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Society Position Statement

Canadian Cardiovascular Society Position Statement on Radiation Exposure From Cardiac Imaging and Interventional Procedures

Primary Panel: Madhu K. Natarajan, MD, MSc (Co-chair),[a] Narinder Paul, MD (Co-chair),[b] Mathew Mercuri, MSc, PhD,[c] Edward J. Waller, PhD, CHP,[d] Jonathon Leipsic, MD,[e] Mouhieddin Traboulsi, MD,[f] Hamid S. Banijamali, MD, PhD,[f] Lee Benson, MD,[g] Tej N. Sheth, MD,[a] Secondary Panel: Christopher S. Simpson, MD,[h] Allan Brydie, MBChB,[i] Michael P. Love, MBChB, MD,[j] and Richard Gallo, MD[k]

[a] *Department of Medicine, McMaster University, Hamilton, Ontario, Canada*
[b] *University Health Network, Toronto, Ontario, Canada*
[c] *Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, Ontario, Canada*
[d] *University of Ontario Institute of Technology, Oshawa, Ontario, Canada*
[e] *University of British Columbia, Vancouver, British Columbia, Canada*
[f] *Department of Cardiac Sciences and Cardiology, University of Calgary, Calgary, Alberta, Canada*
[g] *Hospital for Sick Children, Toronto, Ontario, Canada*
[h] *Division of Cardiology, Queen's University, Kingston, Ontario, Canada*
[i] *Department of Radiology, Dalhousie University, Halifax, Nova Scotia, Canada*
[j] *Division of Cardiology, Department of Medicine, Queen Elizabeth II Health Sciences Centre, Halifax, Nova Scotia, Canada*
[k] *Montreal Heart Institute, Montreal, Québec, Canada*

ABSTRACT

Exposure to ionizing radiation is a consequence of many diagnostic and interventional cardiac procedures. Radiation exposure can result in detrimental health effects because of deterministic (eg, skin reaction) and stochastic effects (eg, cancer). However, with the levels experienced during cardiac procedures these risks can be difficult to quantify. Healthcare providers and patients might not fully appreciate radiation-related risks. Though in many cases radiation exposure cannot be avoided, a practice of minimizing exposures to levels "as low as reasonably achievable" (ALARA principle) without compromising the

RÉSUMÉ

L'exposition au rayonnement ionisant est la conséquence de plusieurs actes de cardiologie diagnostique et interventionnelle. L'exposition au rayonnement peut entraîner des effets préjudiciables à la santé en raison d'effets déterministes (par ex. la réaction cutanée) et stochastiques (par ex. le cancer). Cependant, moyennant les niveaux d'intensité subis durant les actes de cardiologie, ces risques peuvent être difficiles à quantifier. Les prestataires de soins et les patients pourraient ne pas réaliser pleinement les risques liés au rayonnement. Bien que dans plusieurs cas l'exposition au rayonnement ne puisse être évitée, la

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Corresponding author: Dr Madhu K. Natarajan, Department of Medicine, McMaster University, Clinic Room 508, 237 Barton St East, Hamilton, Ontario L8L 2X2, Canada. Tel.: +1-905-527-6241; Fax: +1-905-527-2337.
E-mail: nataraja@mcmaster.ca

The disclosure information of the authors and reviewers is available from the CCS on the following websites: www.ccs.ca and/or www.ccsguidelineprograms.ca.

This statement was developed following a thorough consideration of medical literature and the best available evidence and clinical experience. It represents the consensus of a Canadian panel comprised of multidisciplinary experts on this topic with a mandate to formulate disease-specific recommendations. These recommendations are aimed to provide a reasonable and practical approach to care for specialists and allied health professionals obliged with the duty of bestowing optimal care to patients and families, and can be subject to change as scientific knowledge and technology advance and as practice patterns evolve. The statement is not intended to be a substitute for physicians using their individual judgement in managing clinical care in consultation with the patient, with appropriate regard to all the individual circumstances of the patient, diagnostic and treatment options available and available resources. Adherence to these recommendations will not necessarily produce successful outcomes in every case.

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utility of the procedure is encouraged. The purpose of this document is to inform health care providers on the key concepts related to radiation risk from common cardiac procedures and provide specific recommendations on ensuring quality of care.

pratique d'une radioprotection par une exposition à une intensité « aussi faible que raisonnablement possible » (principe ALARA : as low as reasonably achievable) ne compromettant pas l'utilité de l'acte est encouragée. Le but de ce document est d'informer les prestataires de soins sur les concepts principaux liés au risque du rayonnement provenant des actes habituels en cardiologie et de fournir des recommandations particulières pour assurer des soins de qualité.

Introduction

The medical use of ionizing radiation for diagnostic and interventional procedures and the subsequent exposure burden to the population is ever increasing. For example, estimates in the United States show a 15-fold increase in the number of radiologic and nuclear medicine procedures over the past half century.[1] Likewise, use of computed tomography (CT) has increased at an estimated rate of 10% per year and the number of cardiac catheterization procedures has doubled over the decade ending in 2006.[1] Because of the combination of increased procedure volumes and, in some cases, increased individual procedure-related (acute) radiation exposure,[2] the total per capita effective exposure from medical sources now outweighs that from natural background sources in the United States.[3] Furthermore, a small number of patients undergo multiple procedures that have relatively high radiation exposure in a short period of time. These repeat procedures can result in high cumulative exposures.[4-6] However, the increased use of ionizing radiation-emitting medical modalities, and the potential risks they carry must be viewed in the context of the benefits to patients. For example, in the United States where advanced diagnostic imaging procedures increased rapidly, there was a concomitant increase in life expectancy in the exposed population[7] (Supplemental Text S1).

Terminology

When biological tissue is exposed to ionizing radiation some of the energy might be absorbed. The amount of energy deposited in the tissue per unit mass is known as the absorbed dose (measured in greys; Gy). The equivalent dose is obtained by multiplying the absorbed dose by a radiation weighting factor; for x-rays the weighting factor is 1. This is distinct from the effective dose (measured in sieverts; Sv), which accounts for the different radiosensitivities of various biological tissues. The effective dose is estimated by multiplying the equivalent dose with a tissue weighting factor. The sum of the tissue weighting factors over all tissues in the body is equal to 1. The cumulative effective dose (Sv) is the summation of all (effective) doses to an individual over a specified period of time. The collective effective dose is the summation of all (effective) doses to a specified population over a specified period of time. Collective effective dose is generally used for optimization and comparison of radiological technologies or procedures. Collective effective dose is not intended and should not be used for epidemiological studies or for risk projections.[8] The different categories of dose are outlined in Table 1. It is important to realize that absorbed dose is a physical quantity, whereas equivalent and effective dose are derived quantities used for radiological protection purposes.

There are 2 general classes of radiation-induced effects: deterministic, and stochastic. Deterministic effects are threshold-dependent, largely because of cell death, with the severity increasing relative to the exposure. Tissue reactions, including cataract induction, lung fibrosis, and skin depilation, erythema, and necrosis, are considered deterministic in nature.[9-11] Stochastic effects are those in which the severity of the effect is not determined by the magnitude of the exposure. However, there is a greater chance of stochastic effects as the radiation exposure increases. Radiation-induced genetic disorders and cancers (eg, solid tumour, leukemia) because of DNA alterations in living cells are considered stochastic in nature.[12]

There is debate over (1) the magnitude of risk at low levels of radiation exposure (in the range of many medical procedures), and (2) how to best extrapolate risks from relatively higher exposures (eg, atomic bomb survivors) in which such data exist to lower levels for which there is no robust epidemiologic evidence. A common method is to use a linear projection of risk extrapolated from exposures of atomic bomb survivors (ie, linear nonthreshold model [LNT]; Fig. 1 and detailed in Supplemental Text S2). However, the current evidence suggests no conclusive proof of risk at very low

Table 1. Basic dose definitions

Quantity	Description	Equivalency	Unit
Absorbed dose (*D*)	Energy absorbed per unit mass	Number of J absorbed per kilogram of material	1 J/kg = 1 Gy
Equivalent dose (*H*)	Takes into account the effectiveness of different radiation types in doing damage to tissue using a dimensionless radiation weighting factor w_r	$H = w_r \times D$	Sv
Effective dose (*E*)	Takes into account the potential for detrimental effects to the various organs and tissues using a dimensionless tissue weighting factor w_t	$E = w_t \times H$	Sv

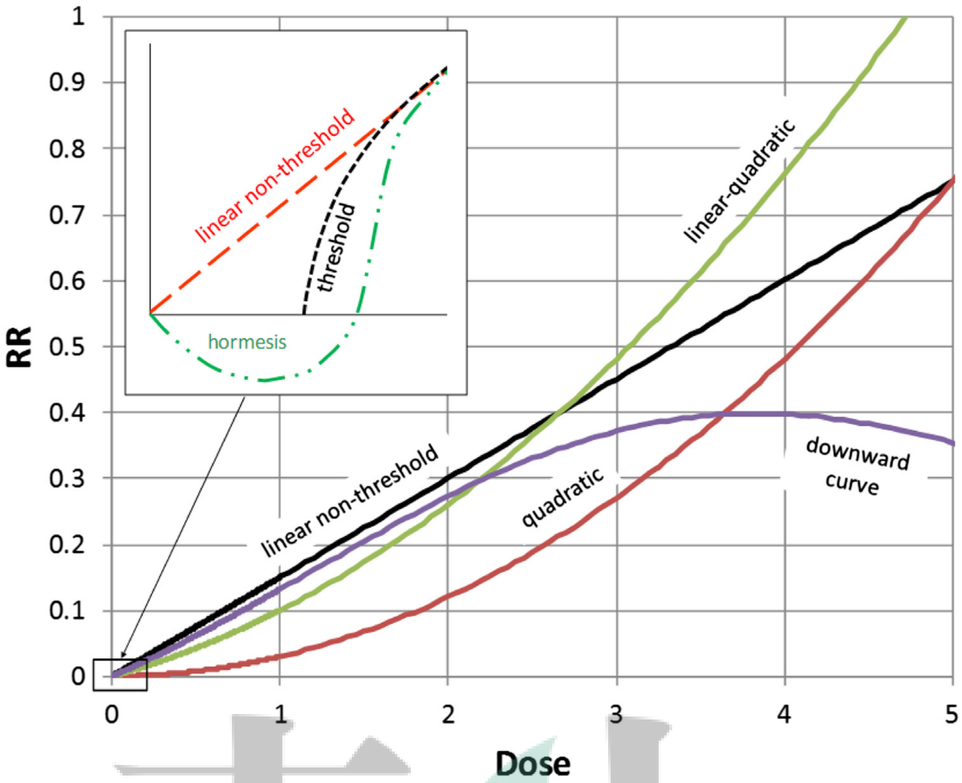

Figure 1. General characteristics of typical risk model curves. The curves are not intended to be compared quantitatively with each other. It is also worthy to note that the curves are representative of shape and do not indicate any particular risk-response as a function of (arbitrary) dose. All models, except for the threshold model, assume that there is risk at all doses greater than zero. The hormesis curve, inset at low dose, shows positive effect as a function of dose at low dose. The downward curve depicts the effect of attenuation as a result of cell killing at higher doses. RR, relative risk.

exposures, and weak evidence at less than acute doses of 50 mSv and protracted doses of 100 mSv. Though the literature suggests potential for skin injury from fluoroscopic procedures, the overall radiation-related risks to the patient should at this time be considered very low.

RECOMMENDATION

1. That Canadian cardiologists adopt the LNT model for purposes of general radiation protection (Strong Recommendation, Low-Quality Evidence).

Values and preferences. Though the evidence is weak, considering the general acceptance of the LNT model among major radiation protection agencies and for encouragement of the "as low as reasonably achievable" (ALARA) principle, there was broad consensus that cardiologists and radiologists should adopt this model. However, meaningful thresholds in clinical practice might include:

i. Patient skin doses exceeding 4 Gy are at risk of skin injury.
ii. Acute whole body effective doses of greater than 50 mSv or whole body cumulative effective doses of greater than 100 mSv are at risk of stochastic effects, with risk being inversely proportional to age because of tissue radiosensitivities. Furthermore, we suggest that more large epidemiological studies be undertaken to determine the magnitude of risk of radiation-induced injury from cardiac procedures.

Cardiac Diagnostics and Procedures Using Ionizing Radiation

In total, cardiology is the source of one-third of the collective dose from medical modalities.[13] Furthermore, the magnitude and proportion of the collective exposure directly attributable to cardiology practice is variable and likely increasing, because myocardial perfusion imaging, cardiac CT, and percutaneous coronary intervention procedures are on the rise. Though these estimates are based on U.S. data, Canadian figures are similar.[14] Typical doses for various cardiac procedures are listed in Table 2.[1]

Fluoroscopy-driven diagnostic tests and procedures

The reported radiation doses for fluoroscopic procedures vary widely because of operator and procedural characteristics.[2,16] These procedures are somewhat distinct from other modalities that use ionizing radiation in that the operator also receives a meaningful radiation exposure. Operator exposure in Canada is carefully regulated and monitored by governmental agencies.

Numerous radiation exposure and dose metrics have been developed specifically for this class of procedures. The most basic is fluoroscopy time, which measures the total time the fluoroscopy device is active. Fluoroscopy time is not considered a good measure, because it does not account for the intensity of output from the x-ray tube. Air kerma (Gy),

Table 2. Effective doses for various cardiac imaging procedures

Examination	Average effective dose (mSv)	Range in literature (mSv)
Chest X-ray	0.1	0.05-0.24
CT calcium scoring	3	1.0-12
CCTA (initial reports)	16	5.0-32
CCTA (achievable)	5.0	3.0-7.6
Coronary angiogram*	7	2.0-15.8
Coronary PCI or EPS*	15	6.9-57
Nuclear Stress-rest study†		
^{99m}Tc-sestamibi	9.4 (1100 MBq) (0.0085 mSv/MBq)	
^{99m}Tc-tetrofosmin	11.4 (1900 MBq) (0.0076 mSv/MBq)	
Rest ventriculography		
^{99m}Tc-labelled rbc	7.8 (1110 MBq) (0.007 mSv/MBq)	
Cardiac PET		
18F-FDG	5.0-14.1 (740 MBq) (0.019 mSv/MBq)	
Rubidium-82	2.0-7.5	

CCTA, cardiac computed tomography angiography; CT, computed tomography; CTO, chronic total occlusion; EPS, electrophysiology studies; FDG, fluorodeoxyglucose; PCI, percutaneous coronary intervention; PET, positron emission tomography; rbc, red blood cell; ^{99m}Tc, technetium.

* Effective doses might vary significantly according to complexity of procedure (eg, simple single-vessel PCI < complex multi-vessel or CTO PCI; simple EPS procedure vs complex EPS ablations).

† Effective dose varies significantly based on protocol.

Data from Mettler et al.[15]

measured at a defined interventional reference point, and the related dose area product (Gy-cm^2) are the preferred measures. These measures can be used in conjunction with spatial parameters and tissue weighting factors to estimate organ and whole body effective doses.[17] However, these more discriminatory measures are not routinely or reliably captured and reported. Collection of such information in prospective registries could identify procedures that exceed the 95th percentile for exposure based on national benchmarks.[18-20]

Technique plays an important role in the magnitude of radiation exposure (and thus dose) to the patient and operator during fluoroscopy procedures. Hirshfeld et al. provide a review of how to reduce exposure by optimizing technique and ensuring best practice in using personal protective equipment.[21]

Catheter-based interventions in pediatric patients

Cardiac catheterization in children has become a critical component of diagnosis and therapy. The principles of radiation safety take a predominant role in planning and execution of such procedures because of the repeated exposures over a lifetime, increased radiosensitivity of children, and a longer time for side effects to manifest. Radiation exposure can be very high in the pediatric patient because of the complexity of interventions, small body size, higher heart rates requiring faster frame rates, and wide anatomical variations.

The precautions recommended for adult patients apply equally to children. Children born with congenital heart disease frequently undergo numerous diagnostic and therapeutic catheterizations, with potential harmful cumulative long-term effects of radiation exposure.[22,23] The complex 3-dimensional anatomy of these lesions frequently necessitates multiple digital acquisitions, which increase the radiation exposure. Imaging equipment used for pediatric procedures should be designed and configured for image acquisition modified to accommodate variable procedural requirements and wide age and weight range as seen in the pediatric laboratory.[24] Strategies for radiation exposure reduction and image quality in pediatric populations have been well described[25] and the importance of exposure reduction is emphasized in the Image Gently and Step Lightly campaigns.[26]

Cardiac CT

CT imaging has rapidly increased in use, and become an invaluable tool for the diagnosis of a broad spectrum of disease entities.[27-29] Developments in CT gantry technology in the past 10 years (eg, slip rings, z-axis segmented detector arrays, subsecond gantry rotation) have provided faster image acquisition that facilitated development of cardiac-gated CT angiography (CCTA).[30-32] CCTA has rapidly been adopted for noninvasive coronary artery imaging because it provides high-contrast cross-sectional views of the coronary arteries without limitations on the imaging plane or field of view. Utilization of CCTA has a historically high price: increased radiation exposure to the population. Multiple technological advancements have, however, resulted in a steady decrease in radiation dose over the past decade.[33,34]

Radiation exposure from CCTA is proportional to the tube current, exposure time, and the square of tube voltage and is inversely proportional to the pitch for helical acquisition. Estimated radiation doses for CCTA examinations can be expressed in numerous terms. These are the volume CT dose index (mGy), and dose length product (mGy cm).[28] The estimated effective dose for a patient is obtained by multiplying dose length product by a conversion factor, k (mSv mGy^{-1} cm^{-1}) that varies dependent on the body region that is imaged.[35] These normalized effective dose coefficients are determined using Monte Carlo techniques and consider the radiation sensitivity of the body region scanned based on exposed organ radiosensitivities.

Because of the growth in utilization of CCTA, there is increasing scrutiny regarding its appropriateness and associated radiation exposure.[36,37] In 2009, a sample of 50 international sites as part of the **Pro**spective Multicenter Study on Radia**t**ion Dose **E**stimates of Cardiac **CT** Ang**io**graphy i**n** Daily Practice (PROTECTION) I study highlighted a wide variation in protocols used for CCTA, demonstrating a 6-fold difference in median patient radiation exposure among the participating study sites.[37] More recently, reported doses in CCTA have been significantly lower than those published in PROTECTION with modern publications reporting effective radiation doses of 1-4 mSv.[38-40]

There are patient- and protocol-related factors that can affect patient exposure. However, it is the CT scan parameters that ultimately determine patient exposure. Optimizing scan parameters to ensure diagnostic image quality is achieved with a reasonable dose is the goal of all cardiac CT examinations. The CT physician must be engaged in the protocol selection. Typically, the acquisition mode, routine helical retrospectively gated, prospective triggering, or high pitch helical acquisition has the greatest effect on radiation exposure. This is followed by the selection of tube potential and tube current and planning of scan length. The lowest radiation exposure for conventional cardiac CT requires use of a lower tube potential, typically 100 peak kilovoltage (kVp), a tube current setting that is appropriate to the patient body habitus, a short x-ray exposure window of $\leq$ 10 ms, and a scan coverage of 120-140 mm. Routine use of retrospective electrocardiographic gating is associated with a significant increase in radiation exposure and is not recommended unless ventricular function or wall motion assessment is needed.

Nuclear medicine—radionuclide myocardial perfusion imaging

The most common technique used for radionuclide myocardial perfusion imaging (RMPI) is called single photon emission CT (SPECT) imaging. This technique uses a gamma-emitting radioisotope (called radionuclide) that is injected into the bloodstream of the patient at peak stress and/or at rest. For RMPI studies, the effective dose ranges between 2 and 32 mSv depending on the radioisotope and protocol used, with dual isotope protocols having the highest effective doses.[15,41]

With respect to radiation exposure, there are a number of qualitative differences between RMPI and other cardiac imaging modalities.[42] The primary difference is the source of the ionizing radiation (radiopharmaceutical inside the body vs external radiation field), and consequently, how radiation exposure and dose are measured. In RMPI studies, radiation exposure is expressed in terms of administered activity. This is the number of decays per second and is typically measured in millions of becquerels. The International Commission on Radiological Protection (ICRP) outlines methods for estimating radiation dose based on the administered activity.[43-45] However, these methods assume standard patient biokinetic characteristics and habitus.

The newest SPECT systems use cadmium zinc telluride. These have many advantages including a higher sensitivity for gamma-rays because of the high atomic numbers of Cd and Te, and better energy resolution than older scintillator detectors. These advantages facilitate a lower radionuclide dose in patients. Electrocardiographic cardiac gated acquisitions are possible with SPECT to obtain differential information about the heart at any phase of the cardiac cycle. Gated myocardial SPECT can be used to obtain quantitative information about myocardial perfusion, thickness, and contractility, and to allow calculation of left ventricular ejection fraction, stroke volume, and cardiac output.

Recommendations for reducing dose in RMPI include the use of stress first or stress-only protocols in patients with low pretest probability of coronary artery disease, because a stress-only protocol in conjunction with attenuation correction is likely to provide sufficient information to rule out the disease at a relatively low radiation dose.[46] Dual isotopes have been shown to have much higher radiation exposure rates and when possible technetium agents/isotopes should be used over and above thallium. Attenuation correction and new software acquisition with iterative reconstruction have also facilitated lower dosing of radionuclides.

Positron emission tomography is an expanding area of RMPI. Ongoing advances in cardiac SPECT and positron emission tomography imaging techniques and incorporation of rubidium-82 has the potential to significantly reduce the radiation exposure per procedure by almost 50% compared with previous techniques.[47,48]

RECOMMENDATION

2. We suggest that the operator and institution adopt processes to minimize the radiation exposure for each cardiac imaging modality (Strong Recommendation, Low-Quality Evidence).
3. We suggest that each site measure radiation exposure for each cardiac imaging modality at regular intervals as a quality initiative (Strong Recommendation, Low-Quality Evidence).

Values and preferences. In cardiology, there are a variety of imaging modalities and techniques that might provide similar information, making it difficult in many clinical scenarios to recommend a "1 size fits all" approach based solely on risks of radiation exposure. Therefore, a more reasonable approach would be to recommend that clinicians and laboratories adopt processes of protocol selection to match the specific patient needs and follow the "as low as reasonably achievable" principle approach to optimize imaging techniques. These steps would aid in providing optimal diagnostic information and minimizing patient risks.

Recording and Monitoring Radiation Exposure/Dose to the Patient

Currently there are established standards in Canada for monitoring and reporting of exposure to healthcare workers from radiation-based procedures. However, similar policy or standards do not exist for patients. Increasingly, many individuals are undergoing several procedures using ionizing radiation, which results in individual cumulative effective doses of greater than 100 mSv. This might be especially true in cardiology, in which acute exposures/doses are relatively high compared with other domains. The concern for potential health risk because of high cumulative doses forms the basis for programs to track procedural exposures and doses. A recent joint statement by several agencies outlines the need and potential benefits of radiation exposure tracking strategies.[49] They confirm that "the major goals of tracking include: (1) supporting accountability for patient safety; (2) strengthening of the process of justification (eg, information available at the point-of-care for the referring practitioner); (3) supporting optimization (eg, use of diagnostic reference levels); (4) providing information for assessment of radiation risks; and (5) establishing a tool for use in research and epidemiology."[49; p. 1] The International Atomic Energy Agency (IAEA) Smart Card/SmartRadTrack program is one way to track individual patient exposure histories and perhaps, cumulative dose.[50,51] For the operator, technologies that allow personal dose monitoring and feedback in "real-time" are available or under development.

A cumulative dose-tracking strategy requires at least two important features: (1) a common measure of radiation dose across modalities; and (2) a platform for recording radiation exposures and doses for each procedure and summation of radiation doses across procedures. As previously discussed, each modality has a unique set of radiation exposure and dose metrics. Each of these can be used to estimate an effective dose. Therefore, effective dose might serve as a means to integrate collected information across modalities to estimate an individual's cumulative radiation dose.[42] However, it should be noted that effective dose was developed for population level dosimetry, and thus, might be inaccurate for estimating doses to an individual. When there is agreement on which metrics should be recorded, the means by which they are recorded must allow for communication of information such that cumulative doses across procedures can be calculated for an individual. The Digital Imaging and Communications in Medicine header, which is currently part of most imaging modalities, might be appropriate for this purpose.[42] Currently, there is no standard of practice in Canada for measuring and recording radiation exposures and doses to patients, nor is there a standard process to communicate this information to patients and other health care practitioners. A platform for recording and communicating dosimetry information of patients should be established. Cardiologists and radiologists should provide manufacturers with information on which data elements, specific to radiation dosimetry, should be incorporated into imaging technology.

RECOMMENDATION

4. We suggest that a multi-disciplinary committee should be established to develop a consensus on dosimetry standards for cardiac imaging and interventional procedures that use ionizing radiation in Canada (Strong Recommendation, Low-Quality Evidence).
5. We suggest that cardiologists, radiologists, administrators, and policy makers should work together with manufacturers to develop a platform for radiation dose tracking across Canada, conforming to health information communication and privacy regulations (Strong Recommendation, Low-Quality Evidence).

Patient Perspective

Patients might come to clinic with knowledge regarding the potential risks from ionizing radiation, and in some cases with various biases regarding risks gathered from various nonpeer-reviewed sources and media. Thus, it is imperative that the physician obtaining consent for the procedure has a working knowledge of the expected radiation exposure and the potential specific risks to the patient so that a reasoned discussion may take place. Discussions related to risks of radiation will also help verify to the patient and family that the health care provider and institution has acknowledged the potential risks of radiation exposure in their overall decision process.

There is little evidence on which is the most effective strategy to communicate the radiation-related risks to the patient. Assessing the actual long-term risks from any one procedure is not easy for any individual and it is difficult to fit "hard numbers" into the discussion. A generic communication strategy that has potential for greater uptake could be adopted. Use of operational quantities or terms (eg, Sv) in discussion regarding radiation risks with the patient should be discouraged. Such specific terminology might be more useful within individual departments when deciding on dosing strategies rather than for use in patient discussions.[52] The language of communication of risk should be simple, well understood by the health care providers relaying the information, and placed in context with the specific test or procedure and clinical indication for which it is being performed. It might be reasonable to state that the long-term risk from radiation exposure is less than the other expected risks from the procedure but nevertheless exists, and all necessary precautions have been taken to minimize this risk to obtain the information needed or to complete the interventional procedure.

A number of articles have reviewed options for discussing radiation risks with patients.[52-57] Options include: (1) expressing risk in comparison with natural background radiation exposure; (2) expressing risk compared with risk of death from natural causes or natural occurrences of cancer itself; or (3) expressing a radiological dose as multiples of a chest x-ray, which might be an even simpler means of communicating risk. This latter method has been suggested by the UK College of Radiologists and has been endorsed in the European Commission's guidelines on imaging.[56] In pediatric practice, examples such as the "Image Gently" campaign have been used to communicate risk to parents of children undergoing radiology-based procedures.[55] Clinicians should encourage a common framework for communicating risk related to radiation procedures.

In some cases, patients might receive a "high dose" of radiation that might result in tissue reactions such as skin injury over the subsequent weeks. In such circumstances it is suggested that there should be processes in place to follow-up patient status and enquiries postprocedure. The intensity of follow-up will depend on the magnitude of dose exposure.[10,58]

RECOMMENDATION

6. We suggest that health care providers establish a mechanism for follow-up of potential deterministic injuries in patients with "high" exposure (Strong Recommendation, Low-Quality Evidence).

Values and preferences. In appropriately selected patients the potential mortality and morbidity benefits of a specific cardiac diagnostic test or intervention far outweighs the potential long-term stochastic risks related to radiation exposure. However, considering a more predictable relationship between very high dose of exposure and risk of skin injury from high procedural-related doses, we suggest that there be a mechanism of identification and follow-up of such patients.

Conclusions

Radiation exposure from cardiac procedures, primarily fluoroscopy-guided procedures, CCTA, and RMPI, can in rare cases cause skin injury and might even be associated with cancer. However, the nature of resulting injuries is such that they may often go unnoticed by those providers ordering and performing the single (or multiple) procedure(s) that lead to such injuries. There is little robust evidence for definite long-term risks at the levels of radiation exposure experienced by most cardiac patients, particularly considering the age at which most patients receive examinations that use ionizing radiation. All providers should remain vigilant regarding regular surveillance of radiation exposure levels from imaging modalities with a constant review of procedure metrics and techniques to limit exposure to ionizing radiation and maintain quality. It is important to emphasize that small adjustments in procedure metrics, such as reducing fluoroscopy time during interventional procedures by 5%-10%, reducing the scan range for CCTA by 1-2 cm, or reducing the administered dose of injected radioisotopes can have a substantial effect on reducing the cumulative population burden from ionizing radiation. Though exposure reduction strategies have had a significant effect on reducing radiation dose perhaps the most powerful strategy is to limit performing studies that do not meet current appropriateness guidelines.[30]

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Supplementary Material

To access the supplementary material accompanying this article, visit the online version of the *Canadian Journal of Cardiology* at www.onlinecjc.ca and at and at http://dx.doi.org/10.1016/j.cjca.2013.06.002.