

InterCardioRisk: A novel online tool for estimating doses of ionising radiation to occupationally-exposed medical staff and their associated health risks

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Abstract. Those working in interventional cardiology and related medical procedures are potentially subject to considerable exposure to X-rays. Two types of tissue of particular concern that may receive considerable doses during such procedures are the lens of the eye and the brain. Ocular radiation exposure results in lens changes that, with time, may progress to partial or total lens opacification (cataracts). In the early stages, such opacities do not result in visual disability; the severity of such changes tends to increase progressively with dose and time until vision is impaired and cataract surgery is required. Scattered radiation doses to the eye lens of an interventional cardiologist in typical working conditions can exceed 34 $\mu\text{Gy}/\text{min}$ in high-dose fluoroscopy modes and 3 μGy per image during image acquisition (instantaneous rate values) when radiation protection tools are not used. A causal relation between exposure to ionising radiation and increased risk of brain and central nervous system tumours has been shown in a number of studies. Although absorbed doses to the brain in interventional cardiology procedures are lower than those to the eye lens by a factor between 3.40 and 8.08 according to our simulations, doses to both tissues are among the highest occupational radiation doses documented for medical staff whose work involves exposures to X-rays. We present *InterCardioRisk*, a tool featuring an easy-to-use web interface that provides a general estimation of both cumulated absorbed doses experienced by medical staff exposed in the interventional cardiology setting and their estimated associated health risks. The tool is available at <http://intercardiorisk.creal.cat>.

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1. Introduction

Interventional cardiology (IC) comprises a variety of minimally-invasive procedures used in the diagnosis and treatment of cardiovascular disease. In fluoroscopy, a key technology used in this work, hard X-rays (photon energies typically above 5-10 keV) are passed through a patient onto a detector; catheters and contrast agents are used thereby allowing real-time visualisation of internal structures, processes and activities [1]. Since interventional cardiologists and electrophysiologists carry out their work in close proximity to the patient on whom the imaging is being carried out, they are exposed occupationally to ionising radiation (IR) under normal working conditions.

Used appropriately to support a variety of procedures, IC provides enormous clinical benefits over other surgical procedures, including minimal invasiveness, reduced pain and risk of complications, shorter hospital stays, and lower costs [2, 3]. The benefits of catheterisation over open surgery have resulted in a considerable increase in workloads for IC staff over the past two decades and, although concomitant improvements in technology and radiation protection (RP) measures have reduced doses per procedure, there is concern that higher cumulated doses result in increased risks to IC staff (particularly surgeons) of cataracts and may increase the risk of brain tumours [4]. Effective use of RP measures can reduce doses to exposed organs and thereby lower the magnitude of associated health risks. Doses to both the patient and IC staff can be lowered via configuration of the fluoroscope. Doses to IC staff are typically reduced through personal use of lead (or lead equivalent) aprons and thyroid shields. International best practice recommendations state that physicians involved in interventional procedures should wear such an apron, a thyroid shield and leaded eyewear as a minimum set of RP measures [5], and these are currently used routinely in most IC procedures. A number of additional protection measures may, however, be employed to further reduce operator doses. As well as personal protective equipment such as lead caps, several radiation shielding devices may be employed, including flexible blanket-type shields laid over the patient during interventions to reduce operator exposure to scattered radiation, table skirts (screens suspended between the operating table and the floor), RP cabins (several screens assembled so as to surround the operator, with apertures for the hands), and ceiling-suspended screens (manoeuvrable screens that can be pulled down in front of the operator's face) [6]. The degree to which such measures are employed vary by procedure, specialisation, experience, individual, hospital and country. There are differences in their availability as well: while table skirts and ceiling-suspended screens are available in most IC environments, flexible blanket-type shields are not commonly available and RP cabins are very seldom installed. It has been suggested that such measures are not employed in all catheterisation laboratories, possibly due, in part, to the lack of available information and training in RP [7]. This is especially true for those protection measures that are widely available such as table skirts and

ceiling-suspended screens. The latter is probably the most important item of protection for the head. In some cases, impracticability, discomfort and occupational back pain may also play a role in IC staff not employing certain measures. Recent substitution of lightweight high atomic number materials for the heavier lead used in protective clothing has reduced discomfort for personnel and increased compliance [8]. Given typical RP practices at the present time, the organs of operators that remain chiefly exposed are those in the head, including the eyes and the brain. This gives cause for concern, since IR is known to have the potential for causing damage to these tissues.

Scattered radiation doses to the eye lens of an interventional cardiologist in typical working conditions can exceed $34 \mu\text{Gy}/\text{min}$ in high-dose fluoroscopy modes and $3 \mu\text{Gy}$ per image during image acquisition (instantaneous rate values) when radiation protection tools are not used [9]. Radiation-induced cataract has been recognised as a highly relevant non-cancer endpoint among those exposed to IR since the 1930s [10]. Radiation-induced cataracts typically develop as central opacities in the subcapsular posterior region of the lens, and consist of small granules and vacuoles that form a roughly circular opacity. Defects in lens transparency cause little or no visual impairment in the early stages of the disease, but eventually cause distortion and clouding. The reaction of the lens to radiation is partly attributable to lifelong continued differentiation of the epithelial cells that make up the lens (fibrogenesis); aberrant differentiation of cells due to exposure to radiation results in their accretion to the superficial posterior cortex [11].

Primary tumours of the central nervous system (CNS) include tumours, both malignant and benign, of the brain, brain stem and spinal cord. The epidemiological literature provides clear evidence for a causal association between brain tumours and exposures to IR [12, 13]. Although some of the available literature supporting this association relate to childhood exposures to low linear energy transfer (LET) radiation (such as X-rays) [14], studies of the Japanese atomic bomb survivors indicate increased risks of various CNS tumours (mainly brain tumours) characterised by linear dose-response in adults [15].

Accurate estimation of health impacts to medical staff from IR under a variety of operational and RP scenarios is increasingly important as use of IC procedures continues to grow. Of the existing online radiation risk assessment tools, the majority are focused on radiation exposures to the general population or to medical patients undergoing specific diagnostic or radiotherapeutic procedures, and tend to provide estimates of cancer risk only [16, 17]. Our primary objective was to produce a tool that estimates the most relevant organ doses in IC staff occupationally exposed to radiation, and to estimate the associated health impacts due to these exposures taking into account all sources of uncertainty, specifically in terms of the risk of cataracts and brain tumours.

2. Methods

We designed a tool that produces distributions of annual and total cumulated absorbed doses to the brain and eye lens by employing robust estimators of parameters [18] based on a multiple linear regression of predictors of dose, and subsequently estimates risk based on published epidemiological data.

We developed the tool in **R** [19] using the **shiny** package [20], which allows construction of interactive web applications from **R** and provides an easy-to-use web front-end. The user interface (Figure 1) comprises two panels, positioned side by side. In the left-hand “input” panel, the users can introduce specific data concerning their career (profession, work period and annual numbers of procedures), the target organ of interest (brain or eye lens), and the required output in terms of either absorbed dose (in mGy) or associated health risk. Results are automatically generated and presented in the right-hand “output” panel.

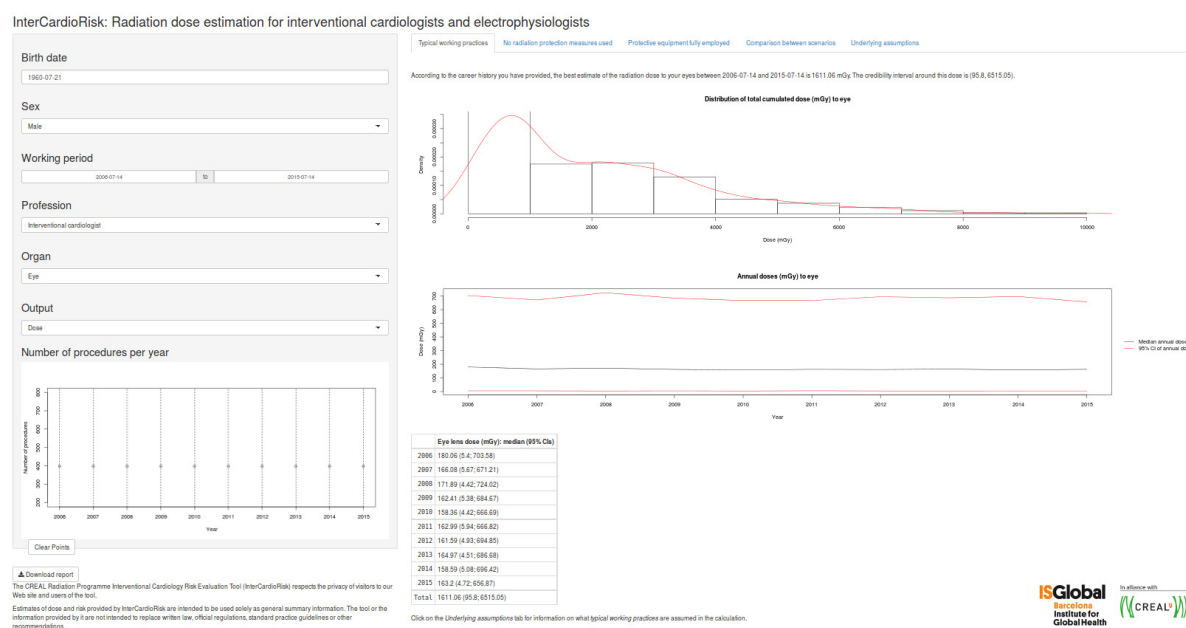


Figure 1. Screenshot of the web-based tool, showing the estimated absorbed dose (in mGy) to the eye lens for an interventional cardiologist, under the “Typical working practices” scenario.

The output panel is further divided into five tabs, the first three presenting the user with organ-specific absorbed doses to the eye lens or brain (in mGy), and the associated risk of cataracts and CNS tumours, respectively. These tabs correspond to dose and risk estimates under different RP scenarios, namely (a) “Typical working practices”; (b) “No radiation protection measures used”; and (c) “Protective equipment fully employed” - a career during which all RP measures typically available throughout that time period were used. Absorbed doses are presented both annually and cumulated across the whole career, together with 95% credibility intervals. The fourth tab presents the cumulated

doses and risk estimates for each of the three scenarios side by side, thereby facilitating comparison of the potential impacts on dose and risk of employing RP measures. The last tab presents a summary of the underlying assumptions employed by the tool in its calculations. In addition to the web version of the results, the user can download a summary report in PDF format that includes all input data and results.

An eye lens dose prediction model was built using data collected in the ORAMED (Optimization of RAdiation protection for MEDical staff) project—described in section 2.1—and from the literature, together with the user-defined occupational history. The potential predictors of absorbed dose to the eye lens included the usage of RP measures, catheterisation access route, tube configuration and operator experience. It was considered unduly cumbersome to input precise details of every cardiological procedure carried out over a career. Instead, the tool was designed so that the user is required to specify only annual numbers of interventions carried out during their career (via a graphical interface), and an occupational history is reconstructed using the proportion of procedures reported as typical for France across each decade between 1970 and 2010 [21], in the absence of country-specific data. For the “typical working practices” career scenario, the occupational history is reconstructed also assuming the RP practices typical amongst French cardiologists over the same time period. For the other two scenarios, the amount of RP practices incorporated into dose calculations is altered accordingly. Changes in dose area product (DAP) typically available to interventional cardiologists over the past four decades were taken into account by fitting a metaregression model using results from the literature [22–34], and subsequently adjusting the computed doses using these values. Probability distributions of measures of risk under each scenario are calculated on the basis of the resulting cumulated absorbed doses, using estimates of dose-response and related uncertainties derived from the epidemiological literature (described in section 2.3). Various sources of uncertainty are taken into account by means of Monte Carlo simulation, which allows uncertainties in several model inputs to be propagated through to results, and thereby expressed as 95% credibility intervals on estimates of dose and risk.

2.1. Data

The data used for fitting the dose prediction model were collected previously within the framework of the ORAMED project, a collaborative project funded in 2008 by the European Union under its 7th Framework Programme. Its remit included the development of methodologies for better assessing and reducing exposures to medical staff from procedures that potentially result in large radiation doses or are associated with complex radiation fields, such as those used in fluoroscopically guided procedures and nuclear medicine. The project collected information on the doses incurred to the eyes and the extremities of operators during IC and electrophysiology procedures in seven European countries (Belgium, Greece, France, Italy, Poland, Slovakia and Switzerland) through a measurement campaign. In total, 381 such procedures

were monitored, including coronary angiography (CA) and percutaneous transluminal coronary angioplasty (PTCA), radiofrequency (RF) ablations and pacemakers and cardiac defibrillator implantations (PM/ICD). For each type of procedure, detailed data were collected on the configuration of the X-ray tube employed, the degree of usage of RP measures, and operator experience. These data are the most extensive data (in terms of number of monitored procedures and countries included) so far collected through measurements following a common protocol [35].

2.2. Dose estimation

Doses to the eye lens were estimated by means of a robust linear regression model on the basis of ORAMED data (dose per unit DAP considering the most exposed eye), including usage of table skirt, cabin and ceiling screen, on the type of procedure, on tube configuration, and on operator experience (defined as high after 4 years of working in IC or electrophysiology) as predictors of the absorbed dose. The obtained estimates are shown in Table 1.

	$\hat{\beta}_0$ (95% CI)
Intercept	1.031 (0.56; 1.51)
Protection method	$\hat{\beta}$ (95% CI)
Table	-0.011 (-0.369; 0.346)
Screen	-0.486 (-0.788; -0.184)
Cabin	-0.648 (-1.118; -0.177)
Procedure	$\hat{\beta}$ (95% CI)
CA PTCA	Reference
PM/ICD	0.610 (0.225; 0.995)
RF ablation	-0.025 (-0.355; 0.305)
Tube configuration	$\hat{\beta}$ (95% CI)
Above	Reference
Below	-0.869 (-1.249; -0.489)
Biplane	-1.183 (-1.681; -0.684)
Experience	$\hat{\beta}$ (95% CI)
High	Reference
Low	0.057 (-0.178; 0.293)

Table 1. Parameter estimates and confidence intervals

For instance, the dose estimated by the model for an interventionalist with relatively little work experience, using a biplane tube configuration and conducting a CA intervention, protected only by screen and table is $\exp(1.031 + 0.057 - 1.183 - 0.486 - 0.011) = 0.55\mu\text{Sv}/\text{Gy} \cdot \text{cm}^2$. The corresponding average dose in the ORAMED database is $0.52\mu\text{Sv}/\text{Gy} \cdot \text{cm}^2$.

In theory, dose to the eye lens is typically reduced by a factor of around 30 when 0.5mm lead-equivalent eyewear are used, but this degree of attenuation is only achieved under frontal exposure to non-scattered radiation. In reality, interventionalists tend to position themselves sideways to the primary beam, are also subjected to scattered radiation emitted from the patient, and coverage of the eye may be reduced due to poor eyewear fit [36]. The reduction factor of absorbed dose to the eye lens due to the usage of protective eyewear was therefore assumed to follow a Project Evaluation and Review Techniques (PERT) distribution [37] with minimal, modal and maximal values of 1, 3 and 10 respectively, based on expert opinion and a review of the literature [8, 38–40]. The PERT distribution is a particular case of the Beta distribution, characterized by the density function

$$f(x) = \begin{cases} \frac{x^{\alpha-1}(1-x)^{\beta-1}}{B(\alpha,\beta)} & : 0 \leq x \leq 1 \\ 0 & : \textit{Otherwise} \end{cases}$$

where $B(\alpha, \beta)$ is the beta function, defined by

$$B(\alpha, \beta) = \int_0^1 y^{\alpha-1}(1-y)^{\beta-1} dy. \quad (1)$$

Sampling from the beta distribution requires minimum and maximum values (scale) and two shape parameters, α and β . The PERT distribution uses the mode or most likely parameter to generate the shape parameters α and β . An additional scale parameter λ scales the height of the distribution; the default value for this parameter is 4. In the PERT distribution, the mean μ is calculated as

$$\mu = \frac{\textit{min} + \textit{max} + \lambda \cdot \textit{mode}}{\lambda + 2} \quad (2)$$

And it can be used to compute the Beta distribution parameters α and β :

$$\begin{aligned} \alpha &= \frac{(\mu - \textit{min}) \cdot (2\textit{mode} - \textit{min} - \textit{max})}{(\textit{mode} - \mu) \cdot (\textit{max} - \textit{min})} \\ \beta &= \frac{\alpha \cdot (\textit{max} - \mu)}{\mu - \textit{min}} \end{aligned} \quad (3)$$

The PERT distribution was preferred over the triangular distribution, which is commonly used to model data elicited from experts or assembled from a variety of published courses, as it does not suffer the same potential for systematic bias [37]. Like the triangular distribution, the PERT distribution emphasizes the “most likely” value over the minimum and maximum estimates. However, unlike the triangular distribution the PERT distribution constructs a smooth curve which places progressively more emphasis on values around (near) the most likely value, rather than on values around the edges.

The considered PERT distribution profile is shown in Figure 2.

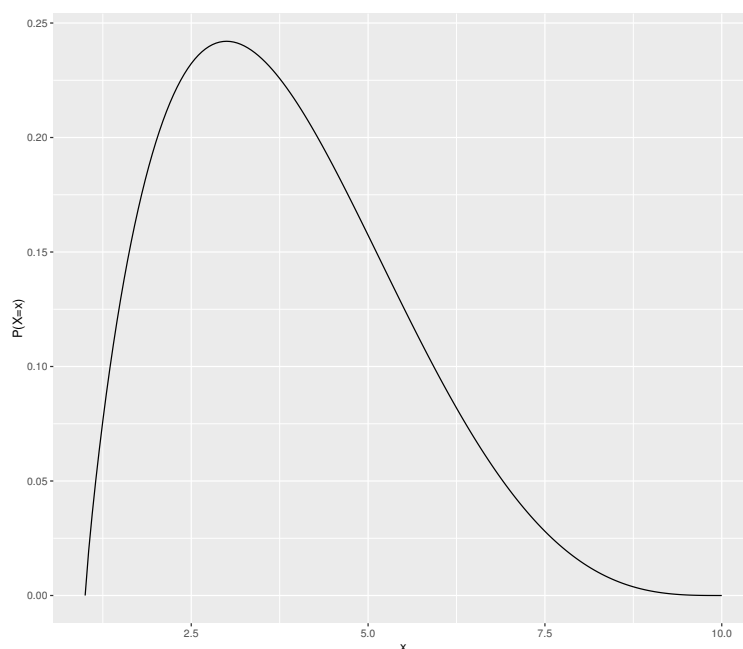


Figure 2. Profile of a PERT distribution with minimum 1, maximum 10 and mode 3.

The metaregression model fitted to incorporate the changes in DAP over time was $893.34 - 0.43 \cdot year$. Therefore, the estimated dose in $\mu Sv/Gy \cdot cm^2$ is multiplied by the corresponding factor taking into account the year to obtain an estimated dose per procedure (in μSv). This dose is finally multiplied by the number of procedures carried out that year by the user and converted into mGy to be reported by the tool.

Doses to the brain were estimated as a function of modelled eye lens dose assuming a linear relationship. This function was estimated by way of carrying out measurements in a typical angiography room. Doses were measured using thermoluminescent dosimeters (TLD) in a CIRS 702-D anthropomorphic female phantom, which was draped with a lead apron and a thyroid shield, and positioned laterally to a single flat panel detector (Philips Allura XPer FD10)(Figure 3). The patient was simulated with polymethyl methacrylate (PMMA) slabs assembled as a rectangular cuboid of dimensions 25.2 cm x 20 cm x 40.5 cm. Eleven TLDs were used for brain dosimetry (distributed across four 2.5 cm slabs), and 2 TLDs were used to measure doses to the eye lens. Absorbed doses were measured for the eyes and for the brain (those parts considered most relevant in terms of tumours). The ratios between each measured eye dose and a brain dose weighted on the volumes of individual anatomical regions in which the TLDs were placed, were calculated for use as a conversion factor from eye dose to brain dose. This conversion factor was found to be between 3.40 (eye furthest from fluoroscope) and 8.08 (eye closest to fluoroscope). Operators increasingly work from both sides of the patient during procedures [1]. In order to account for uncertainties due to positioning of the interventionalist in our estimation of brain dose, the conversion factor was defined as a uniform distribution between 3.40 and 8.08.



Figure 3. Set-up of anthropomorphic phantom in angiography room.

2.3. Risk estimation

In addition to providing estimates of dose to the eye lens and to the brain, the tool also provides the user with estimates of the magnitude of health impacts associated with cumulated doses of IR, specifically in terms of the relative risk (RR) of radiation-related cataracts and the lifetime fractional risk (LFR) of CNS tumours, a measure that scales the lifetime attributable risk (LAR) to the lifetime spontaneous cancer incidence or mortality [41]. For the sake of internal consistency and to ease comparisons to other studies, RR of CNS tumours are also shown.

In the case of the eye lens, we calculated a dose-response coefficient for stage 1 to 5 cataracts, by scaling summary risk estimates at 1 Gy derived from the epidemiological literature [11] (Odds Ratio: 1.70; 95% confidence intervals: 1.22, 1.38). Using the published 95% confidence intervals for the summary risk estimates it was possible to calculate the standard error (SE) and thereby define the dose-response function probabilistically. Although the risk estimates at 1 Gy proposed in [11] were obtained through a log-linear model, the excess relative risk model was preferred in InterCardioRisk tool in order to ensure reasonable risk estimates at the highest doses.

The time between irradiation and the appearance of lens opacities is still uncertain but nevertheless, early work on radiation-induced cataract among the atomic bomb survivors showed an approximate average latency period for development of lens opacities of 2-3 years [42, 43]. As we are quantifying risks of cataracts of a range of

severities, starting from stage 1, which are just minor changes in the lens, lower severity than those studied in atomic bomb survivors, we considered a lag of 5 years.

By way of Monte Carlo simulation, the tool uses the dose-response function and the scenario-specific distributions of cumulated absorbed dose to the eye lens to calculate a distribution of RR under each scenario.

The LFR of CNS tumours was estimated using the methods developed by the BEIR VII committee [44] and data from the 1958-98 Life Span Study data [45], as was carried out in developing the NCI RadRAT tool [16]. This is computed as $LFR = \frac{LAR}{B}$, where $B = \int_0^{110} m(a)S(a)$ is the baseline risk for a general population ($m(a)$ is the background cancer incidence in the European population) and LAR is the lifetime attributable risk, computed as suggested by the BEIR VII committee:

$$LAR = \frac{\int_{e+L}^{110} \beta_s D e^{\gamma e^*} \left(\frac{a}{60}\right)^\nu \frac{S(a)}{S(e)}}{DDREF}, \quad (4)$$

where e is the age at exposure, $e^* = \frac{e-30}{10}$ if $e < 30$ or $e^* = 0$ otherwise, a is the attained age and according to the BEIR VII committee and [16], $\beta_s = 0.71, 0.24$ for males and females respectively, $\gamma = -0.3$ and $\nu = -1.4$. L is the latency period, considered to be of 5 years for all solid cancer by BEIR VII committee. $\frac{S(a)}{S(e)}$ is the probability of being alive at age a , given that an individual is alive at age e , and D is the estimated dose. The approach used here for dose and dose-rate effectiveness factor (DDREF) is the same that was used in [16], i.e. described by a lognormal distribution with a geometric mean of 1.5 and a geometric standard deviation of 1.35. LAR can be understood as an approximation to the premature probability of developing a cancer that can be attributed to radiation exposure, while LFR is useful because it is a relative number. Uncertainty in the LAR definition parameters (4) have been taken into account by means of Monte Carlo simulation.

The RR of CNS tumours are calculated according the values reported in [12].

3. Results

The tool provides us with a means to estimate the cumulated absorbed doses to the eye lens and brain (in mGy)—and associated health risks—under the three scenarios, and easily make comparisons between them. As an example, we can estimate the doses and health risks for a “typical” male interventional cardiologist born in 1960, who worked from 1985 to 2014, carrying out 300 procedures per year between 1985 and 2000, and then 350 per year until 2014. Distributions of cumulated absorbed doses to eye lens and brain under the three RP scenarios (“Typical working practices”, “No radiation protection measures used”, and “Protective equipment fully employed”) are presented as histograms (Figure 4).

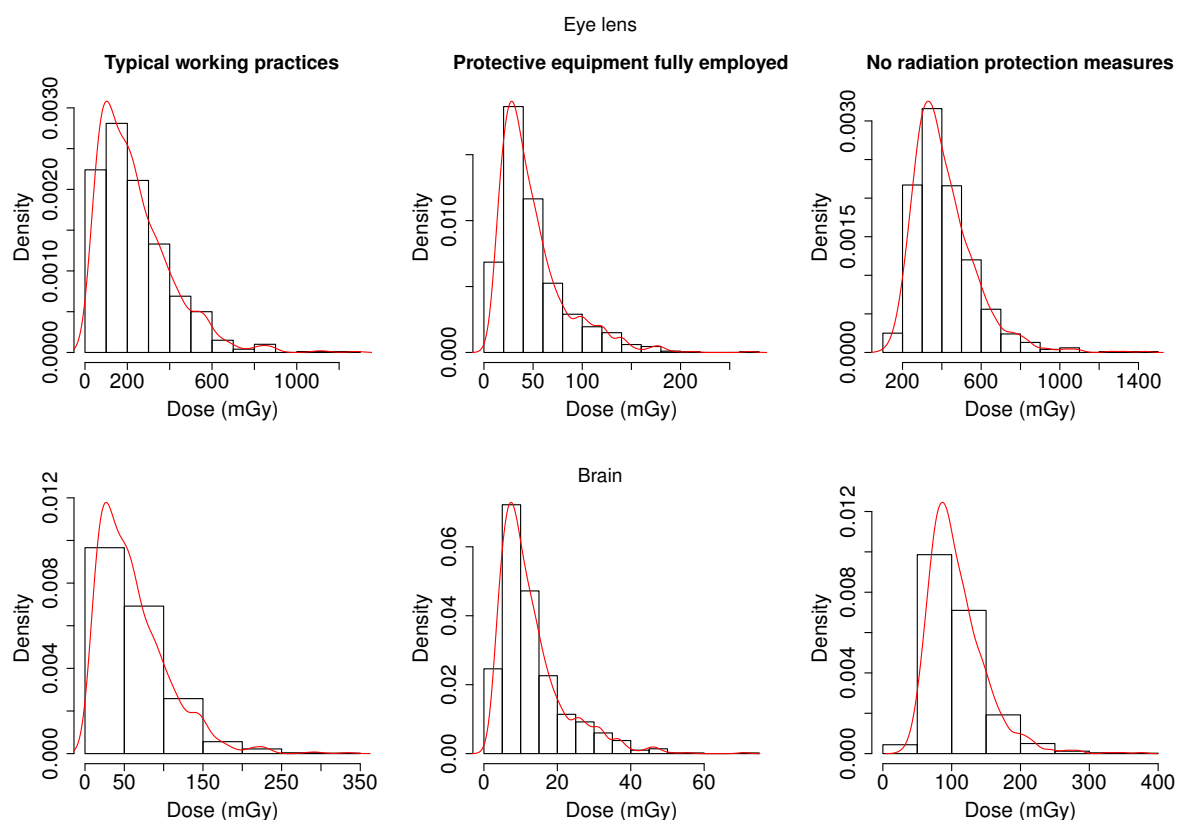


Figure 4. Estimated probability density function of distributions of cumulated absorbed doses (mGy) to the eye lens (upper panel) and brain (lower panel), for a typical cardiologist working between 1985 and 2014.

Median annual absorbed doses for each scenario (Figure 5) are also presented by the tool in tabulated form, along with 95% credibility intervals (CI). The figure illustrates an increase in dose of about 15% - 20% (depending on the scenario) after 2000 due to increased workload (from 300 annual procedures to 350). It also reflects the impact of the introduction of new radiation protection measures, for instance a large reduction in annual absorbed doses can be seen in 1990, when an increase of 25% in the usage of lead glasses is assumed. In this example, the estimated total cumulated absorbed lens dose is about 200 mGy (95% CI: 40, 645) under the “typical working practices” scenario. If no protection methods are used, these values are increased to 380 mGy (95% CI: 200, 800). In the scenario under the usage of all available protection methods, the estimated dose is 40 mGy (95% CI: 10, 140). The resulting differences in estimated health risks calculated for the three scenarios are shown in Table 2.

It is clear that the use of protection methods has a great impact on reducing cumulated absorbed doses to the eye lens and, subsequently, on reducing the risk of cataracts. If we compare the doses to the eye lens incurred under a scenario in which no protection methods are used at all, these impacts become all the more apparent. The user can also see the difference between the different protection methods usage scenarios on the cataract risk. For example, Figure 6 shows the difference in the distribution of

RR and LFR of CNS tumours and RR of stage 1-5 cataracts.

Outcome	Scenario	Measure of risk	Estimate (95% CI)
Stage 1-5 cataracts	Typical working practices	RR	1.11 (1.02, 1.51)
	Protective equipment fully employed		1.02 (1.01, 1.10)
	No radiation protection measures used		1.22 (1.09, 1.58)
CNS tumours	Typical working practices	RR	1.05 (1.01, 1.30)
	Protective equipment fully employed		1.01 (1.00, 1.06)
	No radiation protection measures used		1.10 (1.02, 1.44)
CNS tumours	Typical working practices	LFR	1.00 (1.00, 1.01)
	Protective equipment fully employed		1.00 (1.00, 1.00)
	No radiation protection measures used		1.01 (1.00, 1.02)

Table 2. Estimates of potential health risks for the three different RP scenarios, in terms of relative risks of cataracts for doses to the eye lens and RR and lifetime fractional risk (LFR) for CNS tumours, for a typical cardiologist working between 1985 and 2014.

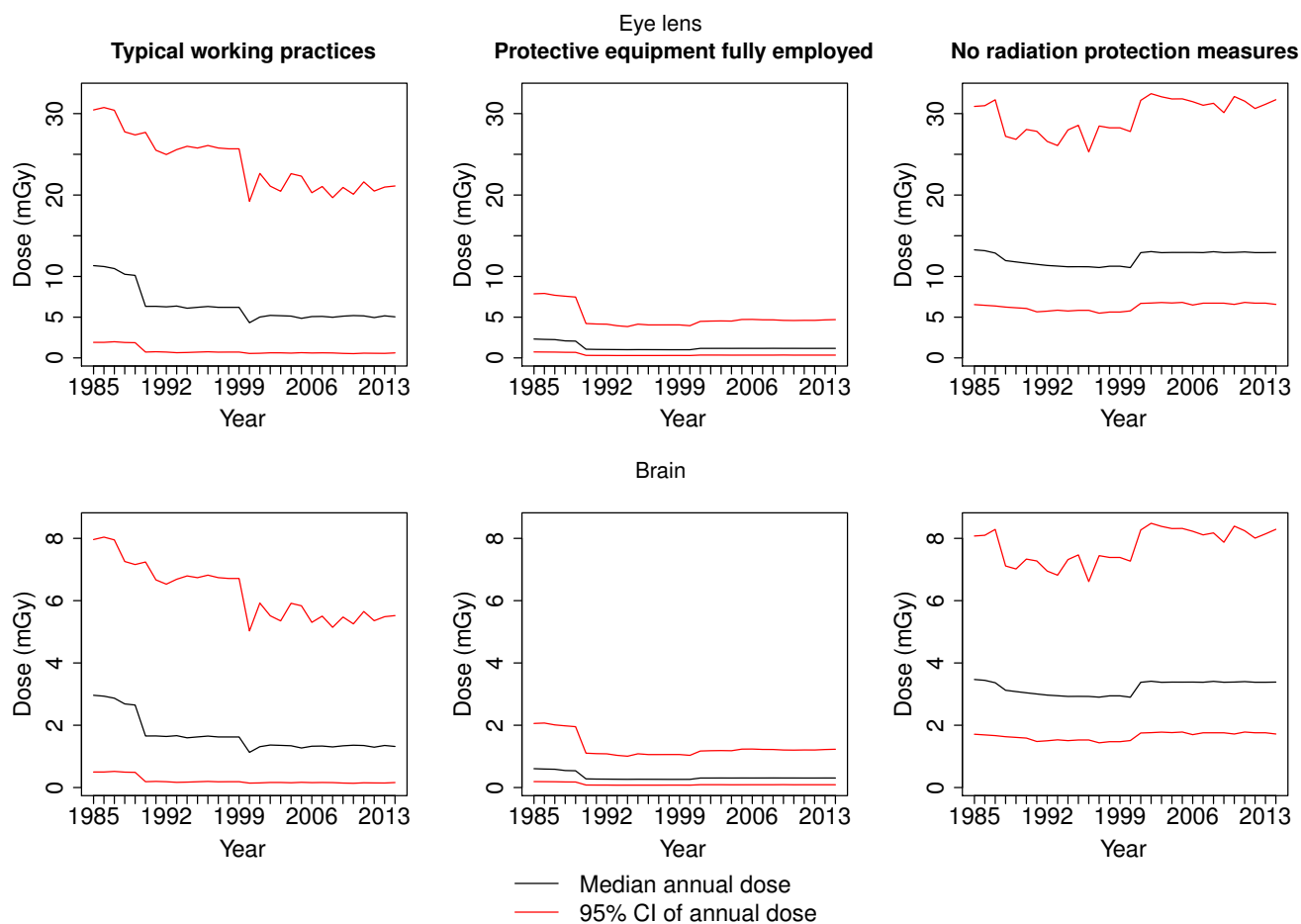


Figure 5. Annual absorbed doses (mGy) to eye lens (upper panel) and brain (lower panel), for a typical cardiologist working between 1985 and 2014.

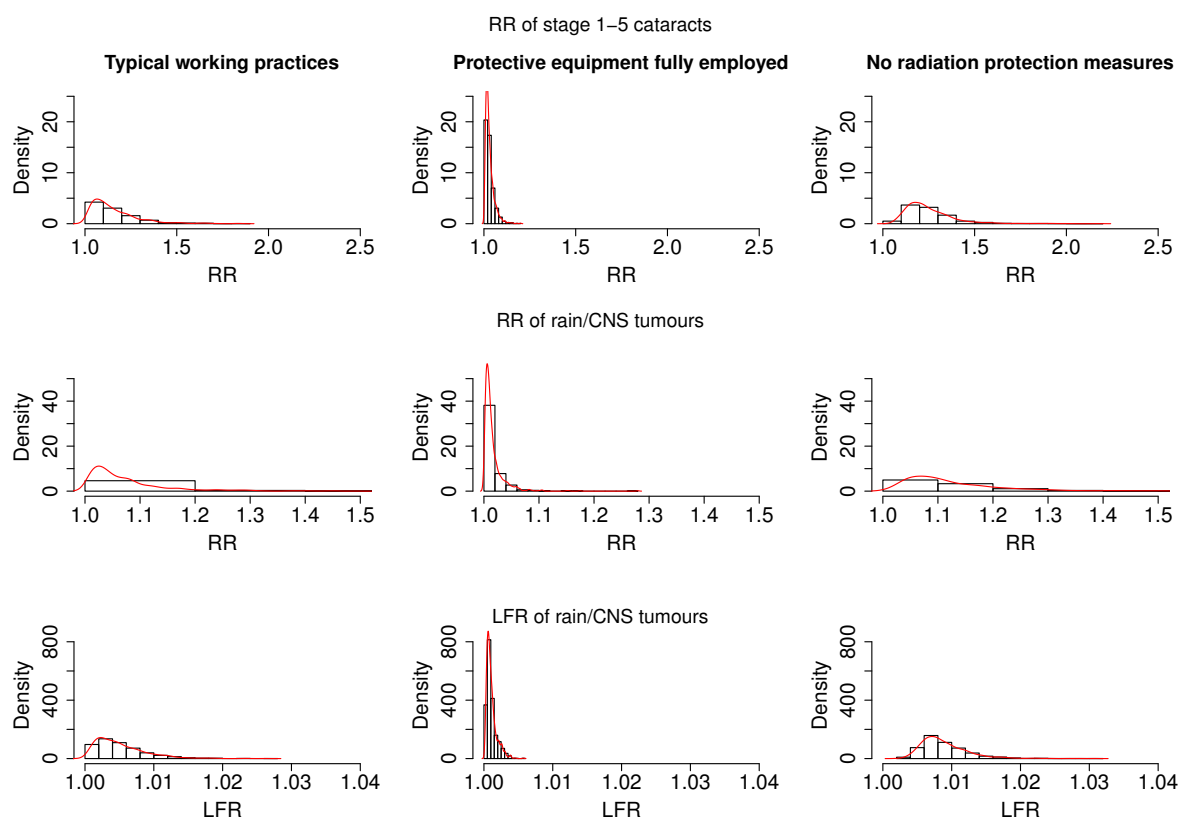


Figure 6. Estimated probability density function of distributions of stage 1-5 cataracts RR (upper panel) and CNS tumours RR and LFR (lower panel) for a typical cardiologist working between 1985 and 2014.

4. Discussion

We developed a novel tool, InterCardioRisk, that allows IC personnel to estimate their annual and cumulated doses to the eye lens and brain, and associated potential health impacts in terms of risk of cataracts and CNS tumours. Specifically, the tool allows the user to compare estimated doses to a worker with a typical career and typical use of RP measures, and the associated estimated risks of cataract and CNS tumour, with the reductions in dose expected where protective equipment is employed to the maximum possible extent. By extension, the output of the tool allows for estimation of the expected health benefits for that population associated with increased use of available RP measures. The InterCardioRisk tool directly supports the aims of RP, and would make a useful addition to the RP training of those working in IC. In particular, the use of LFR as the risk metric facilitates direct comparison with the lifetime cancer risk of a person of the same age and sex in the general population. For those already employing RP practices effectively in their work, the small magnitude of increased risks serves as a reassurance that they are successfully minimising their occupational exposure. By the same token, those not following RP guidelines may be motivated towards employing RP measures to reduce their cumulated doses and attendant health risks.

Cumulative eye lens doses estimated by the InterCardioRisk tool are consistent with the results of the French O'CLOC study [21]. This study presented a retrospective assessment of cumulative eye lens doses for interventional cardiologists and electrophysiologists using dose data from the ORAMED project, as well as information on the workload, radiation protection equipment and dose reduction factors. The authors reported a median cumulative eye lens dose of 309 mSv, ranging from 25 mSv to more than 1600 mSv, for 129 interventional cardiologists at an average age of 51 who had worked for an average period of 22 years, similar to the estimates provided by the InterCardioRisk tool using Jacob's data under the typical working practices scenario (median of 314 mSv, with a credibility interval of (61 mSv - 1142 mSv)). In contrast with these dose levels, other studies report cumulative eye lens doses significantly higher. These studies are based on a different, common methodology [46–49], using experimental data of scattered dose factors per unit DAP measured with electronic dosimeters, corrected by the operator position and the use of protective devices, and reported workload. Cumulative eye lens doses reported in these works are of 6 Sv (100 mSv - 27 Sv) (median value, average age of 46, average working period of 14 years) [46], 3.7 Gy (20 mGy - 43 Gy) (mean value, average age of 42, average working period of 9.2 years) [48] and 420 mSv (46 mSv - 7.3 Sv) (median, average age of 43, average working period of 8 years) [49]. These values lead to average annual doses ranging from 53 mSv to 429 mSv, in contrast with an annual dose of 14 mSv issued from InterCardioRisk and Jacob's paper. The different doses estimated by each methodology fall within the large ranges of dose reported in the literature. The variation in reported doses is associated with the high degree of uncertainty in measurements of lens dose, with different methodologies used, and the assumptions used to extrapolate eye doses from other dose measures [50]. However, we consider that estimates based on ORAMED measurement campaign are likely to provide more realistic outcomes because doses were measured under real conditions.

There have been several reports made regarding radiation-induced cataract in ICs who have performed procedures for a number of years, and of equivalent doses to the lens approaching the annual limit of 150 mSv during angiographic procedures [46, 51–53]. Recent studies have shown that under typical workloads of an IC, the radiation dose to the lens may exceed the current threshold for tissue reactions after several years of work if radiological protection devices are not used and radiological protection principles are not followed [6, 51]. Several surveys of cardiologists and support staff working in catheterisation laboratories, conducted with co-ordination provided by the International Atomic Energy Agency (IAEA) in Latin America and Asia, have found a high prevalence of lens opacities of the type associated with occupational radiation exposure [48, 51]. These recent data and the mechanistic uncertainties regarding cataract development highlighted the need for a detailed re-appraisal of the radiosensitivity of the lens of the eye. This issue is addressed in Publication 118 of the ICRP and in the Commission's statement on tissue reactions [54, 55]. The previous Commission recommendation [56] of an equivalent dose limit of 150 mSv/y for occupational exposure

in a planned exposure situation (e.g. occupational exposure of interventionalists) has been changed. The Commission now recommends that the lens-equivalent dose limit for chronic occupational exposure should be 20 mSv/y, averaged over a defined 5-year period, with no single year exceeding 50 mSv (i. e. the same as the annual whole-body limit for workers) [54, 55]. Note that a study performed with data from 1984 through 1988, when both cardiac interventions and fluoroscopic equipment were less sophisticated than they are now, determined that the annual equivalent dose to cardiologists' heads was approximately 20–30 mSv [57]. The Commission considers the threshold for absorbed dose to the lens of the eye to be 0.5 Gy [54]. The Commission judges, based on existing evidence, that an acute dose of up to around 0.1 Gy (100 mGy) produces no functional impairment of tissues, including the lens of the eye with respect to cataract, although the use of a threshold model remains uncertain for this tissue [54].

As the degree of usage of available RP measures determines an operator's absorbed dose to a great extent, our tool provides an invaluable means for an individual to quantify the efficacy of using those measures in their daily practice. Some RP measures like cabins are not generally available or usable. However, very appreciable reductions in absorbed doses can be attained through using the most common protection measures properly, in particular lead glasses and ceiling-suspended screens. The presentation of the estimates of absorbed dose in the various scenarios side by side exemplifies the very real importance of making use of the measures available to reduce dose, further supported by estimation of the associated health risks. The most important sources of uncertainty are taken into account through Monte Carlo simulation, thereby showing these outputs as ranges. Upon identifying a high rate of radiation lens injuries in a population of Colombian interventional cardiologists [46], the authors highlight the urgent need to take appropriate action to increase the use protective measures and strengthen training programmes in RP. Tools such as the one presented in this work can be useful for this purpose, as the difference in absorbed dose and associated health risks between the distinct scenarios of use of protective measures is easily quantified. Although treatment of cataracts is a relatively straightforward procedure nowadays, this should not encourage interventional cardiologists to take an increased risk of cataracts lightly: not all operations to remove cataracts are successful, and complications may result in irreversible opacities which could diminish a surgeon's ability to continue with their work.

5. Limitations

We consider that the outputs of InterCardioRisk tool are of potentially great usefulness to the IC and RP communities, but with some limitations. Relatively sparse historical data were available on working practices—both in terms of IC procedures and RP measures taken—so estimates of dose made by the tool may be inaccurate when used in those working environments where practices over the past 40 decades have

differed greatly to those common in France. Also, it is conceivable that as cardiologists progress through their careers, they may increasingly focus on a particular type of intervention. This may also result in divergence between their true cumulated dose and those estimated by the tool. For example, those working in paediatric IC may be required to work much closer to the X-ray beam due to the size of the patient, and as a result have higher doses. Similarly, those working predominantly in emergency interventional treatment of heart attacks have less time to configure radiation shields prior to catheterisation.

The tool predicts various kind of cataracts at all stages of development from stage 1—defined as discrete posterior subcapsular cataract (PSC) or cortical opacity in a small area of the lens—to stage 5—defined as a mature cataract with complete lens opacification. This is a broad definition, and includes a variety of different kinds of cataract, each of which has a different pathogenesis and prognosis. IR has been found to be most strongly associated with PSC formation [10, 58]. Unlike age-related cortical or nuclear cataracts, which primarily cause a change in visual acuity, a PSC cataract is more likely to result in changes in both visual acuity and contrast sensitivity [59]. The RR of radiation-induced PSC cataracts is somewhat higher than that of other kinds of cataract, hence the tool may be slightly underestimating the risk of cataract specifically related to radiation dose.

Evidently, the validity of our assumption that OR is a good estimate of the RR is dependent on the incidence of the health outcome of interest in the unexposed population (i.e. the baseline rate). Although such an assumption is reasonable for rare outcomes such as cancers, the high incidence of cataracts in the unexposed population results in a slight overestimation of the risk of cataracts when using OR to estimate measures of risk and health impact. It was not possible to adjust the ORs using baseline rates as reliable baseline rates of the specific cataract types of interest were not available for European populations. We simulated the effect of using the OR in place of the RR on our estimates of health impact for a number of baseline rate scenarios. If baseline rates of stage 1-5 cataracts were 25%, we estimated that our risk estimate might be overestimated by less than 10%. The OR reported in [11] are obtained from Chernobyl clean-up workers, and although these are the most comprehensive estimates to date, and are compatible with those obtained from studies of surgically removed cataracts in the atomic bomb survivors study [45], there are issues concerning the adequacy of current dosimetric estimates.

In order to calculate a dose conversion factor between absorbed dose to the eye lens and absorbed dose to the brain, it was necessary to make a number of relatively crude simplifications. TLDs were positioned only in some of the anatomical regions of the brain, and dose was averaged over those regions using their approximate sizes as weights. When combining the brain dose data with dose-response and population data on cancer incidence in the calculation of LFR, it was necessary to assume that the brain and the whole CNS could be considered as “equivalent”, in the sense that dose-response and incidence data were only available for brain/CNS tumours combined. Any dose

estimate to the brain is therefore considered to be valid for the CNS; when considering the CNS as a whole, it is therefore possible that dose has been overestimated. Since the majority of CNS tumours occur in the brain, however, and that the brain makes up the greater part of the CNS, we do not imagine that this overestimation has a large impact on the estimates of CNS tumour risk generated by the tool.

6. Recommendations for further work

Following discussions with cardiologists and RP staff, a number of improvements and extensions are planned for the tool. In particular, we would like to include the estimation of absorbed doses for other organs and calculation of risks for other endpoints. Extension of the tool to include other measures of health impact would be merited as a means of maximising the population for which the tool provides useful information. For example, it would be possible to estimate the total disability-adjusted life years (DALYs) for the health outcomes considered. Although not without its drawbacks, the use of DALYs allows for the synthesis and comparison of health impacts due to multiple diseases within a single framework. Currently, it is far from clear which metric might best communicate the gravity of potential health impacts to the target populations of interest i.e. interventional cardiologists, electrophysiologists and RP staff in hospitals. Further work on quantifying the efficacy of the tool to communicate health impacts to IC staff is necessary in order to refine it. A pilot version of the tool was sent to a group of over 100 experts in RP, medical radiation dosimetry and IC together with an online questionnaire designed to gauge their opinions on the user-friendliness of the tool, their perceptions of the magnitude of estimated doses, and the tool's usefulness in terms of improving compliance with RP guidelines and, ultimately, in reducing potential health impacts, and as a perspective to this work, with the aim of keeping the tool updated with the current standard procedures and RP methods usage in IC, a survey will be prepared including questions regarding the protection methods the IC use and their reasons for not following all guidelines.

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