Controlling the radiation dose received by patients undergoing cardiac imaging

“...controlling the radiation dose received by patients undergoing cardiac imaging should be a major concern for any individual involved in the cardiac care process...”

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Paradoxically, while societal pressures on systematic evaluation and risk minimization exist, the hazard of exposure to low-dose ionizing radiation from medical imaging procedures has long been underestimated or ignored. This is particularly true for cardiology. Since the 1970s, the development of imaging techniques using ionizing radiation has resulted in considerable progress in the diagnosis, understanding of the pathophysiology, and treatment of valvular, ischemic and rhythm heart diseases. The use of these techniques by interventional or noninterventional cardiologists, most often untrained in radiation protection, has led to both patients and operators being exposed to significant doses of radiation, without a real quality control of practice. Assessing patient exposure due to complex interventional procedures is one of the most important requirements of the Council Directive 97/43/Euratom1 on health protection of individuals against the dangers of ionizing radiations in relation to medical exposure [1].

Cardiac patient exposure to ionizing radiation

To treat a patient with heart disease, the cardiologist may use a wide variety of techniques to deliver ionizing radiation, either for diagnosis (e.g., radionuclide scintigraphy, angiography, coronary angiography or computed tomography coronary angiography [CTCA]) or intervention (e.g., percutaneous coronary interventions [PCIs], percutaneous valvuloplasty or ablative techniques for cardiac rhythm disorders). In developed countries, where supply of care is important, access to these techniques became easy and, in our experience, it is often quicker to get a CTCA or an invasive coronary

angiography than a stress ECG test or a stress echocardiography. However, each exploration delivers relatively high doses of radiation (equivalent dose [ED] in milli Sievert [mSv]), ranging from 4 to 8 mSv for diagnostic electrophysiology, 5 to 10 mSv for coronary angiography, 6 to 15 mSv for cardiac nuclear scintigraphy, 7 to 20 mSv for PCI, 4 to 21 mSv for CTCA, and 15 to 25 mSv for catheter ablation of atrial fibrillation [2,3]. As a result, a patient who undergoes a CTCA, a conventional coronary angiography, PCI, and stress radionuclide myocardial perfusion imaging to detect restenosis, cumulates in a radiation dose of approximately 22–65 mSv within 3–6 months, which is equivalent to 1250 chest x-rays (0.04 mSv) or 20-fold the annual natural radioactivity in the UK (~2.2 mSv per year). Fazel *et al.*, from a large survey conducted in the general population, demonstrated that imaging procedures are an important source of exposure to ionizing radiation in the USA and can result in high cumulative effective doses of radiation [4]. Generalization of their findings to the nonelderly adult population suggests that medical procedures lead to cumulative effective doses that exceed 20 mSv per year, the upper limit allowed in workers in healthcare and the nuclear industry, in approximately 4 million Americans. Unsurprisingly, six out of the 20 procedures with the largest contribution to the annual cumulative doses were cardiac procedures. Myocardial perfusion imaging alone accounted for more than 22% of the total effective dose from all study procedures, diagnostic cardiac catheterization for 4.6% and PCI for 1.8%. CTCA was not widely performed at the time of the study and was not taken into account.

Keywords

- computed tomography
- coronary angiography
- coronary angiography
- dose-area product
- percutaneous coronary intervention ■ radiation protection

What are the risks for the patient?

Risks associated to radiations are deterministic, occurring when dose exceeds a threshold, and stochastic (or probabilistic), such as cancer or leukemia, occurring randomly with a linear dose–response effect. Even though improvements in radiologic equipments have reduced x-ray dose rates, the number and complexity of fluoroscopically guided procedures increase, and may expose the patient to deterministic radiation-induced injuries, such as skin ulceration and necrosis [5]. The commonly accepted threshold is a skin-entrance dose of 2 Gray (Gy), which was reached in approximately 3% of coronary procedures in a recent study [6].

Based on International Commission for Radiation Protection (ICRP) assumptions, the total risk for the development of radiation-induced fatal cancer has been estimated as one for every 1300 patients subjected to coronary intervention, and between one in 3000 and one in 9000 for diagnostic procedures [7]. Based on almost the same assumptions, radiation exposure from 64-slice CTCA has been associated with a higher estimated risk of cancer, varying from one in 143 for a 20-year-old woman to one in 261 for an 80-year-old man [8]. For PCIs, given the fact that more than 620,000 PCIs are performed annually in Europe and more than 1.2 million are performed in the USA annually, theoretically, one might expect 1500 excess cancers cases as a result of the PCIs performed. This rough estimate is almost certainly wrong, since all procedures are not performed in independent patients. A single patient is increasingly exposed during their life to iterative diagnostic and therapeutic techniques of cardiac imaging using ionizing radiation, resulting in high cumulative doses and an increased stochastic risk. On the other hand, the underlying model of a linear dose–response, without threshold for assessing the effects of low radiation doses, has been criticized. The principal source for the development of these risk estimates is the Life Span Study, which is researching malignancies associated with radiation exposure in Japanese survivors of atomic bombs. There is no consensus as to whether the effects observed in individuals who experienced whole-body acute exposures to primarily high levels of radiation can be extrapolated to the partial-body exposures at lower levels of radiation delivered to patients who are undergoing medical imaging procedures. Although the ‘true’ risk of fatal cancer induced by low doses of radiation (e.g., <100 mSv) remains unknown, the ICRP recommendations, updated in 2007, stated that [9]:

“The estimates of cancer risk attributable to radiation exposure have not changed greatly in the past 17 years, whereas the estimated risk of heritable effects is currently lower than before. The central assumption of a linear dose–response relationship for the induction of cancer and heritable effects, according to which an increment in dose induces a proportional increment in risk even at low doses, continues to provide the basis for the summation of doses from external sources of radiation and from intakes of radionuclides.”

According to the ICRP, assuming a linear response at low doses, the combined detriment due to excess cancer and heritable effects remains unchanged, at approximately 5% per Sv.

Operators’ exposure to ionizing radiation

Occupational doses of radiation in interventional procedures guided by fluoroscopy, such as coronary angiography, PCI and ablative techniques, are the highest doses registered among medical staff using x-rays. Interventional cardiologists represent the most important group of medical specialists involved in such practices. This occupational component of radiation protection alone fully justifies training in radiation protection for all interventional cardiologists and paramedical staff. Optimized individual radiation protection devices, such as lead apron, glasses and cap, extension tube and lead screens are essentials, but one should emphasize the fact that the best way to reduce the dose to the in-room operators is to reduce the dose to patient.

Reduce the radiation dose to the patient: necessary & feasible

From the aforementioned paragraphs, one can draw a conclusion: although a patient’s risk of fatal cancer associated with radiation from medical imaging has not been clearly identified, it is necessary to reduce the patient dose to as low as possible. This requires the three steps of radiation protection, suggested by the ICRP, to be followed [9]: justification, optimization and dose limitation. Justification means that any proposed activity that may cause exposure should yield a sufficient benefit to society to justify the risks incurred by the radiation exposure. Optimization, which is also known as the practice of ‘as low as reasonably achievable’ (ALARA), means that the radiation exposures resulting from the practice must be reduced to the lowest level possible, considering the cost of such a reduction in dose. The third element, dose limitation, involves setting upper limits on the dose that may be received by any

member of the public from all man-made exposures other than medical exposures. These limits are imposed by regulatory agencies.

In cardiology, 'diagnostic reference levels' have been proposed by national and European working groups [10]. These reference levels, defined as the third quartile of the mean doses of centers, are useful tools to evaluate the performance of a center for radiation delivered to a patient. A French comparative survey showed broad differences between centers: mean values of each parameter of dose were in a ratio of 1–3 (number of images), 1–4 (fluoroscopy time), 1–5 or more (dose–area product, linearly related to ED), ranging from the lowest to the highest mean values [11].

For conventional coronary angiography and PCI, the dose during catheter angiography depends upon several fixed or relatively fixed factors, such as the patient's BMI, procedural complexity, emergency circumstances, workload, operator's experience, target vessel involved in PCI and catheterization laboratory equipment. It is also highly dependent on factors that may be controlled by the operator and, therefore, various techniques aimed at reducing the dose have been proposed [2,3,9]. Kuon *et al.* demonstrated that, to reduce the fluoroscopy and fluorography times,

the number of views and selecting less irradiating projections was highly effective, and resulted in very low levels of doses for coronary angiography (dose–area product: 12.9 Gy•cm²; ED: 2.2 mSv), elective PCI (13.3 Gy•cm²; ED: 2.3 mSv) and combined intervention (25.9 Gy•cm²; ED: 4.4 mSv) [12].

After a phase of prospective monitoring of the dose received by patients during coronary angiography and PCI [13], we evaluated the effectiveness of a program for radiation dose reduction, implemented in our catheterization laboratory in 2006 [14]. For the first part of the program, all medical and paramedical staff participated in a national 2-day training course in radioprotection (15 h training). The second part of the program consisted of implementing simple technical recommendations for operators, who were encouraged to routinely use low fluoroscopic and cine pulse rates (6.25 and 12.5 frames/s, respectively), large intensifier field size (23 cm) with an *a posteriori* numeric magnification, maximal collimation and optimal x-ray tube/patient/image intensifier distances (maximal source–patient distance, minimal patient–image intensifier distance). Routine left ventriculography was discouraged and was contraindicated when left ventricular

Figure 1. Time course of radiation dose received by patients during percutaneous coronary interventions (n = 2900) in Centre Hospitalier de Versailles, France (2002–2009).

Median and interquartile range of DAP in Gy•cm².

DAP: Dose area product; RX: X-ray.

ejection fraction was assessed using a noninvasive method. In contrast to Kuon's experience, the number of runs, choice and angulation of the projections necessary to obtain the best possible analysis of the coronary arteries were not limited. This very simple and costless program, well accepted by operators, was associated with a significant 50% reduction of the doses to patient (and operators), without loss in image quality and with an important reduction of the interoperator variability [14].

Manufacturers of cardiac imaging equipment have recently made considerable efforts to reduce x-ray doses. In addition to improving the production and detection of x-rays (flat-panel detectors), the latest equipment provides useful tools for monitoring dose in real time and reducing the exposure time – virtual collimation on the last image hold, virtual centering without fluoroscopy, single-image acquisition and automation of preselected projections. In our experience, the replacement of the x-ray equipment was associated with a further 50% of the doses to the patient, reaching a median of 1.4 mSv for coronary angiography and 2.9 mSv for PCI (FIGURE 1). Great improvements in dose reduction have also been achieved for CTCA. With the first 64-slice ECG-gated coronary CT scanners, the effective radiation dose averaged approximately 20 mSv [8,15]. Several techniques to reduce the radiation exposure have been evaluated [3] and include ECG-based tube-current modulation, tube-voltage reduction and attenuation-based tube-current modulation. We performed a multicenter study to investigate a reduction-dose protocol with adjustment of the tube current or voltage to patient BMI. In this study, estimated effective radiation dose was significantly reduced from 20 to 13 mSv [16]. Currently, the new cardiac computed tomography generation with prospective pulse acquisition is associated with very low radiation exposure of approximately 4 mSv. New techniques, such as imaging of pulmonary vein anatomy using low-dose computed tomography, or robotic navigation of the ablation catheter, have also been shown to successfully reduce both fluoroscopy time and total radiation dose during percutaneous ablation of persistent atrial fibrillation.

Conclusion & future perspective

In conclusion, controlling the radiation dose received by patients undergoing cardiac imaging should be a major concern for any individual involved in the cardiac care process, from the prescription of explorations to their realization, including patients.

- Training in radiation protection for interventional cardiologists and paramedics working in catheterization laboratories, as recommended by European Commission Council Directive 97/43 /Euratom and many international guidelines, is the cornerstone of practice improvement.
- The administered dose to the patient should be known, registered and monitored in all catheterization laboratories and computed coronary scanner units, as is currently done in nuclear medicine departments. The dose should be registered systematically in a patient's record file, as it can improve the follow-up of patients.
- Comparisons with national or international reference levels for each activity (coronary angiography, PCI, CTCA or percutaneous ablation) should be performed regularly. The radiation dose to a patients (and operator) should become one of the main quality indicators of cardiac imaging activities.
- Long-term follow-up of patients and operators should be improved. Systematic clinical follow-up of patients receiving high doses during cardiac intervention is not currently proposed. The thresholds of dose–area product have been proposed for coronary interventions [6]: a first dose–area product action level of 125 Gy•cm² (ED: 21 mSv) corresponding to the dose threshold of 2 Gy for deterministic effects would imply an optional radiopathological follow-up, depending on the cardiologist's decision. A second dose–area product action level of 250 Gy•cm² (ED: 43 mSv), corresponding to the 3-Gy skin dose, would imply a systematic follow-up. In addition, one may suggest the need for an individual 'radiation monitoring logbook' for the patients, filled after any procedure using ionizing radiation. Only the recording of all cumulative doses received by patients could allow a longitudinal follow-up of radiation doses from medical imaging and may accurately estimate the association between low-dose radiation from medical imaging and risk of cancer.

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