

Core Curriculum

Radiation Safety Program for the Cardiac Catheterization Laboratory

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The Society of Cardiovascular Angiography and Interventions present a practical approach to assist cardiac catheterization laboratories in establishing a radiation safety program. The importance of this program is emphasized by the appropriate concerns for the increasing use of ionizing radiation in medical imaging, and its potential adverse effects. An overview of the assessment of radiation dose is provided with a review of basic terminology for dose management. The components of a radiation safety program include essential personnel, radiation monitoring, protective shielding, imaging equipment, and training/education. A procedure based review of radiation dose management is described including pre-procedure, procedure and post-procedure best practice recommendations. Specific radiation safety considerations are discussed including women and fluoroscopic procedures as well as patients with congenital and structural heart disease. © 2011 Wiley-Liss, Inc.

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INTRODUCTION

In 1992, the Society of Cardiovascular Angiography and Interventions (SCAI) published Guidelines for Radiation Safety in the Cardiac Catheterization Laboratory [1]. Since then, complex percutaneous coronary interventions (PCI) and electrophysiology procedures (EP) have increased the average procedural radiation dose. Adverse radiation effects are now well recognized as infrequent but potentially serious complications of prolonged procedures [2–6]. The Joint Commission has identified peak skin dose from fluoroscopic guided procedures above 15 Gy as a sentinel event. Governing agencies have increased oversight with regulations established in some states [7].

SCAI presents here a practical approach to assist individual laboratories in establishing a radiation safety program. This article serves as a summary for program development with recommendations for best practice in radiation dose management.

BACKGROUND

A successful Cardiac Catheterization Laboratory radiation safety program must manage patient and staff safety by reducing exposure to ionizing radiation to a

level that is as low as reasonably achievable (ALARA). The first step in radiation safety is to avoid unnecessary use of ionizing radiation by justification of

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exposure, one of the basic principles of radiation protection. This principle dictates that exposure to radiation should produce sufficient benefit to the exposed individual to offset the radiation risk it causes [8,9]. Dose optimization recognizes the potential risk of any radiation and emphasizes the need for appropriate dose management for all imaging procedures [10,11]. A tutorial on the physics of X-ray imaging, essential to the safe practice of radiation dose management, has been published in the ACCF/AHA/HRS/SCAI Clinical Competence Statement on Physician Knowledge to Optimize Patient Safety and Image Quality in Fluoroscopically Guided Invasive Cardiovascular Procedures [12]. All individuals involved in fluoroscopic imaging procedures should familiarize themselves with this document as well as other relevant literature and appropriate terminology in this area.

Assessment of Patient Dose

Fluoroscopic time (FT, min) is the time during a procedure that fluoroscopy is used. This does not include cine acquisition imaging. Therefore, considered alone, FT is not a useful descriptor of patient radiation dose [13–15].

Total air kerma at the interventional reference point ($K_{a,r}$, Gy) is the procedure cumulative air kerma (X-ray energy delivered to air; formerly exposure in air) at the interventional reference point. This is the radiation monitoring value required on interventional X-ray systems since 2006. $K_{a,r}$ is used to monitor patient dose burden as it is associated with deterministic skin effects, though is not the true peak skin dose. Deterministic effect is the dose-dependent direct health effects of radiation, for which a threshold is believed to exist.

Air kerma area product (P_{KA} , $Gy\ cm^{-2}$) is the cumulative sum of the product of instantaneous air kerma and X-ray field area. It is commonly reported by modern interventional X-ray systems and is used to monitor patient dose burden and therefore the possible risk of stochastic effects (radiation induced cancer). Stochastic effect is the nonthreshold biologic effect of radiation that occurs by chance to a population of persons, whose probability is proportional to the dose and severity independent of the dose.

Peak skin dose (PSD, Gy) is the maximum dose received by any local area of patient skin; both the probability and severity of deterministic skin effects increases 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. P_{KA} is indicative of the total radiation delivered to a patient and can be utilized to accurately estimate skin dose as a research tool, not in clinical

practice [16,17]. 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, as described as significant radiation dose limits (SRDL) in this document under postprocedure issues, it is essential to initiate early postprocedure the estimation of PSD with a qualified physicist so that accurate relevant information can be collected.

Radiation Doses: Patient and Operator

Frequently performed imaging procedures and their associated effective radiation dose are listed in Table I [18,19]. Though longitudinal records are not currently available, health care providers and patients should be aware of the potential for significant cumulative dose when multiple imaging studies are performed. The deterministic effects of radiation on patient's skin and hair have recently been reviewed (Table II) [20]. Examples of these effects are presented in Fig. 1.

Operator effective doses are less well studied and are hindered by the variable use of personal dosimeters by the operators. Kim et al. reviewed available literature and found the effective dose per procedure ranged from 0.02 to 30.2 μSv for diagnostic catheterization, 0.17 to 31.2 μSv for percutaneous coronary interventions, 0.24 to 9.6 μSv for ablations, and 0.29 to 17.4 μSv for pacemaker or intracardiac defibrillator implantations [21]. A busy interventional cardiologist using good technique and proper protective equipment receives 2–4 $\text{mSv}\ \text{yr}^{-1}$, with dose dependent upon time in the lab and case complexity [22–24].

TABLE I. Typical Effective Dose Estimates for Select Procedures Performed Using Ionizing Radiation

Study	Typical effective dose estimate (mSv)
Chest X-ray	0.1
Chest CT (standard)	7.0
Chest CT (cardiac)	16
Diag. coronary angio.	7.0
PCI	15.0
RF arrhythmia ablation	15.0
TIPS	70.0
ERCP	4.0
Tc-99m heart (stress-rest)	11.4
Thallium heart (stress-rest)	16.9
General exposure	Typical effective radiation dose (mSv)
Natural background	3.1
Average US medical	3.0

Modified from Mettler et al. [18] and Laskey et al. [19].

TABLE II. Chronology and Severity of Tissue Reactions From Single-Delivery Radiation Dose

Single site (Gy) acute skin dose	Prompt (<2 weeks)	Early (2–8 weeks)	Mid term (6–52 weeks)	Long term (<40 weeks)
0–2	No observable effects expected			
2–5	Transient erythema	Epilation	Recovery from hair loss	None expected
5–10	Transient erythema	Erythema, epilation	Recovery; high doses cause prolonged erythema and permanent partial epilation	Recovery; higher dose cause dermal atrophy/induration
10–15	Transient erythema	Erythema, epilation; dry/moist desquamation	Prolonged erythema permanent epilation	Telangiectasia; dermal atrophy/induration
>15	Transient erythema; Very high dose causes moist desquamation edema/ulceration	Erythema, epilation	Dermal atrophy with secondary ulceration; atrophy/induration; High dose dermal necrosis surgical repair likely	Telangiectasia; dermal Late skin breakdown

Modified: Balter S. Fluoroscopically guided interventional procedure: A review of radiation effects on skin and hair. NCRP SC 2–3, Feb 2010.

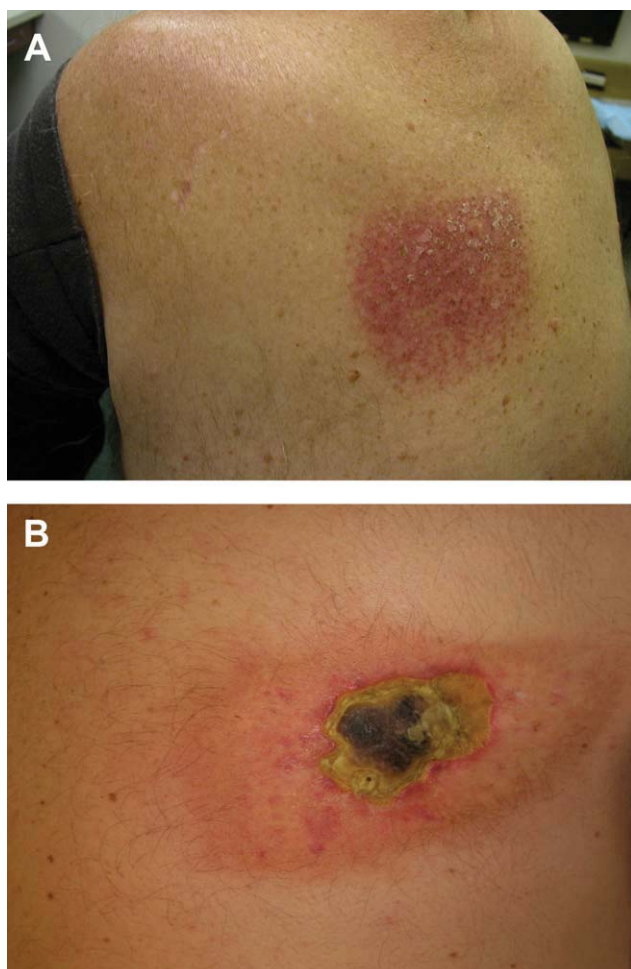


Fig. 1. Radiation skin (deterministic) effects. A. Dry desquamation (Poikiloderma) at one month in a patient receiving ~11 Gy calculated peak skin dose. B. Skin Necrosis at 6 months in a patient who received ~18 Gy calculated peak skin dose.

SYSTEM COMPONENTS FOR A RADIATION SAFETY PROGRAM

Personnel

The Catheterization Laboratory Medical Director, or designee, must be actively involved in the radiation safety program for it to be effective [25]. The catheterization laboratory staff should have a specific radiation safety person to coordinate all radiation safety issues as well as education [26]. This laboratory radiation safety coordinator must work conjointly with the medical or health physicist. This medical physicist or health physicist must assure minimum regulatory compliance and will be most effective by assuming an active role in the cardiac catheterization laboratory radiation safety program. Patient and staff radiation management should be included in the cardiac catheterization laboratory quality assurance (QA) process. Hospital administration must provide adequate financial and staff support to sustain a viable program while ensuring all regulatory requirements for patient and staff safety are addressed.

Radiation Monitoring

The cardiac catheterization radiation safety program must monitor staff radiation dose through the use of personal dose monitors. Though it is the individual's responsibility to wear this dosimeter, institutional enforcement of the personnel dose monitor policy establishes a safer environment. If a specific individual's dosimeter records an unusually high dose, a review of their practice patterns may benefit the individual, staff, and patient. All states require individuals working in areas utilizing X-ray imaging to wear a dosimeter with fines for willfully violating this policy. Investigation

should occur if an individual's dosimeter readings are substantially above or below the expected range for their in laboratory responsibilities. The approach a catheterization laboratory facility takes toward this personal dose monitoring program is an overall reflection of a radiation conscious facility.

Radiation worker effective dose estimates are based upon the number and location of dosimeters. Though a single dosimeter worn outside at collar level can be used to estimate effective dose, 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 at the collar [27]. The waist high dosimeter worn under the lead will underestimate exposure to hands or face and should not be worn as a single dosimeter [28]. Dosimeter reports should be provided to each individual on a regular basis. Individuals should, and institutions must, maintain lifelong radiation exposure records. Physicians and staff who work at multiple institutions should have all their exposure records collated. Table III lists the current regulatory radiation limits.

Shielding

Protective garments must be worn by all persons who are in the procedure room when the X-ray beam is on. These garments are designed to protect the gonads and 80% of the active bone marrow. The standard is a 0.5-mm lead apron, which stops ~95% of the scatter radiation [1]. Separate thyroid shielding is recommended for younger workers as well as all individuals whose externally worn dosimeter at collar level exceeds 4 mSv in a month [27]. Long term deleterious effects from protective garments are well documented with methods for potential improvement currently being addressed by the Multispecialty Occupational Health Group in the Interventional Laboratory [29]. Proper protective garment care, including hanging aprons on desig-

nated racks with adequate hangers and periodic inspection for damage, is an essential part of radiation safety.

Radiation specific eye protection has been shown to be effective in controlled studies [30]. Concerns about cost, comfort, and effectiveness have limited their use. However, recent epidemiological studies give reason for concern regarding potential eye injury, presenting as posterior subcapsular cataract formation [31–33]. For eye protection to be effective, the glasses must fit properly for both protection and comfort, provide 0.25-mm lead equivalent protection, and have additional side shielding.

Fixed barriers provide additional protection from scattered radiation. Though prior generations of below table mounted shielding limited movement of the C arm gantry, current shielding is less cumbersome with a substantial reduction in operator dose and should be used routinely [34,35]. Transparent ceiling mounted shielding with a patient contour cutout protects the operator's upper body and should be used routinely [36]. When positioning this shield, consider the origin of scatter X-rays from the patient and then carefully place the shield to block this scatter directed toward the operator's head and arms. The operator should only see the area being imaged by looking through the shield, decreasing ocular exposure. In laboratory moveable barriers provide protection for staff required to be in the procedure room, while individuals not required in the fluoroscopic suite should remain in the control room. Disposable radiation-absorbing patient sterile drapes may also help to reduce staff dose [37].

Imaging Equipment

Interventionalists and qualified physicists should participate in the purchase and configuration of new fluoroscopic imaging equipment. Current X-ray systems offer features which provide for greater customization with the potential for more effective dose management [27,38]. Independent fluoroscopy and acquisition programs may be configured as needed to the different image quality requirements of PCI vs. EP procedures. 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). Real-time display of total air kerma at the reference point ($K_{a,r}$, Gy) and air kerma area product (P_{KA} , Gy cm⁻²) assist the operator in radiation dose management during the procedure.

The quality of the X-ray image is a function of multiple patient, procedure, and equipment variables. As a

TABLE III. Current Regulatory Considerations for Radiation Limits

Tissue	Risk	Recommended maximum dose	
		NCRP	ICRP
Occupational	Stochastic	50 mSv yr ⁻¹ 10 mSv × Age (yr)	100 mSv (5 yr) ⁻¹
Lens of eye	Cataract	150 mSv yr ⁻¹	
Extremities	Stochastic	500 mSv yr ⁻¹	
Embryo-fetus ^a	Stochastic	0.5 mSv month ⁻¹ 5 mSv per term ^b	1 mSv per term
General public	Stochastic		1 mSv yr ⁻¹

10 mSv = 1 rem; Sources NCRP 116; ICRP 103.

^aAfter declaration of pregnancy

^bNRC recommendation.

general rule, image quality and radiation dose are tightly coupled such that reduction of one results in reduction of the other [11]. Automatic dose rate controls increase X-ray tube output for a specific patient size in a specific projection to achieve adequate detector entrance dose rate and image quality. This is controlled by a combination of manufacture selections and regulatory limitations. Operating parameters are set at installation and may be reset over the life of the equipment. These parameters should be periodically assessed and updated by a qualified physicist in cooperation with the equipment manufacturer. This in house or contracted nonvendor assessment of equipment performance and image quality is a regulatory requirement. Significant variation in image quality and dose between individual laboratories in the same facility and laboratories from facility to facility has been identified [24,39]. Knowing your equipment and working with a qualified physicist is essential for dose optimization.

Training/Education

Though certain states require training for personnel involved in fluoroscopy, this is not universally mandated [7]. The training described in this document is for the independent high dose fluoroscopic operator and is intended to provide guidance when state regulations are insufficient or unavailable [40]. All support staff should similarly receive radiation dose management and safety training commensurate to their responsibilities. Depending on state regulations, mid-level practitioners may be permitted to utilize fluoroscopy with supervision almost always required. However, physicians should never supervise procedures for which they do not have both clinical and fluoroscopic privileges. Documentation of current and appropriate knowledge of radiation safety should be required for institutional fluoroscopic privileging [12,40].

For board certification, interventional cardiologists must pass an examination which includes physics and radiation safety [41]. The 2004 ACCF/AHA/HRS/SCAI Clinical Competence Statement recommended training without identifying specific time requirements [12]. As the profession moves to standardize patient safety, training in fluoroscopic imaging and radiation safety will be more strictly regulated. The following is recommended:

1. The catheterization laboratory radiation safety education program should be coordinated in conjunction with the hospital radiation safety officer, hospital medical or health physicist, or an outside consultant. This should include the following components:
 - a. initial didactic training or verification of prior training for all physicians and staff using fluoroscopy
 - b. periodic updates on radiation safety
 - c. hands on training for newly hired operators and current operators on newly purchased equipment
 - d. documentation of initial training and periodic updates for all staff
2. The didactic program can be a series of on-line and/or standard classroom lectures with the focus on content, not hours. Written examination and documentation of course completion should be included with the following topics addressed:
 - a. physics of X-ray production and interaction
 - b. and modes of operation of the fluoroscopy machine
 - c. characteristics and technical factors affecting image quality in fluoroscopy
 - d. dosimetry, quantities, and units
 - e. biological effects of radiation
 - f. principles of radiation protection in fluoroscopy
 - g. applicable federal, state, and local regulations and requirements
 - h. techniques to minimize patient and staff dose

PROCEDURE-BASED RADIATION DOSE MANAGEMENT

Preprocedure Issues

Assessment of the risk/benefit ratio is an essential component of the radiation safety program [9,16,17]. Obese patients create a unique challenge with often poor image quality, high input dose, and significant scatter radiation. Patients with multi-vessel disease in distal, calcified, tortuous, or chronic totally occluded vessels require prolonged fluoroscopy/cine images, steeper angles, and potentially single ports/gantry positions [42–45]. Patients with recent radiation exposure are at particularly high risk of radiation skin injury [46]. When repeat procedures are required within 30–60 days, particularly if complex and/or requiring similar X-ray tube angles to the previous PCI, the physician must consider these factors, assess risk/benefit, and potentially postpone “elective” cases [47,48].

Informed consent should include radiation safety information, particularly in the high risk patient. While a knowledgeable and caring physician and staff are essential to performing the appropriate test as safely as possible, an informed patient, aware of the inherent risks and benefits, is similarly important. The following are issues to be considered for the PCI consent:

- a. procedures are performed using ionizing radiation in the form of X-rays
- b. X-rays are delivered both by fluoroscopy to guide equipment as well as cine to acquire images for storage

- c. your physicians will deliver the dose required to perform the procedure
- d. although both short and long term risk is present with radiation exposure, this rarely results in significant short or long term injury
- e. in the rare event that local injury to the skin or even underlying organs occurs, additional follow-up and treatment may be required

Procedure Issues

The physician must manage radiation in the cardiac catheterization laboratory from the outset to the completion of the procedure [9,49]. This includes fluoroscopy and cine imaging. While radiation is never completely safe and should never be administered without indication/justification, procedures cannot be terminated solely on the basis of the radiation dose administered. When high dose radiation has been administered, the operator must balance risk with benefit when deciding to proceed with additional vessel interventions or continuing to achieve a “better” angiographic result.

During the case, the physician should consider the following variables, which are summarized in Table IV:

1. Limit exposure duration with “beam-on time” occurring only when the physician is looking at the monitor.
2. Standard fluoroscopy dose mode should be chosen for each case, with the high dose mode (also known as high contrast mode, override mode, boost mode) limited as required.

TABLE IV. Strategies to Reduce Radiation Exposure to Patient and Operator

Precautions to minimize exposure to patient and operator

Utilize radiation only when imaging is necessary to support clinical care

Minimize use of cine

Minimize use of steep angles of X-ray beam

Minimize use of magnification modes

Minimize frame rate of fluoroscopy and cine

Keep the image receptor close to the patient

Utilize collimation to the fullest extent possible

Monitor radiation dose in real time to assess patient risk/benefit during the procedure

Precautions to specifically minimize exposure to operator

Use and maintain appropriate protective garments

Maximize distance of operator from X-ray source and patient

Keep above-table and below-table shields in optimal position at all times

Keep all body parts out of the field of view at all times

Precautions to specifically minimize exposure to patient

Keep table height as high as comfortable possible for the operator

Vary the imaging beam angle to minimize exposure to any one skin area

Keep patient’s extremities out of the beam

3. Change the imaging beam angle, when the procedure is prolonged, so that the primary beam entrance site is altered and peak skin dose minimized.
4. Avoidance of steep angulations will decrease effective patient thickness, radiation dose rate, scatter radiation, and staff exposure.
5. Examination table height should be placed such that the primary operator is comfortable. Radiation safety devices can be moved to accommodate changes in table height.
6. X-ray source to skin distance is a concern when the patient is placed too close to the X-ray source (low table height or steep angulations) significantly increasing the patient’s skin dose.
7. Image receptor placement must be as close to the patient as possible to minimize input dose and significantly decrease scatter radiation.
8. Cine mode should be utilized only when required, realizing that the cine acquisition dose rate is significantly greater than fluoroscopy. Use lower framing rates and store X-ray fluoroscopy (for balloon inflation) when appropriate.
9. Cine frame rate should be utilized appropriately for needed temporal resolution understanding that increasing the frame rate increases dose.
10. Higher magnification (zoom) increases the image-receptor’s dose requirements, potentially increasing patient dose, and should be utilized only when needed.
11. Utilize collimation to decrease scatter radiation. The use of additional copper filters will decrease primary beam exposure with some combination of reduced skin dose and improved iodine visualization.
12. Patient’s nontarget anatomy, such as extremities, must be kept out of the primary X-ray beam. Automatic dose rate controls are designed to increase X-ray tube output with increasing patient thickness; this may result in significant skin dose if extremities are in the field of view, similar to steep angulations or morbidly obese patients.
13. Operator appendages (hands) must be kept out of the field of view.
14. Remember distance from the X-ray beam significantly decreases radiation dose for both operator and staff (Inverse Square Law).
15. Protective shields should be utilized to the fullest extent possible.
16. Communication between staff and operator, noting monitor displays, in high dose cases is essential. The staff should notify the physician operator during the procedure when $K_{a,r}$ is in excess of 3 Gy and then every 1 Gy thereafter (Table V).

TABLE V. Suggested Values for First and Subsequent Notifications and the Substantial Radiation Dose Level (SRDL)

Dose metric	First notification	Subsequent notifications (increments)	SRDL
$D_{\text{skin,max}}$ ^a	2 Gy	0.5 Gy	3 Gy
$K_{\text{a,r}}$ ^b	3 Gy	1 Gy	5 Gy ^b
P_{KA} ^c	300 Gy cm ^{-2d}	100 Gy cm ^{-2d}	500 Gy cm ^{-2d}
Fluoroscopy time	30 min	15 min	60 min

NCRP (2010) National Council on Radiation Protection and Measurements. Radiation Dose Management for Fluoroscopically Guided Interventional Medical Procedures, NCRP Report No. 168 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

^a $D_{\text{skin,max}}$ is peak skin dose, requiring calculations by physicist.

^b $K_{\text{a,r}}$ is total air kerma at the reference point.

^c P_{KA} is air kerma-area product.

^dAssuming a 100 cm² field at the patient's skin. For other field sizes, the P_{KA} values should be adjusted proportionally to the actual procedural field size (e.g., for a field size of 50 cm², the SRDL value for P_{KA} would be 250 Gy cm⁻²).

Postprocedure Issues

All patient radiation should be documented postprocedure with the special circumstance identified when high dose radiation, referred to as substantial radiation dose level, (SRDL) is delivered [40]. The following protocols are recommended:

1. Cardiac catheterization reports should routinely have radiation dose included in the procedural records. This should include all of the following if they are available: fluoroscopic time (FT, min), total air kerma at the reference point ($K_{\text{a,r}}$, Gy), and air kerma-area product (P_{KA} , Gy cm⁻²). Peak skin dose (PSD, Gy) should be included if technology permits its measurement [28]. Institutions performing interventional cardiology procedures should utilize equipment capable of measuring and reporting $K_{\text{a,r}}$ and P_{KA} , so as not to rely on FT for radiation dose management.
2. Patient notification, chart documentation, and communication with the primary care provider should routinely occur following procedures with radiation dose levels exceeding total air kerma at the reference point ($K_{\text{a,r}}$) of 5 Gy. Table V presents reference values for $D_{\text{skin,max}}$ (PSD), $K_{\text{a,r}}$, P_{KA} , and FT that have been proposed to trigger follow-up for the substantial radiation dose limit (SRDL), a radiation level that might produce a clinically relevant adverse event in an average patient [40,49–51]. While FT is the least useful, P_{KA} may similarly be used with action levels multiples of ~ 100 in Gy cm⁻² of the $K_{\text{a,r}}$ in Gy [11,40]. The physician should discuss and document why it occurred, and verify that the patient is aware of the potential for adverse skin effects.

3. Postprocedure patient follow-up is suggested based upon assessment of dose as follows:

- a. $K_{\text{a,r}} > 5$ Gy ($P_{\text{KA}} > 500$ Gy cm⁻²). Patients should be educated regarding potential skin changes (e.g., a red patch on the back) and call the interventionalist if seen. Patients should be contacted at thirty days. Phone calls may be sufficient (if $K_{\text{a,r}} < 10$ Gy) with an office visit arranged if questions arise or an adverse skin effect is suspected.
- b. $K_{\text{a,r}} > 10$ Gy ($P_{\text{KA}} > 1,000$ 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 to 4 weeks with examination for possible skin effects.
- c. PSD > 15 Gy. Hospital risk management should be contacted within 24 hr with appropriate notification to the regulatory agencies.

4. Adverse tissue effect is best assessed by history and physical exam (Table II). If suspected, the patient should be referred to a specialist made aware of potential radiation etiology. A biopsy should be performed only if required, as the biopsy “wound” may result in a secondary injury potentially more severe than the radiation effects.

SPECIFIC RADIATION SAFETY CONSIDERATIONS

Women and Fluoroscopic Guided Procedures

The relationship between occupational exposure to radiation and breast cancer has been studied. Though an increased risk associated with higher cumulative radiation exposure has been suggested, study results have been inconsistent [52–55]. To minimize breast exposure, in addition to good radiation safety techniques and proper shielding, lead aprons should be fitted to ensure adequate protection over the breast tissue. Styles which have less coverage around the axilla should be avoided.

The pregnant patient poses a risk for radiation injury to the fetus resulting in potential stochastic injury and, at high (fetal) dose, the induction of a deterministic effect [56]. Deterministic effects in the embryo-fetus for absorbed doses below 50 mGy are seldom detectable, while doses in excess of 100 mGy are more likely to cause dose dependent developmental effects [57–59]. The safest policy is to avoid elective procedures during pregnancy, especially in the first trimester. The benefits and risks to both mother and fetus of performing or not performing a planned procedure need to be carefully considered with informed consent essential. Even in the absence of known risk factors, $\sim 5\%$ of live births possess some form of congenital malformations.

With proper procedure planning to exclude abdomen or pelvis exposure and, if available, consultation with a qualified medical physicist, embryo-fetus exposure may well be limited to scatter radiation with very low and usually acceptable risk.

Whether it is staff or physician, the pregnant worker is best protected in a laboratory that utilizes best practice for radiation safety. It is unlawful to prevent pregnant employees from working in occupations that may expose them to radiation. Each hospital should have a radiation safety policy for pregnant workers that address occupational exposure, dosimeter use and readings, duties including call, and risk/benefit of additional shielding. All pregnant workers should have a specific dosimeter, to be worn at the waist under the protective garment, issued and read monthly. The work related restriction limit for the embryo-fetus radiation exposure equivalent dose is 0.5 mSv/month. Once a pregnancy is identified, the expectant mother should not receive more than 1 mSv per ICRP and 5 mSv per NRC for the remainder of the pregnancy [60,61]. It should be noted that reference values of 1 mSv are seldom recorded for an entire year in this location [61].

The Patient With Congenital and Structural Heart Disease

Patient radiation dose management. Many of the precautions recommended for patients undergoing PCI apply equally to those with congenital and structural heart disease. However, structural and congenital transcatheter interventions often have longer procedure times and are performed on younger patients. Children born with congenital heart disease frequently undergo numerous diagnostic and therapeutic catheterizations, with potential harmful cumulative long-term effects of radiation exposure [62,63]. This raises significant concern when children survive to potentially manifest these late effects of radiation exposure [64,65]. Gamma-H2AX foci have been used as a biomarker of radiation induced biological effects in children, suggesting possible attributable lifetime cancer risk values of 1–4% [66]. The importance of radiation dose reduction in the pediatric patient has been emphasized through the Image Gently and Step Lightly campaigns [67].

While regulatory bodies are interested in providing reference levels for patient and staff exposure, little is known regarding the safety and thresholds of radiation exposure in pediatric patients as well as the appropriate variable(s) to monitor. Even though specific $K_{a,r}$ thresholds are generally good criteria for determining the need for follow-up in adult patients, using the same thresholds may not be appropriate for pediatric patients. Therefore, specific thresholds for follow-up

should be in place for patients with congenital and/or structural heart disease. The Quality Metrics Working Group (QMWG) of the ACC recently presented a “Radiation Dose Metric” which includes fluoroscopy time, but more importantly $K_{a,r}$ and P_{KA} for all catheterization procedures [68]. The IMPACT registry has recently been established as one of the National Cardiovascular Data Registries, specifically for catheterization procedures performed in patients with congenital heart disease (CHDz); collection of this information within this registry could identify those procedures that exceed the 95th percentile for dose based on a national benchmark [69,70].

Equipment routinely used for pediatric procedures should be appropriately designed, equipped, and configured for this purpose with modifications made to accommodate the variable procedural requirements as well as the wide age and weight range of these patients [71]. Flexible presets in fluoroscopic equipment and modifications in cath-lab table design to accommodate unusual angulations may result in an overall patient dose reduction. Hybrid therapies, such as intraoperative stent placement, require newer means of staff radiation protection to include lightweight radiation protection pads [72]. The complex three-dimensional anatomy of congenital and/or structural heart disease patients often necessitates multiple cine recordings. Integrating other imaging modalities during catheterization (trans-esophageal and intra-cardiac echocardiography) may reduce radiation exposure. CT 3-dimensional reconstruction can be used for intraprocedural real-time overlays during complex transcatheter interventions, such as closure of para-valvular leaks. Rotational angiography is increasingly used in the management of patients with CHDz [73,74]. While the acquisition usually takes up to 4–5 sec, the gained information obtained through 3D reconstructions may eliminate the need for several biplane cine acquisitions and is particularly useful in patients requiring complex pulmonary artery rehabilitation, where it allows to exactly determine the best angles that profile individual lesions that require transcatheter interventions. Furthermore, the dose of rotational angiography is distributed over a larger skin area.

Physician responsibility, education, and training. The physician should always balance the possible risk related to radiation exposure to the benefit of the procedure for each patient. It is inappropriate to set fixed radiation dose limits with potential lockouts since exceeding these values is occasionally in the best interest of a specific patient. Appropriate physician management of radiation dose from the beginning of each procedure is essential with continuous awareness of administered dose.

Board certification examinations for physicians performing PCI assess knowledge of radiation physics and

safety. No such board certification exists at present for congenital and structural interventions. Guidelines being developed for training in structural interventions by the Structural Heart Disease Council (“Interventional Fellowship in Acquired and Congenital Structural Heart Disease”, unpublished) serve as an important first step in training adequate radiation safety. Institutionally appropriate modifications in the cardiac catheterization radiation safety training program should provide for a specific focus on patients undergoing cardiac procedures for congenital and structural heart disease.

CONCLUSION

Establishing a radiation safety program for the catheterization laboratory should be a collaborative effort involving physicians, staff, medical or health physicists, quality assurance personnel, and hospital administration. Establishing safe radiation practice improves patient, staff and physician safety. The interventional cardiologist, as the person responsible for all aspects of patient care in the catheterization laboratory, must be actively involved in managing radiation dose to maximize patient safety. SCAI presents this review as a practical best practice approach to radiation dose management in the setting of a comprehensive radiation safety program within the cardiac catheterization laboratory.

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