

Radiation safety during percutaneous coronary procedures: how to reduce radiation exposure and its complications

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Introduction

It is well known that cardiologists, in the field of invasive diagnostic angiography and percutaneous interventions, are among the most frequent users of fluoroscopy in the medical world. Recent attention to the high radiation doses utilised in other cardiac imaging modalities such as nuclear and computed tomographic angiography has increased awareness of this important issue. Interventional cardiology currently accounts for at least 50% of total effective dose by radiation used in medical imaging in Europe and in the United States^{1,2}. While there has been recent attention to this issue by the scientific and lay press, along with increasing regulatory scrutiny, many cardiologists have been slow to adopt better practices to reduce radiation exposure to their patients and themselves. The short and long term risks of excessive radiation exposure are well known. Excessive patient radiation exposure from fluoroscopy in the United States must now be reported as a sentinel event as mandated by the Joint Commission or Accreditation of Healthcare Organizations (JCAHO)³. The aim of this brief contribution is to review and describe the different tools and techniques available to decrease radiation exposure and risk in the cardiac catheterisation laboratory and to suggest additional strategies and improvements in technology. We have attempted to make this document easy to understand and to be of practical value for invasive cardiologists, regardless of the depth of their knowledge of radiation physics.

Definitions, measurement units and radiation risks

For the purpose of this review, the emphasis has been placed on patient exposure and risk. However, it is a reasonable assumption that by decreasing radiation exposure to the patient, exposure to the

operator and attending personnel will also be reduced. Radiation exposure to radiation workers (principally by scattered radiation from cardiac fluoroscopy) is described in terms of effective dose and equivalent dose in the International Commission on Radiological Protection report 60 (ICRP)⁴. The effective dose (ED) is a weighted sum of equivalent doses delivered to various organs and is used to assess the stochastic risk (no threshold dose and includes cancer and genetic mutations)⁵. This is typically estimated using the readings from radiation badges and is reported in units of mSv⁶. Maximal annual permissible levels among radiation workers are stated in most countries. Dose to professionals as cardiologist in the range of 20 mSv correspond to an elevated risk of death by cancer of 1/1000⁷.

Radiation risks to patients are of two types: stochastic (as above and usually long term) and deterministic (threshold dose leading primarily to skin burns and ulceration and occurs early). Although stochastic risks are difficult to predict, growing concern of their risks lies with increasing numbers of procedures performed on younger patients, multiple and complex procedures, all with risks that go unnoticed because procedures are often associated with doses that are below the deterministic threshold. In high dose ranges, the severity of the effect is dose and organ dependent. These deterministic effects in the case of fluoroscopy are related to the skin dose. Thus the dose delivered locally to the skin should be minimised to prevent burns (ranging from a transient erythema to skin necrosis) and more serious problems.

To evaluate and hopefully limit this deterministic risk, cardiologists require an estimate of the highest dose delivered to the skin (entrance skin dose). Unfortunately it is impractical to measure this directly in routine clinical practice. Instead, an estimate of this dose

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can be provided by the “Reference Point Dose” (RPD) available from current imaging systems which is reported in Gray (Gy) or mGy units. This is also referred to in a practical sense as the “cumulative dose” and is measured at a fixed reference point from the isocentre towards the X Ray tube⁸. It is only an estimate of the local skin dose since actual skin local dose will depend on distribution of the dose during the procedure as determined by different gantry angulations. All of these data can be collected and analysed off-line following the procedure. It is this measurement that the FDA has mandated be used to trigger a sentinel event report (currently 15 Gy).

The other commonly available measurement is the dose-area product (DAP) or kerma-area product ($\text{Gy}\cdot\text{cm}^2$)⁹. This is an important measurement to look at in terms of control of the stochastic risk. The most important factors influencing DAP are field size, fluoroscopy level, use of cine-angiography, complexity of the procedure, and operator skill - all of which are under the control of the operator¹⁰. Therefore, cardiologists currently can limit risk of short term complications of their patients by following the RPD during the procedure. In addition, monitoring the DAP allows benchmarking of their practice and providing target dose limits in an effort to reduce the long term effects associated with use of fluoroscopy.

Steps to limiting radiation exposure

Most steps to limiting the amount of radiation exposure to patients and operators are well documented, but adherence to these by cardiologists is highly variable.

- A) Equipment: modern and well maintained and calibrated fluoroscopic systems are essential. Modern systems provide pulsed progressive fluoroscopy and choices of dose and frame-rate¹¹. Options also include ability to store fluoroscopic images, thus avoiding the need to repetitively perform cine-angiography during PCI. Appropriate filtration should be used along with easy-to-use collimators. Adequate shielding above and below the table should always be provided and used¹².
- B) Operator practice: The operator should be knowledgeable of the equipment's features designed to limit radiation exposure such as adjusting frame-rate, using collimators, avoiding unnecessary magnification, etc. Minimising cine-angiographic (digital acquisition) runs, minimising total fluoroscopic time, ensuring the image detector-to-patient distance is as low as possible and fluoroscopic tube to patient distance as high as possible, avoiding unnecessary steep angulated views (particularly in the left anterior oblique), limiting use of high dose fluoroscopy (vascular access: femoral versus radial^{13,14} approach), awareness of situation and attending personnel, and remembering the “inverse-square rule”. Use of lead aprons and eye protection should be routine¹⁵.
- C) Patient factors: Increasing thickness and body weight are key contributors to total radiation dose delivered. Morbidly obese patients present challenges to the equipment and the operator; poor image quality (with temptation to consider using even higher doses), prolonged procedures and more scatter to the operator can be anticipated. The operator needs to account for these factors when planning and performing these procedures in such patients⁶.

Further strategies to decrease radiation exposure

While the above points are deserving of continuing emphasis, newer strategies are also warranted. There is an urgent need for real-time monitoring and alert system to the operator of the RPD: this is a relatively new concept. Some labs now routinely make the operator aware via verbal alerts that threshold RPD limits have been approached or exceeded (e.g. 3 Gy followed by 6 Gy and higher). This has obvious benefits in a system in which exceeding certain limits will initiate reporting of the event to the local radiation safety office or to state regulatory agencies. There is a need for industry help to improve the visibility of display and alerts of RPD and DAP measurements in real-time. Perhaps systems could be designed to automatically vary angulation, collimation and dose once excessive exposure in an unchanged gantry position has been detected.

The complexity of the procedure is also a critical factor in the cumulative dose measurement. Highly complex procedures such as treatment of bifurcation lesions and chronic total occlusions can be associated with very high exposure to radiation. Appropriate planning of the procedure with an emphasis on strategies to decrease the amount of x-ray exposure should be strongly encouraged. Additional complicating factors such as patient obesity, and difficult vascular access etc should also be taken into account. Complexity indexes have been described¹⁶ but will need further exploration with validation in large numbers of patients and in individual labs.

Patient follow-up

Clinical follow-up of any patient identified as having been exposed to excessive radiation exposure should be arranged. An explanation of the dose measurement and why it was so high should be given to such patients along with instructions on what to look for with respect to erythema and/or burns. Routine clinical re-evaluation and examination should be arranged for these patients over the next few weeks. Referral to a dermatologist should also be made whenever there are signs of significant burns.

Quality assurance and education

It would be helpful if regular feedback was provided to operators with their RPD and DAP measurements of their patients, with comparison to their colleagues. Cumulative radiation dose for each patient should be recorded and stored in each lab and consideration also made to adding this to the medical record. Each lab could then set goals and strategies for reducing the total amount of radiation exposure.

New cardiology trainees, particularly those in interventional training programs, require more focussed practical education of radiation exposure and safety issues¹⁷. Importantly, we as practising specialists need to set a better example as we teach these operators of the future. Continuing education in this field should be mandatory; more sessions – educational and research – should be devoted to this entire field at major cardiology meetings.

Practical hints

One of the main issues in the daily practice of the interventionist is to establish a practical guideline for the management of patient who underwent procedure in interventional cardiology. to our

knowledge, there is currently no standard "radiation risk score" in interventional cardiology correlated to a clinical follow up of the patients. The Tables 1 and 2 introduce the concept of a suggested radiation clinical management exposure score (RCME) correlated with a practical clinical follow-up guideline. This proposed score can be used in daily practice of cardiac percutaneous procedure. In addition we summarised practical recommendations in Table 3 to optimise radiation protection of the patients, staff and operator.

Table 1. Suggested radiation exposure clinical management score (RECMS): How to plan patient follow-up.

Classification of patients at risks (pre and post CA/PCI)	Score
Weight > 100 Kg	2
Diagnostic coronary angiography	1
Emergency PCI	1
Simple elective PCI (lesion type A, B1)	1
Complex elective PCI (lesion type B2,C) and/or multivessel PCI	2
Repeated procedure (< 6 months)	2
Status post thoracic/neck radiotherapy	2
RPD: to determine the risks of burn	
< 1000 mGy	1
1000 mGy to 3000	2
>3000 mGy to 6000 mGy	3

CA: Coronary angiography; PCI: percutaneous coronary intervention

Table 2. Suggested consensus on practical radiation clinical management score (PRCM) based on clinical practice: How to plan patient follow-up.

Score	Recommendation proposal
1-3	No specific follow-up
4-5	Call at 3 weeks post CA/PCI to check for deterministic effects
>6	Strict clinical follow-up at three weeks

Table 3. Measures to improve radiation protection of the patients, staff and operator^{18,19}.

Limitation of cineangiographic coronary runs to one cardiac cycle
Use the lowest level of fluoroscopy needed (Total fluoro and acquisition times)
Limit use of high (boost) fluoro doses (10x normal)
Avoid unnecessary magnification
Restrict to the ostial region during coronary intubation and use the largest image-intensifier field
Avoid unnecessary use of steep angulations: prefer projections that rotate out the spine
Collimation of the field decrease the level of scattered dose
Be aware of scattered radiation
Minimise patient-to-detector distance but maintain a large radiologic tube-to-patient distance
Remember the inverse square law
Adequate use of shielding and lead aprons
Recommendation to wear 2 dosimeter badges (waist level and neck level) and a ring dosimeter
Periodic inspections and testing of X-Ray unit and lead shields
In all cases apply the ALARA "as low as reasonably achievable" rule ⁴

Conclusion

The key message of this contribution is that no safe dose exists and we must assume that there is a need for improvement in the practice of radiation protection. The linear, no-threshold dose-effect relationship adopted by the international community is a convenient and broadly accepted tool. Finally, the application and the respect of simple rules as described in this discussion will increase the protection of the patient and all the staff present in the catheterisation laboratory.

References

1. Bedetti G, Botto N, Andreassi MG, Traino C, Vano E, Picano E. Cumulative patient effective dose in cardiology. *BJR*, 2008.
2. Regulla DF, Eder H. Patient exposure in medical X-Ray imaging in Europe. *Radiat Prot Dosimetry* 2005, 114:11-25.
3. Balter S, Miller DL. The new Joint Commission sentinel event pertaining to prolonged fluoroscopy. *J Am Coll Radiol*. 2007 Jul;4(7):497-500.
4. International commission on Radiological Protection (1990). Recommendations of the International Commission on Radiological Protection. ICRP Publ 60, Ann ICRP 21 (1-3).
5. Balter S. An overview of radiation safety regulatory recommendations and requirements. *Catheter Cardiovasc Interv* 1999;47:469-74.
6. Balter S, Moses J. Managing patient dose in interventional cardiology. *Catheterization and cardiovascular interventions* 2007;70:244-249.
7. Folkerts KH, Muenz A, Jung S. Estimation of radiation exposure and radiation risk to staff of cardiac catheterization laboratories. *Z Kardiol* 1997;86:258-63.
8. IEC. Medical electrical equipment, Part 2-43: Particular requirements for the safety of X-Ray equipment for interventional procedures. Geneva. IEC;2000. IEC Report 60601.
9. Bushberg JT, Seibert JA, Leidholdt EM, Boone JM (2002). The essential physics of medical imaging. Lippincott Williams & Wilkins, Philadelphia.
10. Kuon E, Schmitt M, Dahm JB. Significant reduction of radiation exposure to operator and staff during cardiac interventions by analysis of radiation leakage and improved lead shielding. *Am J Cardiol*. 2002;89:44-9.
11. Stisova V. Effective dose to patient during cardiac interventional procedures (Prague workplace). *Radiat Prot Dosimetry*, 2004;111: 271-274.
12. Kuon E, Schmitt M, Dahm JB (2002). Significant reduction of irradiation exposure to operator and staff during cardiac interventions by analysis of radiation leakage and improved lead shielding. *Am J Cardiol* 89:44-49.
13. Brasselet C, Blanpain T, Tassan-Mangina S, Deschildre A, Duval S, Vitry F, Gaillot-Petit N, Clément JP, Metz D. Comparison of operator radiation exposure with optimized radiation protection devices during coronary angiograms and ad hoc percutaneous coronary interventions by radial and femoral routes. *European Heart Journal*, 2008;29, 63-70.
14. Lange HW, von Boetticher H. Randomized comparison of operator radiation exposure during coronary angiography and intervention by radial or femoral approach. *Catheter Cardiovasc Interv*. 2006;Jan;67(1):17.
15. Maeder M, Verdun F, Stauffer JC, Amman P, Rickli Hans. Radiation exposure and radiation protection in interventional cardiology. *Kardiovaskuläre Medizin* 2005;124-132.

16. Balter S, Miller DL, Vano E, Ortiz Lopez P, Bernardi G, Cotel E, Faulkner K, Nowotny R, Padovani R, Ramirez A. A pilot study exploring the possibility of establishing guidance levels in X-Ray directed interventional procedures. *Med. Phys.* 35 (2), February 2008.

17. Brateman L. The AAPM/RSNA Physics tutorial for residents-Radiation safety considerations for diagnosis radiology personnel. *Radiographics* 1999;19:1037-1055.

18. Vano E. Radiation exposure to cardiologists: how could it be reduced. *Heart* 2003;89:1123-4.

19. Limacher MC, Douglas PS, Germano G, Laskey WK, Lindsay BD, McKetty MH, Moore ME, Park JK, Prigent FM, Walsh MN. ACC expert consensus document. Radiation safety in the practice of cardiology. *J Am Coll Cardiol* 1998;31:892-913.