regional and national patient dose evaluations have been reported in the European Union. The IAEA is also promoting surveys of patient dose data in interventional radiology [28•, 29], and has one of the best collections of radiological protection training material in the world [30•, 31•, 32•]. The European Commission has launched a new program, DOSE DATAMED 2, to collect and analyze data on patient imaging exposures [33].

In Spain, with the technical support of Complutense University and San Carlos University Hospital, the national societies of interventional radiology and interventional cardiology started surveys some years ago involving ten to 12 representative hospitals to collect and analyze patient and staff dose values on an annual basis, to foster optimization actions, and to update periodically the national DRLs [34•, 35•, 36•]. Recently, a wider national program (DOPOES) to collect patient dose data from all X-ray examinations has been promoted by the Spanish regulatory and health authorities, coordinated by the University of Malaga [37], in line with the European action DOSE DATAMED 2 [33].

Key Point

- Patient dose surveys are necessary for real implementation of the optimization strategies and to update the national DRLs (in Europe, this has been included as mandatory in the upcoming European Directive on BSS).

Interventional Procedures in Pediatrics

Paediatrics is an area of special interest, and interventional procedures also have a clear clinical benefit, but radiological protection criteria and proper radiation safety management should be a priority. The ICRP has published a new report on recommendations entitled "Radiological protection in paediatric diagnostic and interventional radiology" [14•].

The IAEA is promoting programs on radiological protection in pediatric interventional radiology in Latin America [38•], and several relevant articles with results on patient and staff doses have been published recently [39••, 40, 41•].

Image Gently, the alliance for radiation safety in pediatric imaging, also has a specific group (Step Lightly) on paediatric interventional radiology [42].

In 2013, the European Commission is expected to launch a program to review in Europe the DRLs in paediatrics including interventional procedures.

Balter [43•] recently commented on the results of an analysis of patient doses at the Children's Hospital in Boston and the dose reductions obtained with a radiation management program [44•]. As recommended by the ICRP [26•], it is suggested that DRLs be applied and possible excessive radiation be investigated if the facility's median value exceeds the published third quartile values.

Ubeda et al. [39••] have published results on a pilot program on patient dosimetry in pediatric interventional cardiology in Chile involving 544 patients and reporting kerma–area product (KAP) (median values from 0.94 to 5.03 Gy cm^2) and cumulative air kerma at the patient entrance reference point (median values from 23.9 to 51.6 mGy) for the four typical age bands (less than 1 year, 1 year to less than 5 years, 5 years to less than 10 years, and 10 years to less than 16 years).

Verghese et al. [44•] have performed a retrospective study on patient doses (from 2005 to 2008, including 3,365 procedures). In this study, they used five age bands and also reported KAP (median values from 7.4 to 34.2 Gy cm^2, until 15 years) and cumulative air kerma (median values from 215 to 467 mGy, until 15 years). They reported a statistically significant decrease in radiation dose after the introduction of a radiation threshold monitoring and notification policy. In the conclusions of this study, it is suggested that their data may help other pediatric interventional cardiologists anticipate radiation doses for different procedures.

Staff doses are also an issue in pediatric interventional radiology. In a workshop organized by the IAEA in 2010 for pediatric interventional cardiology [38•] involving 11 Latin American countries, it was reported that only 64 % of the cardiologists used their personal dosimeters regularly. Ubeda et el. [40] published results from scatter dose measurements in four X-ray systems in Chile using (polymethyl metacrylate) phantoms with thicknesses ranging from 4 to 16 cm to simulate pediatric patients for the different acquisition modes. Scatter dose rates measured at the position of the cardiologist's eyes ranged from 0.8 to 12 mSv h^{-1}. The estimated personal dose equivalent for the lens of the eye may be around 0.5 and 1 mSv throughout a typical pediatric cardiac procedure if additional protection is not used. Simultaneous cine acquisition in biplane systems yielded rates of scatter dose to cardiologists increased by factors from 5 to 21 compared with a single C-arm acquisition case, depending on the geometry.

Key Points

- More data on patient doses in interventional procedures are needed in pediatrics to derive and update DRLs.
- Great differences exist in the published literature. Data from different hospitals and countries should be compared to share experiences regarding X-ray settings and imaging protocols to help improve radiation safety.
- Staff doses are also a topic of concern. Patient doses and scatter dose rates are lower than in adults, but some of the procedures are longer, staff need to be closer to the patient, and radiological protection tools (as a ceiling-suspended screen) are sometimes more difficult to use properly. Also, biplane systems are used, which implies an additional source of staff doses.

Automatic Patient Dose Registry and Analysis

The European regulations and guidelines suggest that patient doses from interventional procedures should be measured and recorded. In some European countries, this measurement and registration is mandatory, and in the upcoming European Directive on basic safety standards [5•] this requirement will probably be included as one of the articles in the Directive.

In the past, patient dosimetry in interventional radiology was performed with a small sample of procedures to calculate mean or median values of different dosimetric quantities as part of the clinical audit and to use the DRLs. With the introduction of digital systems, it is possible to easily collect and archive dosimetric and demographic data from the imaging procedures together with the images, as part of the Digital Imaging and Communication in Medicine (DICOM) headers or in other DICOM services as the modality performed procedure step (MPPS) or radiation dose structured reports.

The advantages are (a) the possibility to process data from all the procedures (instead of only a small sample), (b) to do it automatically, and (c) to process other data (e.g., geometry details as C-arm angulations and distances) from the procedures in addition to dosimetric parameters. The distribution of patient doses in a hospital may be analyzed in full, and not only using some statistical parameters (as median or mean values). Some optimization actions may be launched not only when median or mean values are consistently much higher or much lower than the DRLs, but also when some other parameters are out of the normal range (e.g., the distance of the imaging detector from the patient), or some individual patients could receive doses higher than several times the DRLs. This automatic massive collection of data will allow one, when appropriate, to calculate organ patient doses or skin dose maps to decide if some patients should be included in the follow-up protocol for potential skin injuries.

The analysis of the results needs to be submitted to quality control and should include (a) periodic calibration factors for patient dose quantities reported by the X-ray systems, (b) automatic detection and alerts of high patient doses, (c) statistical analysis to periodically update local DRLs and to make comparisons with the existing national or regional ones, and (d) suggesting corrective actions to fulfill the requirements of the quality assurance programs and the clinical audits.

Some experience has already been gained with this possibility for interventional radiology [45•] by developing an automatic management system (called dose on line for interventional radiology, DOLIR) to archive and analyze the major study parameters and patient doses for FGPs performed in cardiology and interventional radiology in a university hospital in Madrid. The X-ray systems used for this trial have the capability to export at the end of the procedure and via e-mail the technical parameters from the study and the patient doses. An application was developed to query and retrieve from a mail server all study reports sent by the imaging modality and store them in a Microsoft SQL Server database. The results from 3,538 interventional study reports generated by seven interventional systems were processed in the initial analysis. In the case of some abnormal values of the technical parameters or patient doses, alarms were added to receive malfunction alerts so as to immediately take appropriate corrective actions. The system is now adapted to also use the MPPS DICOM service and it is also expected to be adapted for the DICOM radiation dose structured reports.

The Society of Interventional Radiology Standards of Practice Committee in North America recently published a document entitled "Quality improvement guidelines for recording patient radiation dose in the medical record for fluoroscopically guided procedures" [23•]. The document states that ideally all available patient radiation dose data should be recorded and recognizes that in the future this may become an automatic process, as the US Food and Drug Administration has expressed an intention to establish requirements for computed tomography and fluoroscopic devices to provide radiation dose information for use in patient medical records or a radiation dose registry. The guideline suggests adequate recording of different dose metrics for all interventional procedures requiring fluoroscopy, including skin dose mapping. It also suggests the establishment of thresholds to prompt reviews.

Some articles have recently been published on software to produce patient skin dose maps [46•], and the radiology industry is also applying itself to this issue.

Key Points

- Owing to the increase in the number of interventional procedures in large hospitals (several thousand per year) and the many clinical services that can be involved, automatic systems are required to archive and process patient dose data.
- Patient follow-up for potential skin injuries is an ethical issue, is recommended by several international and national guidelines, and is required by some national regulations. It should be implemented in the quality programs.
- Skin dose mapping is one of the tools that industry should offer in the next generation of X-ray interventional systems.
- DICOM header information, MPPS, and radiation dose structured reports are significant advantages, but more effort will be necessary for the automatic processing of

the relevant dosimetric and additional data from the procedures to verify that the radiological risk is acceptable and to suggest, if appropriate, corrective actions.

- Patient dose tracking is also a compromise adopted by many international organizations, and interventional radiology is one of the major contributors to be included in the upcoming registries.

Occupational and Lens Dose Evaluation

Many of the recent results on lens dosimetry in professionals working in the medical area (especially in FGPs) were obtained during the ORAMED program. Gualdrini et al. [47] made a critical revision of the operational quantity $H_p(3)$, producing a set of air kerma to dose equivalent conversion coefficients for photons from 10 keV to 10 MeV. Carinou et al. [48] published results on Monte Carlo simulations highlighting the important role in the evaluation of lens doses in correlation with many different parameters (tube voltage, filtration, beam projection, field size, and irradiated part of the patient's body). The final results of the simulations of Koukorava et al. [49] indicate that for overcouch irradiation the eyes and the hands are about six times more exposed compared with the case where the tube is below the operating table and that for the lateral left anterior oblique projection, placing the ceiling-suspended shield at the left side of the operator is twice as effective for protection of the eyes compared with the case where it is placed above the patient. Clairand et al. [50, 51] evaluated several active personal dosimeters for interventional radiology in laboratory conditions and in hospitals, raising the difficulties of measuring in pulsed radiation fields. Domienik et al. [52] reported results obtained in interventional cardiology and interventional radiology facilities in 34 European hospitals. They found that the highest eye lens doses were measured during embolizations and concluded that it is difficult to find a general correlation between KAP and extremity or eye lens doses. Doses (for a single procedure) up to 2.4 mSv to the eye during brain embolization were reported by Koukorava et al. [49] during the ORAMED survey. Donadille et al. [53•] reported that for 643 interventional cardiology procedures monitored, in 31 % of the cases no collective protective equipment was used. Nikodemová et al. [54•] reported results on extremity doses, and concluded that a ceiling-suspended shield reduced the median doses to the fingers and wrists by a factor ranging from 1.9 to 2.3. A reduction of the doses to the legs by a factor of 5–7 was observed in the case of femoral access (with a table shield) compared with the radial access. Several authors of the ORAMED team presented very useful results on calibration conditions [55], lens passive dosimeters [56], and active dosimeters [51, 57•]. Vanhavere et al. [58••] reported the final results of the ORAMED project for eye lens doses in interventional radiology and cardiology (using thermoluminescent dosimeter and plastic bags). Median values of eye doses (less than 40 μSv per procedure) and the ratio between eye doses and KAP for cardiac procedures of 0.7 μSv/(Gy cm^2), indicative of the use of a ceiling-suspended screen (or goggles) to protect the eyes, were used in most of the measured procedures. Vanhavere et al. concluded that with an annual dose limit of 20 mSv for the lens of the eye, many physicians could surpass the limit.

The ORAMED team also published several articles containing the evaluation of active personal dosimeters in laboratory conditions for continuous and pulsed X-ray radiation fields [51] and on their use in clinical conditions using phantoms and operators [57•]. Their conclusion is that the response of most active personal dosimeters is roughly within ±30 % compared with a thermoluminescent dosimeter as a reference. During the final workshop of ORAMED, Vano et al. [59•] also presented the initial experience on the use of active personal dosimeters with a real-time display inside the catheterization rooms of cardiology and interventional radiology laboratories. Also in this case, a comparison with thermoluminescent passive dosimeters was made, and the results were satisfactory [60•].

The Working Group on Interventional Cardiology of ISEMIR [11, 24] has produced a set of recommendations for occupational radiological protection and concluded after a wide international survey that the dose received by cardiologists during percutaneous coronary interventions, electrophysiology procedures, and other interventional cardiology procedures can differ by more than an order of magnitude for the same type of procedure and for similar patient doses. Simple methods for reducing or minimizing the occupational radiation dose are included in the recommendations. It is highlighted that effective use of these methods requires both appropriate education and training in radiological protection for all interventional cardiology personnel, and the availability of appropriate protective tools and equipment. Regular review and investigation of personnel monitoring results, accompanied as appropriate by changes in how procedures are performed and equipment is used, will ensure continual improvement in the practice of radiological protection in the interventional suite.

Key Points

- It will still be necessary to evaluate further the lens doses (and in some cases hand/finger doses) in professionals involved in FGPs. The range of variation may be very high, from some μGy to several mGy per procedure, depending on the complexity of the procedures and on the use of radiological protection tools.

- During some surveys, with professionals working under routine conditions, it is possible to measure very low doses (there is a logical tendency to work with better protection during these evaluations). But the reality is that in many interventional laboratories professionals are still not well protected during their daily practice and this situation is sometimes difficult to correct because there is still a great percentage of practitioners who are not using, or are using in an irregular way, their personal dosimeters. In these situations, the monthly occupational dose derived from the personal dosimeter readings is near the background value.
- Another problem to be solved is that most personal dosimeters are worn under the lead apron and it is difficult to estimate radiation doses to the unprotected organs and tissues with these dosimeters worn under aprons.
- Special attention should be paid to the other professionals (different from the medical specialist performing the procedure) present in the catheterization laboratories during the procedures (nurses, anesthetists, technicians, ecographists, etc.), who in many situations do not have the opportunity to be protected with a shielding screen and are very close to the patients during fluoroscopy and imaging procedures.
- Active dosimeters are an excellent opportunity to improve occupational protection during interventional procedures. In addition to having information on the occupational dose during the procedure, it is possible to record the values of the accumulated dose and the instantaneous scatter dose rate, to compare occupational doses registered among different staff during the procedures, to establish correlations between occupational and patient doses, and to establish correlations between staff doses and geometry and radiographic factors used during the procedures. All these features allow retrospective audits of occupational doses with excellent educational feedback.
- The possibility to also have dosimeters of this kind positioned at the C-arm or at another representative position of the operators allows one to know the level of scatter dose produced during the different procedures and to estimate the doses to which occupational professionals present in the room during the procedures are exposed. The value recorded at the C-arm, with the appropriate corrections for distance and attenuation of the protection tools (when used), allow one to make quite realistic estimations of occupational doses, which is especially important for professionals who "forgot" to wear their personal dosimeters.

Lens Injury Surveys

Since the IAEA launched the RELID program [6], many surveys have been made mainly in Latin America and Asia (in most cases on interventional cardiology professionals) [61••, 62••] to measure the percentage of posterior subcapsular lens opacities typically associated with exposure to ionizing radiation. Opacities were measured by dilated slit lamp examinations using direct and, in some cases, retroillumination and using a modified Merriam–Focht scoring system. Ocular radiation doses were derived retrospectively, by application of experimental findings to questionnaire responses by participants. Records of occupational doses allowing verification of the real occupational doses received were not available. In most cases, the subjects were volunteers attending cardiology congresses. The control groups were nonexposed individuals with similar age distribution and working activity. Estimated eye doses during the full professional life (typical mean number of years for cardiologists 10–20 years, and 5–10 years for nurses) with scarce use of protection tools in most cases resulted in doses of several sieverts for cardiologists and around 1 Sv for nurses. The percentage of lens radiation injuries was in the range of 40–55 % for cardiologists and 30–45 % for nurses and technicians. The percentage of posterior subcapsular opacities was less than 10–12 % in the control groups. A certain correlation was found between the estimated lens doses and the severity of the lens opacities.

A similar survey called Occupational Cataracts and Lens Opacities in Interventional Cardiology (O'CLOC) was conducted in France [63•] and involved 126 interventional cardiologists with 22 years of work experience (mean value) and retrospective cumulative lens dose estimation of 0.42 Sv (mean value). In this case the results of the clinical eye examination were classified using Lens Opacities Classification System III in a sample of 106 cardiologists [64•]. Posterior subcapsular opacities were detected in 17 % of the cardiologists but in only 5 % of the control group.

Key Points

- There are great differences between the results of the surveys of the RELID program (mainly in Latin

America and Asia samples) and the French O'CLOC program. Estimated retrospective lens doses were much lower in France, but the regulations are stricter and the radiological protection culture is more developed in Europe.

- One aspect that will need more research is the estimation of retrospective lens doses and if the scoring system to identify and classify lens opacities could influence the differences (lower in France in comparison with the RELID survey) in the percentage of opacities in the control group.
- It is clear that work in interventional radiology without the use of protective tools involves a significant risk of lens opacities.

Patient Dose Follow-Up and Hybrid Rooms

In addition to the compilation of patient and staff doses in interventional procedures outside the radiology and cardiology departments reported in ICRP publication 117 [12••], only a few articles have been published reporting data on these procedures. Tsapaki et al. [65•] reported radiation doses for patients and staff during interventional endoscopic retrograde cholangiopancreatography procedures. A sample of 157 endoscopic retrograde cholangiopancreatography procedures were included in the study. Endoscopist occupational doses monitored using a thermoluminescent dosimeter worn over the lead apron were negligible (using appropriate protective measures: lead apron, collar, and two lead-articulated ceiling-mounted shields). Patient doses resulted in a median KAP of 3.1 Gy cm^2 and KAP in the range 0.1–106.7 Gy cm^2.

More extensive results have been published on cardiology and interventional radiology. Sawdy et al. [66•] have published values on patient and staff doses (and follow-up of skin injuries) in complex congenital and structural cardiac interventions and the different steps to improve radiation safety. They considered that standard follow-up protocols are often inadequate in detecting all patients who may have sustained radiation burns. The study was made in a single center in the USA, in four steps:

1. Phase 1 (413 procedures): follow-up based on fluoroscopy time only; cine acquisition and fluoroscopy at 30 fps.
2. Phase 2 (458 procedures): cine acquisition at 30 fps but fluoroscopy at 15 fps.
3. Phase 3 (350 procedures): cine acquisition at 15–30 fps, fluoroscopy at 15 fps, and use of an added radiological protection drape.
4. Phase 4 (89 procedures): cine acquisition at 15–30 fps, fluoroscopy at 15 fps with a noise-reduction filter and fluoro-record capabilities.

There was a significant reduction in the median cumulative air kerma between the four study periods (710 vs. 566 vs. 498 vs. 241 mGy, $P < 0.001$), even though the overall fluoroscopy times remained very similar (26–23 min). There was a trend towards lower physician radiation exposure over the four study periods (137 vs. 126 vs. 108 vs. 59 mrem, $P = 0.15$). Fifteen patients with radiation burns were identified during the study period. When the protocol was changed to a dose-based follow-up protocol (phase 1 vs. phase 2), there was a significant increase in the incidence of detected radiation burns (0.5 vs. 2 %, $P = 0.04$). Sawdy et al. concluded that dose-based follow-up protocols are superior in detecting radiation burns when compared with fluoroscopy-time-based protocols. The global rate of skin burns (15 cases in 1,310 procedures) in this study was 1.1 in 1,000.

Two other recent articles have reported data on the incidence of skin injuries and the criteria to include patients in the follow-up protocol. Vano et al. [67•] in a study on cardiac procedures following the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) [19••] and American College of Cardiology/American Heart Association/Society for Cardiovascular Angiography and Interventions recommendations [68] reported rates of 3.1 in 1,000 cases for follow-up and 0.3 in 1,000 cases for skin injuries. The second article was on neuradiology procedures [69•] applied in the same hospital and following the CIRSE and Society of Interventional Radiology guidelines (peak skin dose greater than 3 Gy, air kerma at the patient entrance reference point greater than 5 Gy, KAP greater than 500 Gy cm^2, or fluoroscopy time greater than 60 min) [19••]. After optimization, and using the peak skin dose as the main criterion, Vano et al [69•] reported a follow-up rate of 1 %.

The number of hybrid rooms for conventional surgery and FGPs is expected to increase and radiological protection aspects are an important issue to consider. Some recommendations have been made by the Multispecialty Occupational Health Group in the USA [70•]. There is a need to involve and consider medical and paramedical personnel (new staff culture), engineering aspects, industrial interests, and economical aspects. A team approach, involving specialists working together rather than in competition, is most likely to lead to better outcomes for patients. Hybrid rooms need special structural and dimension considerations, ventilation, cooling and other ancillary infrastructure, infection control risk assessment, and special X-ray and imaging systems (including patient table, software, imaging protocols, image archiving, and supporting equipment). Worker and patient safety (including radiation) should be one of the priorities.

The critical aspects concerning radiation risks to be considered should be the following: appropriate structural shielding, training in radiological protection for all the staff, appropriate personal dose monitoring, nomination of a person responsible for radiological protection aspects during procedures (with the support of a qualified medical physicist), patient dose monitoring and recording, ceiling-suspended screens (two or three units could be necessary), and enough protective garments for all the staff.

Key Points

- Patient and staff doses in FGPs outside radiology and cardiology departments are, in general, lower than those reported in such departments (if professionals are properly trained in radiological protection and if radiological protection tools are available), but more complex and more sophisticated X-ray systems are expected in the future, with a potential increase of radiation risks.
- Quality assurance programs should include patient and staff dose evaluation, and recording and analysis of the results obtained.
- The methodology for clinical follow-up of potential skin injuries should also be established. European and North American societies have published guidelines to orientate practitioners on this methodology.
- The percentage of patients requiring follow-up should be reported.
- Hybrid rooms for FGPs require a dedicated specific radiological protection program.

Conclusions

We are seeing an impressive increase in the use of interventional procedures for more complex procedures and they are being used by more medical specialties owing to the undisputed clinical benefits. However, practitioners, scientists, manufacturers, and regulators have an obligation to promote the best level of radiation safety for patients and staff. We summarize the most relevant aspects of this review as follows:

1. New ICRP recommendations in 2007 with new risk factors and use of DRLs for interventional procedures.
2. New ICRP thresholds for tissue reactions and a new occupational dose limit for the lens in 2011. Also, ICRP recommendations on radiological protection training.
3. Update of regulations and many guidelines produced by scientific and professional societies.
4. Relevant international research programs offering a scientific basis for new regulation and trying to help in its implementation.
5. Great advances in radiology systems offering standardized patient dose reports and perhaps skin dose maps in the future, together with new acquisition and postprocessing methods to improve diagnostic information and reduce patient doses (optimized imaging protocols).
6. More interest and actions in radiological protection training and certification (IAEA and many scientific societies).
7. More interest in pediatric interventional procedures and in patient dose management.
8. Concerns with lens and skin radiation injuries and actions to avoid them, promoting better protection and better dosimetry. Expecting the impact of active personal dosimetry.
9. Better postprocedural care as part of the quality programs and better clinical follow-up of patients.
10. Automatic collection and processing of individual patient doses to help in the optimization using DRLs and updating their values. Contribution to patient procedures and dose tracking.

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