Minimizing Radiation Risk to Patients and Staff

The ultimate goal of radiation protection in fluoroscopically guided interventional procedures is optimizing the administered radiation dose.

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With the constantly growing use of fluoroscopically guided interventional procedures (FGIPs), concerns over medical radiation exposure have received more attention in the medical literature, European Union regulations, and press, as well as from members of the public.[1,2] Any interventionist should keep in mind that there is a "Gordian knot"–type connection between patient and operator exposure, and decreasing the patient dose will result in a proportional decrease in the scatter dose to the operator. Clearly, the connection is not linear, as it heavily depends on our working habits and availability of personnel protective tools. These methods are described in detail in another article of this *Endovascular Today* issue.

Technology and medical device development have changed the way health care is delivered to patients during the last few decades. The increasing use of image-guided interventional procedures in medical practice is due to the demonstrated benefits of these procedures.[1,3] FGIPs are now considered the gold standard of care in many diseases of both vascular and nonvascular origins and have almost completely replaced traditional surgical procedures in several fields. A good example is the gradual transition from traditional cardiovascular surgery to endovascular therapies. It has to be noted that in each and every case, the FGIP has to be justified from the point of view of radiation protection.[4-6]

PRINCIPLES OF PATIENT RADIATION PROTECTION

The system of radiological protection promoted by the International Commission on Radiological Protection (ICRP) and adopted by most of the countries in the world is based on the principles of justification, optimization, and dose limitation (Figure 1). Medical exposure of patients has unique considerations that affect how the fundamental principles are applied. Dose limits are not applied to patients.[5]

The medical use of radiation should be justified, as is any other exposure situation, although that justification usually lies with the medical professional rather than with
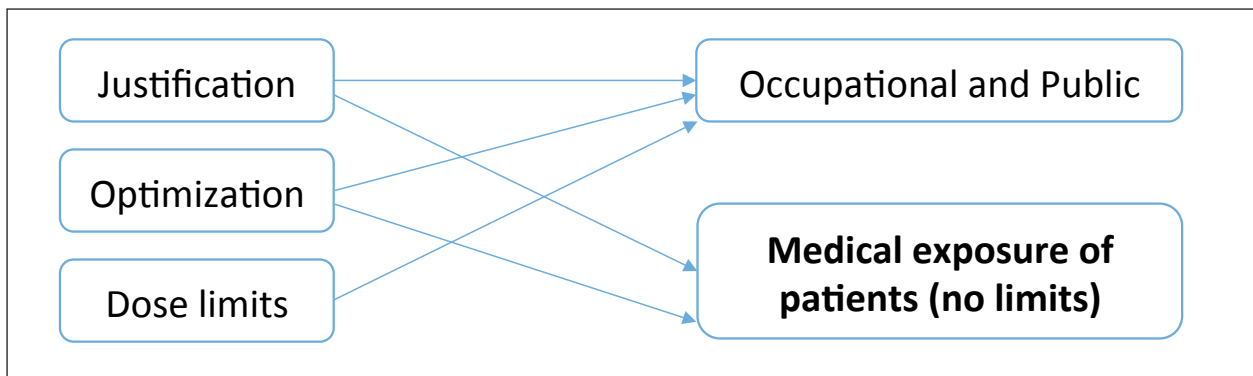

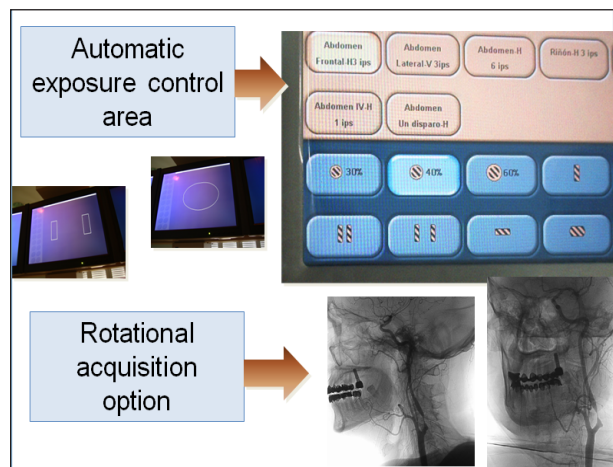Figure 1. Basic principles of patient radiation protection.

Figure 2. The optimization of the procedures requires the evaluation in dose and image quality of the different imaging acquisition protocols. In some x-ray systems, the automatic dose control may be selected (upper part in the figure), and rotational acquisition (lower part in the figure) may have a different dose per image depending on the image quality needed.

government or regulatory authorities. The responsibility for the justification of the use of a particular procedure is shared between the referring physician and interventionist. Medical exposures should be justified in advance, taking into account the specific objectives of the exposure and the characteristics of the patient involved.[1,4,7]

The basic aim of optimization of radiological protection for diagnostic imaging and interventional procedures is to adjust imaging parameters and protective measures in such a way that the required image is obtained with the lowest possible dose of radiation and maximal net benefit (Figure 2). The ALARA (as low as reasonably achievable) principle in medical imaging is only part of the concept of optimization. More precisely, the entire concept implies keeping patient exposure to the minimum necessary to achieve the required medical objective (diagnostic or therapeutic). In diagnostic imaging and FGIP, it means that the number and quality of images are sufficient to obtain the information needed for diagnosis or intervention.[6,8]

X-RAY AND IMAGING SYSTEM PROTOCOLS AND SETTINGS

The selection and installation of the x-ray and imaging system is a relevant issue and should be made by an interdisciplinary teams taking into account the variability of procedures (and the workload) to be carried out at the interventional laboratory or hybrid surgical theater. Electrotechnical Commission Standard 60601-2-43

requires that the interventional x-ray equipment provides a radiation dose structure report (RDSR).[9] The standard also requires a list of protective devices and accessories recommended when the interventional x-ray equipment is employed for FGIP.[10-12]

A medical physics expert should verify basic quality controls (involving aspects of radiation doses and image quality) recommended by the local or international guidelines.[10] Radiation dose settings and image quality for the different acquisition protocols should be measured. Radiation doses and image quality should be verified with appropriate phantoms and in a sample of patients as a cooperative work between the medical physics expert, radiographer, and interventionist.[11]

A challenge in the new x-ray systems for image-guided intervention is the evaluation of the different postprocessing software and its impact on image quality and patient doses. Such assessment is not always possible with test objects and phantoms, and the cooperation of the manufacturer, medical physics experts, and interventionists is essential. If the possible patient dose reduction is significant, particular diagnostic reference levels may be established for the cath labs using this kind of software. Formal acceptance tests should be conducted prior to the first clinical use of the equipment and repeated after major changes or repairs.[13]

IDENTIFYING THE MOST COMMON INTERVENTIONAL PROCEDURES PERFORMED IN THE CATH LAB

In interventional cardiology, the most common procedure performed is diagnostic coronary interventions. Percutaneous coronary interventions (PCIs) are performed following the diagnostic procedure in more than 55% of cases. PCI can be a short procedure but can sometimes be very long with significant radiation. In recent years, PCI is performed in more complex anatomies that, in the past, were referred for bypass surgery. In many cath labs, PCI is performed in cases of chronic total occlusions, complex calcified arteries, bifurcations, and multivessel disease. The average procedure time, and thus the amount of radiation, has increased. A shift of the access site to the radial approach has been seen worldwide, mainly due to patients' preferences and fewer access site complications.[14] However, compared with the traditional femoral approach, the radial approach is generally associated with higher radiation exposure, especially in centers with lower procedure volume and less experienced operators.[15]

Another type of procedure that we see more frequently in the cath lab is structural heart interventions—mainly transcatheter aortic valve replacement

(TAVR), which is expected to include lower-risk patients with aortic stenosis in the near future. In these procedures, a larger group of medical staff is required, and thus exposed to radiation, compared with PCI. During the TAVR procedure in many centers, there are two interventional cardiologists, a surgeon, an anesthesiologist, and an echocardiography cardiologist. Usually, more of the nursing staff is also needed than with PCI. The procedure time is similar to an average PCI; however, the patient is exposed to an additional relevant amount of radiation, as they are submitted to cardiac CT angiography (CTA), which is used to size the aortic annulus and select the optimal implantation plane, valve type and size, and which access to use.[14,16]

The emerging field of interventional oncology, which is based on minimally invasive oncologic treatment, combines various imaging and treatment modalities. The benefit to the patient with the right indication is considered to significantly outweigh the radiation risks, which come via the diagnostic/interventional appliance of the chosen modalities. Transarterial embolization therapy is a superselective endovascular approach to treating the tumor via its feeding vessels, which are blocked. It can be combined with the application of transarterial chemoembolization or a radioembolic substance called selective internal radioembolization therapy. In order to see, reach, and treat a tumor with ablation therapy, different imaging modalities can be used including CT, ultrasound, or two- or three-dimensional (3D) fluoroscopy based on cone-beam CT (CBCT). A tumor embolization procedure with live image guidance via the vasculature is mostly performed using a fluoroscopy system that is capable of performing CBCT. The main radiation dose for these procedures is based on the fluoroscopy and digital subtraction angiography (DSA) runs. Only a small part of the procedural dose during these interventions is usually attributed to the 3D imaging with CBCT.[1,3,7]

OPTIMIZATION OF IMAGING PROTOCOLS

One of the basic tools to help optimize radiation protection in diagnostic imaging and interventional radiology is the use of diagnostic reference levels (DRLs). DRLs for a particular procedure are used to verify that patient doses do not significantly deviate from those achieved at peer departments for that procedure. However, the application of DRLs alone is not sufficient for optimal protection; the diagnostic quality of the corresponding image(s) must also be evaluated.[17]

A critical aspect to be considered when applying DRLs in FGIP is the complexity of the procedure. The impact of the complexity of interventional cardiology procedures has been estimated in European research programs, with

multiplicative factors in patient doses of around 2 to 3 for simple, medium, and more complex procedures.[14,17] Less experience exists for interventional noncardiac procedures. A recent survey promoted by the Spanish Society of Vascular and Interventional Radiology obtained higher multiplicative factors from 3 to 5 for patient doses (reported as kerma area product [KAP]) for transjugular hepatic biopsy, uterine fibroid embolization, hepatic chemoembolization, femoropopliteal revascularization, and iliac stenting.

The optimization strategy requires collaborative work between the interventionists, medical physics experts, and radiographers. Image quality or, more generally, the diagnostic information obtained with the different imaging modes (fluoroscopy, cine, DSA, and rotational angiography) should be considered in addition to the patient dose values in the optimization process. It should be noted that involvement of the manufacturer engineers is very useful to refine the technical parameters during the optimization process for imaging acquisitions (ie, dose per pulse, pulse time, number of pulses per second, additional filtration, etc).

IMPORTANCE OF PREPROCEDURAL IMAGING

Good preprocedural imaging allows proper planning of access, choice of selective catheters for quick access, and safe and accurate performance of the intervention. Invasive diagnostic vascular procedures have been replaced by noninvasive techniques such as color Doppler ultrasound, CTA, and magnetic resonance angiography (MRA). Endovascular interventions traditionally include diagnostic angiography followed by an FGIP in the same session. Use of invasive diagnostic angiography is constantly reducing and being replaced by routine preprocedural noninvasive cross-sectional imaging. Color Doppler ultrasound, CTA, coronary CTA, and MRA are advocated, with a clear preference for the modalities that do not require use of ionizing radiation (ie, ultrasound, color Doppler ultrasound, and MRA).

Compared to nuclear medicine, coronary CTA is expected to take a greater role as a result of reduced radiation protocols. CTA and MRA are readily available and highly accurate noninvasive vascular imaging tools. Some vendors already offer modern angiography systems and CT in the same room using the same pivoting table. Reconstructed images from MRA or CTA allow accurate decision making for treatment recommendations concerning both the anatomical level (as they provide a perfect road map) and the technique of endovascular treatment, thus reducing intraprocedural exposure.[1,18]

In another arena, the routine use of CTA for acute gastrointestinal bleeding as a first-line modality

provides a time-efficient method for directing and planning patient therapy. CTA has a higher sensitivity than DSA for diagnosing bleeding and its extent. Gastrointestinal bleeding has an intermittent nature, and with CTA being a cross-sectional modality (as opposed to angiography, which is intraluminal and will show an abnormality), it can be especially helpful in providing guidance to the suspected area. As with other CTA examinations, it has the advantage of being a readily available, noninvasive, and rapid procedure while providing information regarding a disease with a diagnosis that can often be cumbersome and difficult.[19]

VASCULAR ACCESS AND ADVANCED GUIDANCE TOOLS

Ultrasound has become a routine guidance tool for any endovascular intervention—venous or arterial—with no radiation at all, high accuracy, and less access-related complications. CBCT with 3D road mapping allows quick and accurate catheterization of any vessel anatomy without the need for additional image acquisition.

TRAINING STAFF IN RADIOLOGICAL PROTECTION

According to Medical Radiation Protection Education and Training project in the European Union, knowledge of radiation protection by itself is not enough, and further skills and competencies are required.[20] Annual training in radiation protection and dose management should become an essential part of FGIP teams' training process as a methodology to ensure that all staff comply with appropriate monitoring and that lead screens, aprons, glasses, and other methods of radiation shielding are available and used appropriately. Patient and staff dose management and radiation protection training should therefore be an integral, essential component of any training.[9,20]

FGIPs are team dependent, and therefore, special attention should be given to this aspect, also taking into consideration that most of the interventions are performed in a stressful environment due to patient fragility and procedure complexity. Thus, each team member must be knowledgeable about the entire procedure and also about each staff member's role and responsibilities.

The complexity of FGIP calls for the need for stable teams to allow the establishment of well-known routines to decrease procedure time, maximize the equipment capability, and consequently optimize the procedure, which has clear benefits for the health system, hospital performance, health care professionals, and especially the patients.[15,17,20] The only reliable, scientifically validated concept that meets all of these require-

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KEY ASPECTS FOR PROPER PROCEDURE PLANNING AND MANAGEMENT OF PATIENT RADIATION RISKS

- Proper knowledge of your x-ray system and the dose and image quality settings for the different existing protocols is very important.

- Audit the proper use of all the available options to reduce patient doses (eg, virtual collimation, wedge filters, image detector close to the patient, use of low-dose fluoroscopy mode, archive useful fluoroscopy runs, etc).

- Perform appropriate periodic quality control and dose calibration of your x-ray system.

- Have a system for collecting, archiving, and processing patient dose values for all the interventional procedures performed in your cath lab, and perform a periodic comparison with DRLs as part of the clinical audit.

- Identify procedures with high patient skin doses, and implement a protocol for clinical follow-up of those patients.

- Be aware of previous procedures performed on your patient and the level of radiation dose imparted.

- Routinely use power injectors for contrast material injections when feasible.

- Obtain appropriate training in radiation protection and dose management (initial and periodic) for all the staff involved in interventional procedures.[21-23]

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ments is medical simulation.[24] Implementation of medical simulators can help the FGIP team to improve skills in procedure performance. Simulators have proven to be efficient and safe tools for education and training, as the team can rehearse procedures in an interventional laboratory environment without radiation and without the risk of a patient complication.[1,24]

Endovascular simulators acquire the CTA or MRA images and process them into the volume rendering and/or 3D images, as well as angiography-like images, thus creating a realistic environment.[1,24] Any physician involved in FGIP has to have adequate basic training. Clearly, such training should be based on universally validated standards and means for performance evaluation and follow-up. So far, there are no international intersociety standards for endovascular image-guided intervention simulation to train in medical curricula.

Although simulation is an extraordinary and versatile tool for training across the domains of learning, it must be used appropriately within relevant parts of defined target curricula. Endovascular training should use simulations that have been shown to be a valid representation of the steps of the training objective, replicated with an appropriate level of fidelity (ie, realism of replication).[1,24]

Some vendors have developed a radiation model that takes into account the patient anatomy, C-arm geometry, and operator-controlled settings. It dynamically calculates realistic air kerma, KAP, peak skin dose (PSD), and entrance surface air kerma readings. The delivered dose affects the degree of noise on the simulated fluoroscopy, which allows it to assist in optimal management of complex situations. Moreover, there are a number of instructive visual heat maps with a live display of current dose distributions, both for patient skin dose and for scatter to the operator.

The endovascular interventionist is in full control of the procedure and the disposables, but in many instances is completely dependent on the radiographer. A recently published article assessed whether changing from radiographer-controlled imaging to a system of operator-controlled imaging would influence radiation exposure, screening time, or contrast dose. The authors have clearly shown that operator-controlled imaging allows surgeons and interventional radiologists to perform endovascular aneurysm repair with greater independence while significantly reducing the delivered radiation dose.[25]

PATIENT DOSE REGISTRY AND MANAGEMENT: USE OF DIAGNOSTIC REFERENCE LEVELS

The new European Directive on Basic Safety Standards document indicates that the information relating to patient exposure will form part of the report of the medical radiological procedure in the European Union. The directive also states that the member states of the European Union should promote the establishment and the use of DRLs for patient doses.

ICRP defines DRLs as tools used in medical imaging to indicate whether, in routine conditions, the levels of patient dose for a specified imaging procedure are unusually high or low.[4] If so, a local review should be initiated to determine whether protection has been adequately optimized or whether corrective action is required.

Automatic patient dose registry systems for interventional radiology and cardiology procedures may be useful for the following purposes: (1) registering the information relating to patient exposure in the patient's medical exposure report, (2) auditing patient doses in a
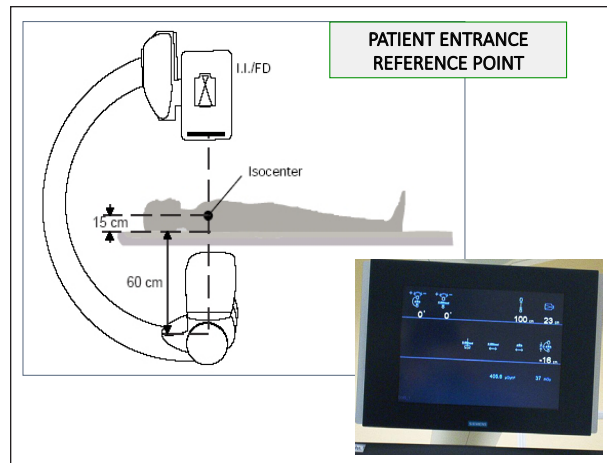

Figure 3. The position of the patient entrance reference point where the CAK is measured or calculated by the x-ray systems. The inset lower part of this figure illustrates how the patient dosimetric data are shown inside the catheterization room by KAP (μGy $\cdot$ m^2) and CAK (mGy).

particular cath lab by comparing with local and national diagnostic reference values for the different interventional procedures, (3) deciding if corrective actions would be appropriate, and (4) identifying patients with high skin dose procedures.[11]

The first three objectives require that automatic systems register information provided by the x-ray system in a database to allow further processing and analysis. For the fourth objective, the system must be able to identify patients who could show tissue reactions after procedures or have shown reactions after previous procedures performed at the same or at different hospitals and for whom a manual analysis by a medical physics expert would be required to estimate the PSD and the most irradiated area of the skin. PSD is the highest radiation dose at any portion of a patient's skin during a procedure and can be calculated using the radiation and geometric parameters of the different radiation events during the procedure.

The most common radiation quantities provided by the interventional x-ray systems are the KAP (usually measured in Gy $\cdot$ cm^2) and the cumulative air kerma (CAK; measured in mGy) at the patient entrance reference point.[20] Figure 3 illustrates the position of the patient entrance reference point where the CAK is measured or calculated by the x-ray systems. Figure 4 shows an example of one of the automatic patient dose registry systems used at the San Carlos University Hospital in Madrid, Spain. The DOLIR (Dose On Line for Interventional Radiology) system allows the automatic management of patient doses in several public hospitals in the Madrid area.

CORRECTIVE ACTIONS AND CLINICAL FOLLOW-UP FOR HIGH PATIENT SKIN DOSES

Corrective actions concerning patient radiation safety should be considered when patient dose parameters are consistently higher (or lower) than the established DRLs or when image quality (or global diagnostic information from all the series of images) is not enough. For FGIP, the patient skin dose is one of the dosimetric quantities to be inspected individually, taking into account the radiation dose already imparted during previous procedures, especially if these procedures have taken place during the last few months. The Society of Interventional Radiology and the Cardiovascular and Interventional Radiological Society of Europe have adopted consensus guidelines that include a set of values for patient follow-up.[8]

Currently, several x-ray system manufacturers[26,27] and existing available software provide information on the skin dose distribution during the interventional procedures with the possibility to optimize the procedure in real time (eg, modifying the C-arm angulations). It is expected that these options will rapidly progress in the near future.

Corrective actions, if considered necessary, should usually be initiated by means of:

- Estimating the impact of the patient size and the complexity of the clinical procedure or procedures.
- Confirming whether the x-ray system is working properly and if the existing radiation dose settings for the different acquisition protocols are in the proper range. The last results of the quality controls should be reviewed.
- Verifying the proper use of the imaging protocols and radiation dose reduction strategies (looking at the DICOM RDSR and the different radiation events).[24]
- Reporting the results of the evaluation and informing the quality assurance and/or radiation safety committee.[28-30]

CONCLUSION

Minimizing radiation risk to patients during interventional procedures requires a joint effort from all the involved medical professionals, with appropriate continuous training in radiation protection, implementation
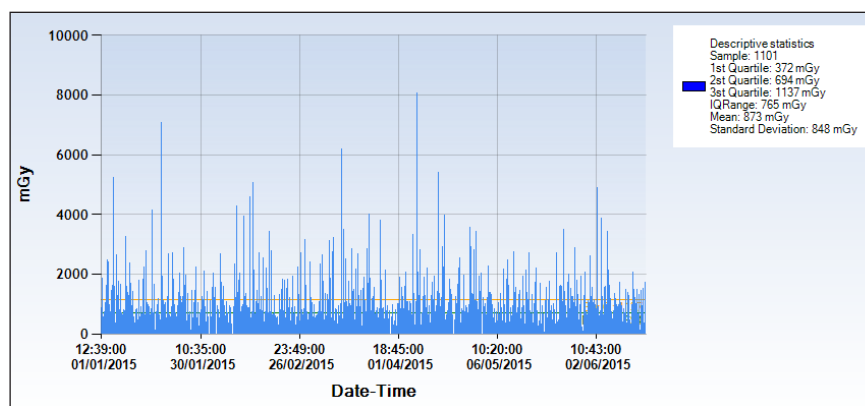

Figure 4. The CAK values from three cardiac catheterization rooms collected during 5 months. It is easy to discriminate procedures with a CAK > 5,000 mGy, which is used as a trigger level in many cardiology labs to evaluate when clinical follow-up for potential skin injuries could be necessary.

of a patient dose registry and management, use of DRLs, and identification of patients with high skin doses for clinical follow-up. The availability of information on previous imaging procedures and integration of radiological protection in the quality assurance programs of the interventional units should be part of the safety culture and medical ethics.[1,31,32] Moreover, minimizing radiation risk to patients also has a direct impact on the reduction of radiation risk to staff in most cases. ■

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