



Egyptian Society of Cardiology
The Egyptian Heart Journal
www.elsevier.com/locate/ehj
www.sciencedirect.com



Radiation exposure, the forgotten enemy: Toward implementation of national safety program



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Received 12 June 2016; accepted 8 October 2016

Available online 15 November 2016

KEYWORDS

Radiation hazards;
Radiation safety;
Shielding;
Fluoroscopy

Abstract Radiation safety is an important counterpart in all facilities utilizing ionizing radiations. The concept of radiation safety has always been a hot topic, especially with the late reports pointing to increased hazards with chronic radiation exposure. Adopting a nationwide radiation safety program is considered one of the most urging topics, and is a conjoint responsibility of multiple disciplines within the health facility.

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Peer review under responsibility of Egyptian Society of Cardiology.

<http://dx.doi.org/10.1016/j.ehj.2016.10.001>

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1. Introduction

The medical use of ionizing radiations for diagnostic and interventional cardiac procedures has been exponentially increasing over the last few years. With the uprising concept of multi-modality imaging, a considerable number of patients undergo multiple procedures that have relatively high radiation exposure within a short period of time. This may result in higher cumulative exposure.¹⁻³

Moreover, cardiac interventional procedures are getting more and more complex, which entail higher patient, physician and staff exposures. This renders radiation safety education and implementation a priority, not a privilege. Currently, radiation safety education is a defined requirement for the cardiology fellowship, with 15% of the interventional cardiology board examination questions pertaining to radiation safety and physics.⁴

Over the past few years, great advances have been accomplished in both equipment and application of radiation safety protocols, which were reflected on reducing both patient and operator exposures, fulfilling the “as low as reasonably achievable” (ALARA) principle. This principle dictates that exposure to radiation should produce sufficient benefit to the exposed individual to offset the radiation risk it causes.⁵

In this review, we are trying to highlight some of the important issues of radiation exposure and its hazards, as well as to shed some light on radiation safety concepts. Finally we will try to adjust a multi-disciplinary protocol to be adopted by our prestigious Egyptian society of Cardiology, toward implementing a comprehensive radiation safety program, and establishing a solid concept of “Safety comes first”.

2. Radiation dose estimation

2.1. Fluoroscopy time (FT, min)

It is the most commonly used parameter for radiation dose estimation. It represents the time fluoroscopy is used during a procedure, not including cine acquisition imaging. As documented in previous studies,^{6,7} the assessment of radiation dose requires more than fluoroscopy time. Steeper angulations, larger patients, varying frame rate, ignoring store fluoroscopy mode, and patient extremities in the field of view all will significantly increase the radiation dose without affecting fluoroscopy time.⁸ Up-to-date fluoroscopic equipment provides measures and displays of more sophisticated and reliable radiation dose estimates.

2.2. Total air kerma at the interventional reference point ($K_{a,r}, \text{Gy}$)

It is also known as cumulative air kerma (Kinetic Energy Released in MAtter). It represents the X-ray energy delivered

Measurement of Air Kerma radiation

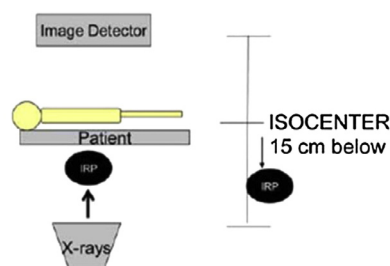


Figure 1 Definition of Air Kerma Radiation. IRP: Interventional reference point. Adapted from Christopoulos et al.⁹

Table 1 Dose limits for occupational exposure according to the International Commission on Radiological Protection (ICRP).^a

Dose quantity	Potential dose risk	Occupational dose limit
Effective dose	Stochastic effect throughout The body (Likelihood of cancer and birth defects)	20 mSv per year averaged over five consecutive years (i.e. a limit of 100 mSv in 5 years), and 50 mSv in any single year
Equivalent doses in	Deterministic effect in specific tissues	
Eye lens	Cataract	20 mSv in a year, averaged over defined periods of five years, with no single year exceeding 50 mSv
Skin	Skin lesions ranging from mild erythema to skin necrosis mandating surgical repair	500 mSv for the skin (average dose over 1 cm ² of the most highly irradiated area of the skin)
Extremities (Hands and feet)		500 mSv in a year

^a International Commission on Radiological Protection, 2011. Statement on Tissue Reactions, April 21, 2011. Available at: <http://www.icrp.org/page.asp?id=123>.

to the air at the interventional reference point (IRP). A point measured 15 cm on the X-ray tube side of isocenter (the point at which the primary X-ray beam intersects with the rotational axis of the C-arm gantry) (Fig. 1). The international system of units (SI) unit of Air Kerma is Gray (Gy = 100 rad).

Air Kerma has been associated with the “*deterministic effects*” of radiation, i.e. the effects that are immediate and have a predictable dose-response relationship with radiation (skin injury, hair loss and lens abnormalities).

2.3. Air kerma area product (P_{KA} , $Gy\ cm^{-2}$)

It is also known as Dose Area Product (DAP). It is the cumulative sum of the product of instantaneous air kerma and X-ray radiation field area. It is commonly reported by modern interventional X-ray systems. It is measured in $Gy\ cm^{-2}$ and is thought to correlate with the “*stochastic or probabilistic effects*” of radiation, i.e. the rare long-term effects that are dose dependent, but not threshold related. Examples of stochastic events are cancer, inheritable defects, and pregnancy complications.^{10,11}

2.4. Peak skin dose (PSD, Gy)

It is the maximum dose received by any local area of patient skin; both the probability and severity of deterministic skin effects increase as PSD increases. PSD is highly dependent upon instantaneous dose rate and the duration of time that the X-ray beam is directed toward a specific area of skin. It is still a research tool and not utilized in daily routine practice. While there is no currently available method to measure PSD, it can be estimated if air kerma and X-ray geometry details are known. Therefore, when a significantly high $K_{a,r}$ is identified, it is essential to initiate early post-procedure the estimation of PSD with a qualified physicist so that accurate relevant information can be collected.¹²

3. Radiation dose limits

Compared with patients, operators are exposed to smaller amounts of radiation during each procedure, but are repeatedly exposed, resulting in higher long-term cumulative exposure. Dose limits for occupational exposure are expressed as equivalent dose for organ-specific exposure and effective dose for whole-body exposure (Table 1). The effective dose represents the sum of equivalent doses from different tissues, adjusted to the radiation sensitivity of each tissue. Operator exposure is measured in milli-Sievert (10 mSv = 1 rem). A busy interventional cardiologist using good technique and proper protective equipment receives 2–4 mSv yr^{-1} , with dose dependent upon time in the laboratory and case complexity.^{13–15}

4. Occupational health hazards and radiation safety concept

Over the last few years, there has been increasing rates of complex and repeated coronary procedures. Moreover, there is an uprising shift to percutaneous management of structural and congenital heart diseases that were previously managed surgi-

cally. This has been accompanied with tremendous technical and imaging advancements entailing higher exposure.

A recent study explored the prevalence of major health conditions in chronic occupational radiation exposure.¹⁶ The study showed that doctors and staff working in Cath labs have significantly higher risk of several health problems compared with unexposed subjects. After adjusting for age, gender, and smoking status, the results showed that Cath lab workers had the following:

- 2.8 times higher risk of skin lesions
- 3.0 times higher risk of cancer
- 3.1 times higher risk of hypercholesterolemia
- 6.3 times higher risk of cataracts
- 7.1 times higher risk of orthopedic (back/neck/knee) problems.

The study also showed that people who were exposed for more than 16 years had even higher odds of having medical problems. Radiation-induced cancer remains the most alarming hazard for interventional cardiologists and electrophysiologists. Recent reports found an increased number of tumors on the left side of the brain, the region of the head known to be more exposed to radiation and least protected by traditional shielding.^{17,18}

Notably, as a secondary finding, exposed workers reported a 6 times higher risk of anxiety/depression, which might not only be due to the stress of the work environment, but also possibly a direct effect of radiation on the worker’s unprotected head.¹⁶

Accordingly, radiation safety became a compelling requirement in all Cath labs. Cumulative evidence contributes to spreading the culture of radiation safety, not only among physicians, but among all Cath lab staff. The WIN study¹⁹ reports that in a “real world” situation 7% of respondents never wear a radiation badge for monitoring purposes and only 66% regularly review their own exposure data, making it difficult to deploy an effective radioprotection strategy.

The International Atomic Energy Agency recently launched a campaign to increase the justification and optimization of radiological examinations through the “3A’s” strategy: “Appropriateness, Audit and Awareness”.²⁰

5. Components of a radiation safety program

5.1. Personnel

Radiation safety is a multi-disciplinary approach, which should involve all Cath lab personnel, with active involvement of the Cath lab medical director. A specific radiation safety person should coordinate all issues of this program, including program implementation and continuous education. This program coordinator should be working closely with a medical/health physicist, who should assume an active regulatory role in the Cath lab. Patient and staff radiation management should be included in the Cath lab Quality Assurance (QA) process. Finally, hospital administration should provide all financial and logistic tools to sustain a viable program and address all regulatory issues.¹²

5.2. Radiation monitoring

Staff radiation exposure should be monitored through personal dosimeters. Although it is the individual's responsibility to wear the dosimeter, yet institutional enforcement should be exerted to establish a "radiation conscious facility" providing safer working atmosphere, with fines and punishments for those who violate the rules. Reporting should be done for those with readings remarkably above or below the expected range of their responsibilities. Investigations should be held, which might show occasionally that the individual involved might not be regularly wearing his dosimeter, and thus falsely reporting a low exposure. On the contrary, several individuals might be sharing one's dosimeter, and falsely reporting an unexpectedly high exposure. The International Commission on Radiation Protection recommends two dosimeters, one under the protective garment, usually at waist height, and a second outside any protective garment, usually attached to the collar.²¹ Individuals and institutions should maintain life-long radiation exposure records. Physicians and staff who work at multiple institutions should have all their exposure records collated.

5.3. Shielding

It is a very important aspect of radiation protection. Several types of shielding exist: architectural shielding, equipment-mounted shields, ceiling-suspended shields, floor standing shields and personal protective devices.²² Architectural shielding is built into the Cath lab walls, and is beyond the scope of this review. Additionally, rolling and stationary shields resting on the floor, made of transparent leaded plastic, provide additional shielding not only to operators, but also to nursing and anesthesia staff.

Equipment-mounted shields include protective table-suspended drapes hanging from the table-side between the under-table X-ray tube and the operator. They substantially reduce operator dose. Occasionally, it cannot be used if the X-ray gantry (C-arm) is in a steep oblique or lateral position.

Ceiling-suspended shields, generally constructed of a transparent leaded plastic, dramatically reduce occupational exposure, including operator eye dose, if they are positioned correctly during the procedure.

Occasionally, Disposable protective patient drapes can be adopted in high dose procedures. Despite being protective to the operator, it doubled patient's exposure.²³

Personal protective devices should be worn by all staff involved in the Cath Lab. Protective garments protect the gonads and 80% of the active bone marrow.¹² The standard is a 0.5 mm lead apron, which stops ~95% of the scatter radiation. Wrap-around aprons with belts or vest/skirt design, offer substantial exposure protection which is doubled anteriorly where the apron folds overlap, while reducing orthopedic strain. Thyroid shield should be routinely worn especially for those whose externally worn dosimeters exceed 4 mSv in a month. Leaded eye glasses with protective side shields are recommended along with the use of ceiling-suspended shields to minimize eye exposure.²⁴ The use of light-weight bismuth-based or leaded protective caps could reduce brain exposure.²⁵ Leaded gloves can be used to limit exposure of the hands; however, they provide little protection when the operator's hands

are placed in the primary radiation beam. In addition, similar to radio-absorbent drapes, placing lead gloves in the direct beam may result in an increase in patient radiation dose.⁹

5.4. Imaging equipment

Modern imaging systems provide customizable built-in features for more effective dose management, thus providing radiation protection.¹² All modern X-ray systems use pulsed fluoroscopy allowing the operators to change the pulse rate for a given procedure. Other standard dose-saving features include virtual collimation, last image hold, and store of X-ray fluoroscopy (when cine image quality, as in documenting balloon inflation, is not required). Since 2006, real-time display of total air kerma at the reference point ($K_{a,r}$, Gy) and air kerma area product (PKA, $Gy\ cm^{-2}$), became mandatory in all X-ray equipments put into action in the US. This assists the operator in radiation dose management during the procedure. As a general rule, image quality and radiation dose are tightly coupled such that reduction in one results in reduction in the other.²⁶ Automatic dose rate controls increase X-ray tube output for a specific patient size in a specific projection to achieve adequate image quality. Finally, knowing your equipment and working with a qualified physicist are essential to get the best out of your equipment and optimize dose.

5.5. Training and education

Radiation safety training has been shown to increase operator awareness and reduce exposure.^{7,27} Comprehensive training should be offered to all members of the catheterization team: both at the time of initial employment and as part of a continuing medical education program.⁹ Radiation training is mandatory in the majority of US states, and for board certification, interventional cardiologists must pass an examination which includes physics and radiation safety.⁴ Specific training recommendations are provided by the National Council on Radiation Protection & Measurements (NCRP).¹³

Kuon et al.,⁷ showed that a 90-min interactive radiation safety mini-course provided a 48% reduction in patient radiation dose for those who completed the workshop. The course participants had approximately 35% lower procedure radiation dose than did those not participating.

Mayo clinic²⁸ achieved a 40% radiation dose reduction (cumulative air kerma) over a 3-year period by implementing a culture and philosophy of radiation safety in the Cath lab.

Chambers et al.^{8,12} proposed a program for radiation safety practice in the Cath lab. This program should include the following:

- initial didactic training or verification of prior training for all physicians and staff using fluoroscopy
- periodic updates (annual) on radiation safety
- hands-on training for newly hired operators and current operators on newly purchased equipment
- documentation of initial training and periodic updates for all staff.

The didactic program can be a series of online and/or standard classroom lectures with the focus on content, not hours.

Table 2 Procedure-based case management of radiation dose (adapted from Ref.^{9,29}).*I. Pre-procedural*

- A. Radiation safety program for Cath Lab
- Dosimeter use, shielding, training/education
- B. Imaging equipment and operator knowledge
- On-screen dose assessment (AK, DAP)
 - Dose saving: Store fluoroscopy, adjustable pulse and frame rate, and last image hold
- C. Pre-procedure dose planning
- Assess patient and procedure, including patient's size and lesion(s) complexity
- D. Informed patient with appropriate consent

II Procedural

- A. Limit fluoroscopy: Step on pedal only when looking at screen
- B. Limit cineangiography: Store fluoroscopy when high image quality not required
- C. Limit magnification, frame rate, steep angles
- D. Use collimation and filters to fullest extent possible
- E. Vary tube angle when possible to change skin area exposed
- F. Position table and image receptor: X-ray tube too close to patient increases dose; high image receptor increases scatter
- G. Keep patient and operator body parts out of field of view
- H. Maximize shielding and distance from X-ray source for all personnel
- I. Manage and monitor dose in real time from the beginning of each case

III Post-procedural

- A. Document radiation dose in records (FT, AK, DAP)
- B. Notify patient and referring physician when high dose delivered
- AK > 5 Gy, chart document; inform patient; arrange follow-up
 - AK > 10 Gy, qualified physicist should calculate skin dose
 - PSD > 15 Gy, Joint Commission sentinel event
- C. Assess and refer adverse skin effects to appropriate consultant

AK: Air Kerma; DAP: dose-area product; FT: fluoroscopy time; Gy: Gray; PSD: peak skin dose.

Written examination and documentation of course completion should be included with the following topics addressed:

- Physics of X-ray production and interaction
- Technology and modes of operation of the fluoroscopy machine
- Characteristics and technical factors affecting image quality in fluoroscopy
- Dosimetry quantities, and units
- Biological effects of radiation
- Principles of radiation protection in fluoroscopy
- Local regulations and requirements
- Techniques to minimize patient and staff dose.

Free online training courses are also available (for example: https://rpop.iaea.org/RPOP/RPoP/Content/InformationFor/HealthProfessionals/5_InterventionalCardiology/index.htm), and can offer comprehensive training on ways to minimize radiation exposure and contribute to a safe work environment. When a "radiation-conscious environment" has been estab-

lished in the cardiac Cath lab, the patients, staff, and physicians will all benefit.⁸

6. Radiation safety management protocol

Radiation safety is a conjoint responsibility of every member in the Cath lab team. A step-wise radiation safety management protocol could be classified into pre-procedural, procedural and post-procedural measures (Table 2).^{9,29}

*6.1. Radiation reduction in the Cath lab**6.1.1. Reducing radiation dose*

As compared to acquisition imaging (cineangiography), fluoroscopy accounts for approximately 40% and 66% of the total Air Kerma dose in diagnostic catheterization and percutaneous coronary intervention, respectively.³⁰ Accordingly, radiation should only be used when the operator is actively looking at the monitor. Fluoroscopy storing is available in new systems, and could be used to document non-critical part of the procedure such as balloon inflation or stent deployment, thus reducing radiation exposure.

6.1.2. Use collimation

Adjust collimator blades tightly to the area of interest. Tight collimation to the "minimal required field size" reduces patient dose, improves image quality by reducing scatter, and reduces occupational exposure by reducing scatter. Routine collimation is essential for reducing the DAP. Virtual collimation, when available, could eliminate the need for fluoroscopy to adjust collimator blade position.¹²

6.1.3. Patient/operator positioning

"Radiation scatter" is the primary mechanism of operator and staff exposure. The amount and direction of scattered radiation are affected by many factors, including patient size, gantry angulation, beam size, patient position, filtration, and fluoroscopic and image acquisition settings.²² For a C-arm Gantry with the X-ray source under the table, the exposure is greatest below the table, less at the operator's waist level, and least at the eye level. The height of the patient table can significantly affect scatter. The patient should be placed at maximal distance from the X-ray tube, and the image receptor should be as close to the patient as possible (Fig. 2).

Radial access increases exposure by reducing the distance between the X-ray beam and the operator; therefore, it is important to use manifold extensions and position the operator as close to the feet of the patient as possible.³¹

The patient's extremities should be kept out of the field of view at all times. With Automatic Dose Rate Control, extremities within the imaging field decrease image receptor quality, triggering an automatic increase in dose and unnecessarily high radiation exposure.⁹

6.1.4. X-ray angulation

Increasing the angulation of the imaging equipment also increases Air Kerma dose during fluoroscopy and acquisition imaging.³² Some equipments are designed to be calibrated to automatically adjust the radiation dose according to the projection.⁹

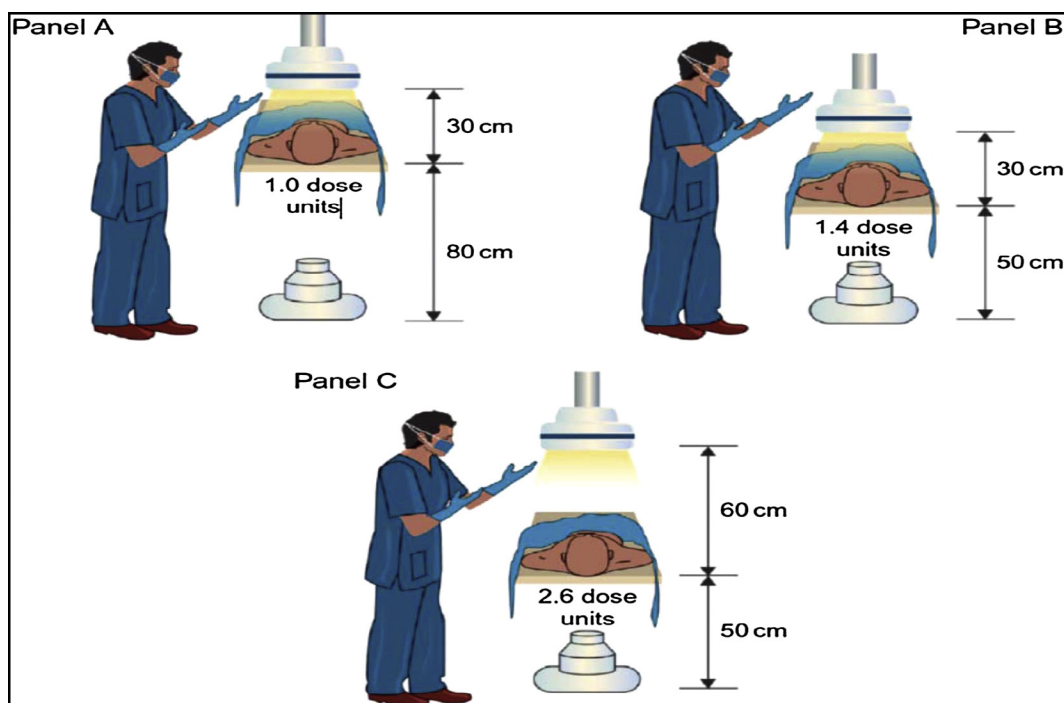


Figure 2 Example of optimal table positioning to minimize patient dose. The patient should be placed away from the radiation source and close to the image intensifier (panel A). A lower table setting without changing the source-intensifier distance results in higher dose due to proximity of the patient to the radiation source (panel B). Elevation of the image intensifier results in higher dose owing to geometric magnification by the intensifier (panel C). (Adapted from Ref.²⁹)

Table 3 Dose reduction technologies (adapted from Christopoulos et al.⁹).

Pulse rate in fluoroscopy (1 and 7/8 or 15/16 pulses-per-second)
Dose-per-frame (input dose 6.6 or 3.2 n Gray-per-frame)
Frame-rate (15 or 7.5 frames-per-second) for image acquisition
Cathode current
Peak tube voltage
Thickness of the spectral beam filters ^a
X-ray beam energy ^a
Real-time Air Kerma and Dose Area Product display
Virtual collimation
Store of X-ray fluoroscopy
Last-image-hold

^a Can only be added during the initial configuration of the fluoroscopy equipment, whereas the remainder are user selectable options that can be changed at any time.

It is important to position yourself, according to your role in the Cath Lab in a “low scatter area”. Stay as far from the X-ray source as possible. When using angulated or lateral projections, keep in mind that the highest intensity of scattered radiation is located on the X-ray beam entrance side of the patient. Cranial left anterior oblique projections result in high levels of scatter to the operator.²²

6.1.5. Adjusting imaging settings

Fine and gross adjustments of the technical parameters of the Imaging system are of utmost importance to achieve optimum radiation reduction. The challenge is to balance between optimum image quality and lower radiation dose, which requires

Table 4 Reference values for notifications and SRDL.^a

Dose metric	First notification	Second notification (increments)	SRDL
PSD	2 Gy	0.5 Gy	3 Gy
$K_{a,r}$	3 Gy	1 Gy	5 Gy
P_{KA}	300 Gy cm ⁻²	100 Gy cm ⁻²	500 Gy cm ⁻²
FT	30 min	15 min	60 min

SRDL: Substantial Radiation Dose Limits; PSD: Peak Skin Dose; $K_{a,r}$: total Air Kerma at the reference point; P_{KA} : Air Kerma area product; FT: Fluoroscopy Time.

^a Radiation Dose Management for Fluoroscopically Guided Interventional Medical Procedures, NCRP Report No. 168 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

an integrated work effort of the physician, qualified medical physicist, and the equipment manufacturer to get the best out of your equipment while maintaining safety. Fluoroscopy is most commonly performed at 15 frames-per-second. Decreasing the fluoroscopy frame rate to 7.5 frames-per-second can significantly reduce radiation exposure. Although image quality is lower with decreased fluoroscopy rates, it is usually adequate for most clinical purposes, with the possible exception of very obese patients or markedly angulated views. Low dose acquisition is a novel modality that uses lower frame rate (typically 10 frames-per-second) to obtain images, which can be stored. Recent studies showed that reducing frame rate to 7.5 frames-per-second resulted in lower operator and patient exposure.^{33,34} Similarly, decreasing magnification can be an easy,

but effective way of reducing radiation exposure, still at the cost of reducing image quality.⁹ Real-time Air Kerma and DAP display can assist the operator in radiation dose management.¹² Table 3 shows outlines of the dose reduction technologies.

6.2. Substantial Radiation Dose Limits (SRDL)

It is the radiation level that might produce clinically relevant adverse events in an average patient.³⁵ All patient radiation should be documented post-procedure especially when substantial radiation dose level, (SRDL) is reached.

Patient notification, chart documentation, and communication with the primary care provider should be a routine following procedures where radiation dose levels exceed total air kerma at the reference point ($K_{a,r}$) of 5 Gy. The physician should discuss and document why it occurred, and verify that the patient is aware of the potential for adverse skin effects.¹²

The following post-procedure follow-up protocol is suggested¹²:

- $K_{a,r} > 5$ Gy ($PKA > 500$ Gy cm^{-2}). Patients should be educated regarding potential skin changes (e.g., a red patch on the back) and call the physician if seen. Patients should be contacted at thirty days by phone calls, with an office visit arranged if questions arise or an adverse skin effect is suspected.
- $K_{a,r} > 10$ Gy ($PKA > 1000$ Gy cm^{-2}). As the joint commission identifies peak skin doses > 15 Gy as a sentinel event, a qualified physicist should promptly be requested to perform a detailed analysis to calculate peak skin dose. The patient should return for an office visit at 2–4 weeks with examination for possible skin effects.
- PSD > 15 Gy. Hospital risk management should be contacted within 24 h with appropriate notification to the regulatory agencies.

Table 4 represents the reference values for first and second notifications and SRDL suggested by the National Council of Radiation Protection (NRC). FT is the least reliable, $K_{a,r}$ and P_{KA} provide better estimations, while PSD requires calculations by a physicist.

7. Summary and recommendations

The Concepts of Radiation dose reduction and Radiation Safety Management are not given the importance they deserve. This makes it a hidden enemy that we have to beware of. In order to achieve a win-win deal for both patient and operator, we have to expand awareness of radiation safety among all involved personnel. It's a collaborative effort of physicians, technicians, nursing staff, medical or health physicists, quality assurance personnel and hospital administration. All should work as an integrated team with predefined job descriptions and targets.

We hope this review would be a nucleus for a broader initiative to be adopted by our prestigious Egyptian Society of Cardiology to trigger a comprehensive program in all Cath lab-equipped facilities under the slogan of "Safety Comes First".

A nationwide awareness program should include educational lectures, and informative and illustrated banners target-

ing all Cath lab personnel, addressing different aspects of radiation exposure and safety precautions. Continuous auditing to ensure compliance with safety program should be routinely held by regulatory authorities.

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