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Protection of the Patient and the Staff from Radiation Exposure During Fluoroscopy-Guided Procedures in Cardiology

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1. Introduction

The volume of diagnostic or therapeutic procedures in cardiology that require the use of ionizing radiation is increasing constantly. Currently, technological developments offer the possibility of exploring not only the cardiac function (measurement of ejection fraction, for example) but also the state of coronary and great vessels. In fact, the management of patients with heart disease often requires the use of investigative techniques using X-rays. For example 3.85 million cardiac catheterizations were performed in the United States in 2002 (Einstein et al., 2007). In Switzerland the last national survey on the exposure of the population by medical radiology revealed that nearly 34 000 coronary angiographies and more than 18 000 coronary dilatations were performed in 2008. They are associated to 65% of the collective dose related to interventional radiology and 8% to that related to all medical X-rays (Samara et al. 2011).

The increase in radiological examinations using ionizing radiation has been mentioned for several years not only in medical journals for professionals but also in the press addressing the general public. For example, in its edition of 17 June, 2007, the *New York Times* questioned the public opinion about the justification of the increasing number of CT examinations.

While most examinations deliver relatively low doses and thus add only a low risk to the procedure itself, there are situations where doses exceed the dose level where an excess risk of death from cancer has been demonstrated. In addition, some complex procedures may result in the occurrence of deterministic effects such as burns to the skin.

The substantial increase of fluoroscopy-guided procedures in cardiology over the past few years has been accompanied by a parallel growth in concern for patient radiation safety and for the safety of the operators who perform these procedures. Thus, radiation safety has become a major issue in radiology departments.

The aim of this chapter is:

- to recall the effects of ionizing radiation on the human body and the radiological risks;
- to introduce the dosimetric quantities (basic and operational) commonly used to quantify those risks;
- to briefly present the principles of radiation protection;
- to provide the tools (actions and means) necessary for operational radiation protection.

2. Radiation effects and dose

The aim of this section is to recall the effects of ionizing radiation on the human body and the radiological risks

2.1 Radiation effects

Effects associated with exposure to radiation are divided into two categories: stochastic and deterministic.

2.1.1 Stochastic effects of radiations

The major risks associated with a radiological procedure using ionizing radiation are due to stochastic effects. They induce a minimal genetic risk on offspring and especially add to the natural risk of developing cancer an additional risk. They strongly depend on age and are three to four times higher in children than in adults. One of the problems related to stochastic effects is that they are considered to be without threshold. It is therefore necessary to justify an examination using ionizing radiation and to be sure that the patient will benefit from the radiological procedure exceeds the associated risk. In addition, when the procedure is justified, the management of the patient dose must be optimized.

2.1.2 Deterministic effects of radiations

Deterministic effects include cataract, skin erythema, epilation, and skin burns at different stages depending on the degree of irradiation of the skin. Unlike the stochastic effects, deterministic effects present a threshold and appear only beyond a certain level of exposure of the skin to radiation. They occur only a few days or months after irradiation and the higher the dose to the skin is, the higher deterministic effects are severe as shown in table 1. Deterministic effects are generally not expected to result from purely diagnostic cardiac investigations, but are sometimes reported with the management of critical cases in particular after some complex interventional procedures such as the dilatation of the coronary arteries (PTCA), recanalizations or thermal ablations. They are certainly rare but they do exist (Suzuki et al., 2008).

Effect	Threshold dose (Gy)	Onset
Early transient erythema	2	Few hours
Temporary epilation	3	3 weeks
Main erythema	6	10 days
Permanent epilation	7	3 weeks
Dry desquamation	10	4 weeks
Dermal atrophy	11	> 14 weeks
Telangiectasia	12	> 52 weeks
Moist desquamation	15	4 weeks
Late erythema	15	6 to 10 weeks
Necrosis	18	> 10 weeks

Table 1. Deterministic effects to the skin

2.2 Basic dosimetric quantities

There are several dosimetric quantities that have been introduced to assess risks and control the exposure of the patient and the staff. This section will briefly describe the fundamental quantities.

2.2.1 Absorbed dose, D

X-rays or gamma rays are indirectly ionizing radiation because energy is released into the tissue through the electrons set in motion by the X-rays or gamma rays, which in turn will make a very large number of ionizations. The energy that these electrons deposit per unit mass of tissue, T, or organ is called the absorbed dose and is denoted D_T. This is the basic physical quantity used to measure the biological effects expected. It has the dimension of one joule per kilogram (J kg^{-1}) and is expressed in gray (Gy). This quantity is used to control the deterministic effects with a threshold of 0.5 Gy.

2.2.2 Equivalent dose, H

To reflect the fact that all types of radiation for a given absorbed dose, do not produce the same effect in humans the concept of dose equivalent in a tissue, T, or organ, denoted H_T was introduced. It is the product of D_T and a weighting factor, w_R, which depends on the type of radiation and expresses its effectiveness.

$$H_T = \Sigma_R w_R . D_{T,R}$$

H_T has the same dimension as D_T (J kg^{-1}), but is expressed in sievert (Sv).
As shown in table 2, X-rays or gamma rays are taken as reference radiation and w_R is therefore equal to unity. Thus, an adsorbed dose of 1 mGy is equivalent to a dose equivalent of 1 mSv

• Radiation type	w_R ($ICRP_{60}$)	w_R ($ICRP_{103}$)
• Photons, electrons, muons	1	1
• Protons, charged particles	5	2
• Alpha particles, heavy nuclei, fission fragments	20	20
• Neutrons	5/10/20, depending on energy	A continuous function of neutron energy

Table 2. Radiation weighting factors according to $ICRP_{60}$ and $ICRP_{103}$

2.2.3 Effective dose, E

The effective dose (E) was firstly proposed by Jacobi in C). The aim of the E was to define a quantity that could be directly related to the probability of a detriment from low-dose exposure to ionizing radiation where only stochastic effects occur. The E concept was adopted by ICRP in 1977 (ICRP26, 1977) and further developed in its Recommendations ICRP60 (ICRP90, 1990) and ICRP103 (ICRP, 2007).
E is defined by the weighed sum of mean tissue and organ doses with radiation weighting factors taking into account a) the different radio-biological effectiveness of various radiations and b) the different sensitivity of tissue and organs with respect to stochastic effects. E is defined as:

$$E = \Sigma_T w_T . H_T = \Sigma_{T,R} w_T . w_R . D_{T,R}$$

where w_T is the tissue weighting factor (see table 3).

• Organ/Tissue	$ICRP_{60}$	$ICRP_{103}$	$ICRP_{103}/ICRP_{60}$
• Gonads	0.20	0.08	0.4
• Colon	0.12	0.12	1.0
• Lungs	0.12	0.12	1.0
• Red bone marrow	0.12	0.12	1.0
• Stomach	0.12	0.12	1.0
• Bladder	0.05	0.04	0.8
• Breast	0.05	0.12	2.4
• Liver	0.05	0.04	0.8
• Oesophagus	0.05	0.04	0.8
• Thyroid	0.05	0.04	0.8
• Bone surface	0.01	0.01	1.0
• Skin	0.01	0.01	1.0
• Brain		0.01	
• Salivary glands		0.01	
• Remainder	0.05*	0.01+	

* ICRP60 remainder tissues/organs: adrenals, brain, kidneys, muscle, pancreas, small intestine, large intestine, spleen, thymus, uterus.
+ ICRP103 remainder tissues/organs: adrenals, extrathoracic tissue, gall bladder, heart, kidneys, lymphatic nodes, muscle, oral mucosa, pancreas, prostate, small intestine, spleen, thymus, uterus/cervix.

Table 3. Tissue weighting factors

2.3 Operational dosimetric quantities

As above indicated to account for stochastic effects the effective dose (E) has to be determined. To estimate E associated with a radiological examination various operational quantities, easy to measure, are used. They are also listed at the end of the examination on the console of the X-ray unit

2.3.1 Entrance dose and dose area product

For radiographic examinations, the operational quantity used is called absorbed dose at the surface at the entrance of the beam in the patient and abbreviated as ESD. The ESD is expressed in mGy and is converted into effective dose, in mSv, by multiplying it by a factor which is for example 0.2 for a chest radiograph.

For fluoroscopy procedures the operational quantity used is called dose-area product and abbreviated as DAP. The unit commonly used is $Gy.cm^2$. Some manufacturers also express the DAP in $cGy.cm^2$ or $\mu Gy.m^2$. To convert the DAP in $Gy.cm^2$ into E in mSv, it has to be multiplied by a converting factor equal to 0.2 in the case of the exposure of the chest region (when $Gy.cm^2$ is used).

Table 4 shows the operational quantity and the effective dose associated with a series of routine examinations in diagnostic radiology.

• Examination	Operational quantity	Typical values	Effective dose (mSv)
• Bite-Wing (dental)	ESD (mGy)	2	0.01
• OPG (dental)	ESD (mGy)	0.7	0.06
• Chest PA	ESD (mGy)	0.1	0.02
• Hip AP	ESD (mGy)	6	0.7
• Abdomen PA	ESD (mGy)	3	1.2
• Coronarography	DAP (Gy.cm^2)	60	12
• PCI	DAP (Gy.cm^2)	80	16
• RFCA	DAP (Gy.cm^2)	130	26
• CTCA	DLP (Gy.cm)	1500	25

Table 4. Operational dose quantity and effective dose for a number of X-ray examinations

2.3.2 Skin accumulated dose

The estimation of absorbed dose at the surface of the skin by fluoroscopy, to account for deterministic effects, is a difficult task since the examination is conducted with changing regularly the incidence X-ray beam. However, it is possible to have an idea of the dose to the skin using a particular operational quantity, called the cumulative dose. This quantity estimates the dose that would have received the skin if the geometry was kept unchanged throughout the procedure. It may be considered that the cumulative dose indicated by the facility in cardiology overestimates the dose to the skin by a factor of 2-3 since several tube-detector incidences are used that distributes the exposure of the skin. If this operational quantity is not available, the skin dose could be estimated from the DAP knowing that we will be much less accurate. To estimate the skin dose in Gy, in a situation where the tube does not rotated around the patient during the procedure one can divide the DAP (Gy.cm^2) by 100 for a well collimated X-ray beam (100 cm^2 : area of the X-ray beam at the entrance of the patient).

2.3.3 Ambient dose equivalent

Another operational quantity used to assess the effective dose delivered to the operator is the ambient dose equivalent, H*(10), at the point of interest in the actual radiation field. It is defined (ICRU, 1992) as the dose equivalent which would be generated in the associated oriented and expanded radiation field at a depth of 10 mm on the radius of the ICRU sphere which is oriented opposite to the direction of incident radiation. This quantity is normalized traceable. It is representative of the effective dose the staff receives.

3. Principle of radiation protection

Radiation protection is assured by respecting three general principles which are: the justification of the practice, the optimisation of the protection and the individual dose limits. The justification of the practice is due to the fact that exposure to ionising radiation has deleterious effects on health. The principle of optimisation is introduced since some of these effects are considered as non-threshold's ones, and thus one has to reduce exposure to levels. The principle of individual limits is introduced as a safeguard to prevent situations where the respect of the two first principles would not be sufficient to protect individuals.

3.1 Justification

The first principle of radiation protection is justification. No exposure is acceptable unless its usefulness is demonstrated. In the medical practice any radiological modality or procedure has to be justified. It should be properly indicated to the diagnostic or therapeutic case. In other words it should be demonstrated that no other non-irradiating non invasive modality can give the same diagnostic or therapeutic results. In order to implement the justification principle, learned society in several countries (USA, UK, France, Switzerland and others) worked out referral guides in order to indicate which radiological modality/examination is suited to which diagnostic or therapeutic case.

3.2 Optimization

The second principle of radiation protection is optimization. When the exposure to radiation is justified, an effort must be engaged in order to keep the radiation dose delivered as low as reasonably achievable (ALARA principle). If justification reflects the will "to do the right thing", optimisation reflects the will "to do it right". In the medical practice the principle of optimization is implemented in different ways contributing together to lower the radiation doses to the patients and to the staff. The quality control of the X-ray unit is important to make sure the optimal settings are used. The auditing of the protocols used for each radiological procedure allows producing the quantity and quality of images sufficient to the diagnostic or therapeutic goal, with an optimum trade-off between image quality and radiation dose, and no unnecessary irradiation of the patient and staff. The use of protecting means contribute to cut down the radiation (direct or scattered) that is not useful in the imaging process. Training, informing, using diagnostic reference levels, all this helps spread a culture of optimization.

3.3 Limitation

The third principle of radiation protection is dose limitation in order to avoid excessive exposure of an individual. The ICRP recommends a set of dose limits for the general public and for people exposed in the course of their occupation (ICRP 103, 2007). The principle of dose limitation applies to health professionals (physicians, radiographers, medical physicists, etc.) but it does not apply to the patient. The sound benefit (diagnostic or therapeutic) from X-rays use implies that higher doses of radiation are tolerated as long as the radiological procedure is justified and optimized.

4. Operational radiation protection

Near a radiological room radiation protection of workers and of public is ensured by the limitation of the weekly ambient equivalent dose through the shielding of the rooms. Surveys have shown that doses to public and workers in such an environment are very low. However there is not ambient equivalent dose limitation near the X-ray imaging unit. Thus, it is mandatory to wear a lead apron when being near a running X-ray imaging device. Many professionals that use fluoroscopy units receive low dose of radiation since they only use these unit a few minutes (or less) per patient. Unfortunately, this is often not the case for cardiologists who can handle very complex procedures that not only expose the patient but also expose the staff present in the suite. Thus an effort to improve the radiation protection should get a high priority.

It is worth mentioning that the exposure of staff is not due to X-ray leakage from the X-ray tube of the fluoroscopy unit. Exposure to the staff is due to the X-ray scatter that is produced when the X-ray beam interacts with the tissues of the patient. Thus, the higher the dose to the skin of the patient the higher the amount of scattered radiation produced. From this, patient and staff exposure are interlinked. One should always remember that the patient is the main source of exposure of the staff. Therefore optimizing the patient dose will improve the staff radiation protection.

4.1 Patient

Patient dose can be quite high but deterministic effects should never be a surprise to the operator. Avoiding as much as possible the appearance of deterministic effects (short term radiological complications) the operator should also minimize the stochastic effects (long term radiological complications).

4.1.1 Patient positioning

The first thing to know is: where the source of radiation and the image detector are. The patient needs to be as far as possible from the source of radiation (X-ray tube). The patient needs to be as close as possible to the image detector.

4.1.2 X-ray tube orientation

The number of X-ray is reduced by a factor of two every 2 to 3 cm of tissue. Nevertheless, the number of photons required to obtain an image remains constant. Thus, the thicker is the patient the higher is the skin rate. Skin dose rate might be also very high when using oblique incidence and one should try to restrict as much as possible incidences where the path of the X-ray in the patient are long.

4.1.3 Image quality level

Fluoroscopy units provide the user with several image quality levels during fluoroscopy and cine runs. There is no free lunch, the better the image quality the higher the patient exposure. The cardiologist should be aware that he/she has control over the image quality level and he/she should avoid any waste of radiation. The temporal resolution (frame rate) should also be chosen according the requirement of the procedure.

4.1.4 Image magnification

Geometric magnification should never be used (see §4.1.1). Electronic or digital magnification requires in general an increase of the skin dose rate. Thus, magnification should be used with parsimony.

4.1.5 Introduction of an “intervention” level

During long procedures the threshold of the deterministic effects might be reached. Since the severity of the lesion is dose dependent one should define a DAP level (for example 100 $Gy.cm^2$) after which a particular care on patient exposure is exercised. One could try for example to change incidences to distribute the dose. A DAP threshold where the patient should be recalled to check for skin lesion should also be defined (for example 500 $Gy.cm^2$).

4.1.6 Patient dose record

The dose indicators (DAP and skin accumulated dose) of the procedure should be recorded in the file of the patient. Moreover dose survey should be organised and the results should be compared with published value to estimated one's practice.

4.2 Personnel

The X-ray beam enters the patient and interacts with the tissue. Some radiation will be absorbed in the patient and thus deposit energy to that patient. The transmitted radiation will impinge the image amplifier to produce images. Unfortunately, the X-ray interaction within the patient will also create scattered radiation emitted all around the patient which will expose the staff to ionizing radiations.

The dose the staff might receive when being at one meter from the patient is approximately 0.1% of the skin dose delivered to that patient when the size of the X-ray beam is large (typically 400 cm^2). For example if the skin dose rate is equal to 40 $mGy.min^{-1}$, ambient dose rate at one meter from the patient can be estimated to 2.5 $mSv.h^{-1}$ (natural background of 0.0001-0.0002 $mSv.h^{-1}$). During cine runs the skin dose rate can reach 1 $Gy.min^{-1}$ which implies a higher dose rate to the staff during this type of acquisition. The ratio between patient skin dose and staff dose is dependent on the size of the X-ray beam. The larger the field size the higher the ratio. It is thus important to always reduce the size of the X-ray beam to its strict minimum. Expressed in terms of DAP one can take 0.3% of the DAP (DAP expressed in $Gy.cm^2$ and E in mSv). Thus when a cardiologist has delivered a DAP of 60 $Gy.cm^2$ he might have received over his/her lead apron a dose of 0.2 mSv.

4.2.1 Shielding

Shielding allows the staff to be isolated from scattered radiation produced by the X-ray interaction in the patient. Barriers used for shielding may be fixed to the unit, movable or worn by individuals. The amount of radiation attenuated by a material depends on the elemental composition of the material, its thickness and the energy of the radiation passing through it. As an example, the transmission through 0.5 mm of lead is 3.2% at 100kV and 0.36% at 70 kV (Yaffe & Mawdsley, 1991).

To reduce the operator exposure, one should begin by creating a sort of booth with shielding devices around him or herself. To do so, an articulated ceiling leaded screen lengthened by a leaded flap beside the table, or a mobile barrier as the one shown in Figure 1, together with a longitudinal protection adjacent to the table can be used (Kuon et al. 2002). Each shield should be at least 0.5 mm lead equivalent. The operator has then to complete his or her protection by wearing a lead apron, which should be adjusted to his or her size. Concerning the lead equivalent content, most of the aprons are either 0.5 or 0.35 mm lead equivalent. The use of a 0.35 mm instead of a 0.5 mm lead equivalent reduces weight by about 30%, but increases the transmission of scattered radiation of almost a factor of 2 at 90 kV. However, Marshall in an experimental study showed that at 90 kV, wearing a 0.35 mm lead equivalent apron with an additional 0.35 mm lead equivalent thyroid shield resulted in a factor 2 greater reduction in effective dose than can be achieved by wearing a 0.55 mm lead equivalent apron alone (Marshall & Faulkner, 1993). Some aprons are made of composite materials which offers equivalent shielding properties but which are significantly less heavy than aprons containing lead as shield material (Yaffe & Mawdsley, 1991).

Figure 1 presents one way the operator can insulate himself from the scatter produced by the patient when the examination is performed in the chest area with a femoral access. One

should always remember that it is at the surface where the X-ray beam enters the patient that the scatter dose rate is at its highest level. One should shield himself from that particular spot.
Figure 2 summarizes the efficiency of the shielding devices presented in Figure 1 for various tube-image amplifier orientations. It can be seen that an operator can significantly decrease his or her exposure when a shielding device is placed in such a way that the operator is as much as possible shielded from scattered radiation (Kuon et al., 2002). Unfortunately this is not always possible, as in the case of biliary drainage for example. In such a case, staff exposure is mainly controlled by the optimisation of patient exposure, the distance from the scatter source and personal shielding (Williams, 1997).

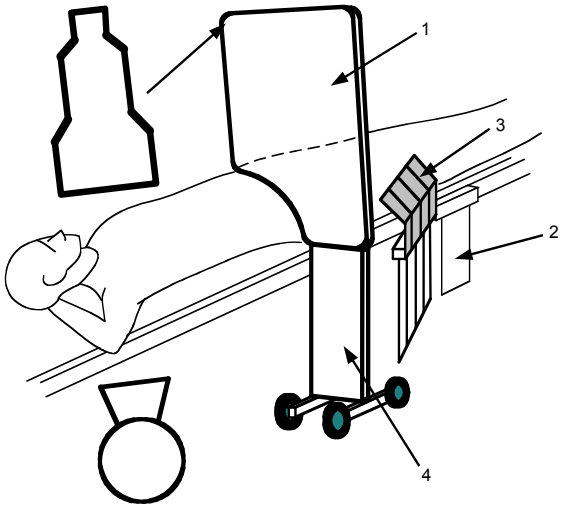

Fig. 1. Example of operator shielding with various devices (1 leaded glass, 2 and 3 leaded curtains, 4 leaded wall; 1 and 4 being on a mobile barrier)

To improve protection against cataract (which is a deterministic effect of ionising radiation), a 0.5 mm lead equivalent eyeglass should be used to reduce exposure to the lens by 10% to 65% (Nicholson, 1995). Finally, gloves made of composite material and offering the same tactile perception than regular chirurgical ones are available. Unfortunately, they offer a limited protection since they usually reduce dose by a factor less than 2 (Vaño & Guibelalde, 1997; Balter, 2001).

4.2.2 Effect of the examination geometry

Backscattered radiation is the radiation that is scattered back from the surface at the beam entrance. It is of high intensity because the entrance surface of the primary beam into the patient has not been attenuated. Thus, ambient dose rate will always be significantly higher when the operator is close to the x-ray tube, than when it is at the image amplifier side. Shielding of the operator should be performed considering these parameters (see Figure 3) (Brateman, 1999).

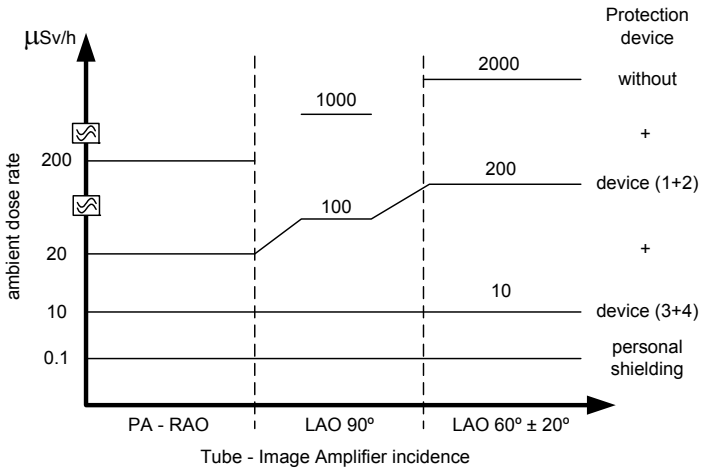

Fig. 2. Mean ambient dose rate to the operator (µSv.h^{-1}) for different tube-image amplifier orientations. The dose rate corresponds to an examination in the cardiac area of a Rando phantom, representative of a 70 kg standard patient, the operator being at about 1 m from the central beam impinging the phantom (situation presented in Figure 1). Without any radiation protection device, the dose rate is in the range of 2 to 0.2 mSv.h^{-1}. As expected, the LAO angulations are the ones which potentially deliver the highest dose to the operator. The addition of the protection devices 1 and 2 allows a reduction of the ambient dose rate at operator's level by a factor of 10. A further reduction is obtained by completing the shielding with devices 3 and 4. Finally, the use of personal shielding devices (i.e. lead apron, thyroid shield and leaded glasses) reduces the ambient dose rate to about 0.1 µSv.h^{-1} (adapted from Kuon et al., 2002).

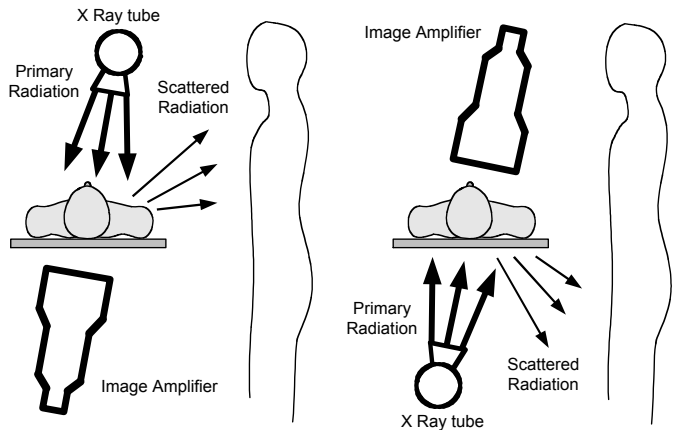

Fig. 3. The schematics show the influence of the tube-image amplifier orientation on the operator's exposure. When the tube is below the table, exposure to the legs and the lower part of the abdomen is the highest. When the tube is above the table, exposure to the face, neck and chest is the highest.

4.2.3 Inverse square law

The exposure rate from a point source of radiation decreases as the distance from the source squared. This inverse square law is the results of the geometric relationship between the surface area, A, and the radius, r, of a sphere: $A = 4 \pi r^2$. As an example, for a field size of the primary beam impinging the patient of about 100 cm^2, the ambient dose rate at 90° to the incident beam decreases from 1.2 $mGy.h^{-1}$ to 0.3 $mGy.h^{-1}$ when moving from 50 cm to 1m from the patient (i.e. a dose rate reduction as a function of $1/r^2$) (Bushberg et al., 2002). Unfortunately, when the size of the field impinging the patient is large, the dose reduction is slightly less efficient since dose rate reduction is no more as a function of r^{-2} but only as a function of r^{-1}. Nevertheless, backing away from the primary beam is a very efficient way to reduce staff exposure.

5. Conclusion

Several recently published studies showed that there is a high potential to reduce radiation doses to the patient and subsequently to enhance radiation safety for the staff. The aim of this chapter was to introduce the effects of ionizing radiation and the radiological risks, and to present various methods that may be used to reduce patient and personnel exposure during fluoroscopy-guided procedures in cardiology, such as the reduction of patient exposure, the increase of the distance from the source of scatter, and the shielding.

Every effort needs to be made in order to reduce patient and staff exposure as much as possible, not for legal purposes but simply for workers health. This applies in particular in the field of interventional radiology where exposure to the staff is potentially very high. Dose reduction to the staff can be reduced by the optimisation of patient exposure. Thus the introduction of the diagnostic reference levels (DRL) will certainly improve the control of staff exposure. Moreover, the application of simple rules, such as the ones mentioned in this contribution, allow radiologists to use fluoroscopy units minimising their exposure as much as possible. The respect of these rules allow also to improve the protection of other medical staff present near the patient and who are less familiar with radiation protection.

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