Interventional Cardiology

Cancer risk from professional exposure in staff working in cardiac catheterization laboratory: Insights from the National Research Council's Biological Effects of Ionizing Radiation VII Report

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Background Occupational doses from fluoroscopy-guided interventional procedures are the highest ones registered among medical staff using x-rays. The aim of the present study was to evaluate the order of magnitude of cancer risk caused by professional radiation exposure in modern invasive cardiology practice.

Methods From the dosimetric Tuscany Health Physics data bank of 2006, we selected dosimetric data of the 26 (7 women, 19 men; age 46 ± 9 years) workers of the cardiovascular catheterization laboratory with effective dose >2 mSv. Effective dose (E) was expressed in milliSievert, calculated from personal dose equivalent registered by the thermoluminescent dosimeter, at waist or chest, under the apron, according to the recommendations of National Council of Radiation Protection. Lifetime attributable risk of cancer was estimated using the approach of Biological Effects of Ionizing Radiation 2006 report VII.

Results Cardiac catheterization laboratory staff represented 67% of the 6 workers with yearly exposure >6 mSv. Of the 26 workers with 2006 exposure >2 mSv, 15 of them had complete records of at least 10 (up to 25) consecutive years. For these 15 subjects having a more complete lifetime dosimetric history, the median individual effective dose was 46 mSv (interquartile range = 24-64). The median risk of (fatal and nonfatal) cancer (Biological Effects of Ionizing Radiation 2006) was 1 in 192 (interquartile range = 1 in 137-1 in 370).

Conclusions Cumulative professional radiological exposure is associated with a non-negligible Lifetime attributable risk of cancer for the most exposed contemporary cardiac catheterization laboratory staff. (Am Heart J 2009;157:118-24.)

Use of radiation for medical examinations and tests is the largest artificial source of radiation exposure.[1] Interventional procedures are only 12% of all radiological procedures but contribute to about 48% of the total collective dose per head in the adult cardiological patient.[2] This value is steadily increasing. In Europe, arteriography and interventions were 350,000 in 1993 and >1 million in 2001.[3] On average, a left ventriculography and coronary angiography correspond to a radiation exposure of about 300 chest x-rays; a coronary stent to 1,000; a peripheral artery intervention to 1,500-2,500; and a cardiac radiofrequency ablation to 900 up to several thousands.[4-8] In most cases, it is the cardiologist who performs these procedures, often without any specific training in radiology and radiation protection.[9] Although there is a general appreciation that radiation by itself is certainly not a good thing for the patient or the operator, radiation safety is rarely much of an overt concern to interventionalist.[10] Interventional cardiology is developing at a rate that is ahead of both the supporting research and regulatory framework, and growth in the field has been accompanied by concern for the safety of the staff directly involved in such high radiation procedures (European DIMOND Action II 1999 and III 2001).[11] Occupational doses in interventional procedures guided by fluoroscopy are the highest doses registered among medical staff using x-rays.[12-14] The aims of this present study are

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Table I. Cardiac catheterization laboratory population and dosimetric data

Age (y)	46 ± 9
Gender (male/female)	19/7
Role	
Interventional cardiologist	18 (69%)
Cardiac electrophysiologists	4 (15%)
Catheterization laboratory nurse	3 (11%)
Catheterization laboratory technician	1 (4%)
Last year (2006) dosimetry (mSv/year)	4.8 ± 4.6
Years of employment in catheterization laboratory	15 ± 10

to assess the current levels of professional exposure in the modern invasive cardiology practice and to estimate the corresponding levels of long-term lifetime attributable cancer risks.

Methods

Selection of subjects

We initially considered all health professionals included in 2006 in the Tuscany Region dosimetric data bank, collected in the Health Physics Departments of Pisa and Florence and composed of >50 hospitals, including 11 high volume cardiac catheterization laboratories. From this initial set of 5,164 workers, we selected cardiac catheterization laboratory staff (interventional cardiologists, cardiac electrophysiologists, interventional radiologists, nurses, technicians) and analyzed the yearly exposure. For catheterization laboratory workers with yearly 2006 exposure >2 mSv, we calculated the entire professional exposure whenever possible. All subjects enrolled gave their written informed consent and allowed the reconstruction of their lifetime cumulative professional exposure from official records of the Health Physics Department (Table I). The study is a part of a larger study on health effects of low-dose radiation exposure and was approved by local Ethical Committee. The study was also endorsed by the Italian Association of Hospital Cardiologists (ANMCO) and endorsed by the Tuscany Health Physics Association.

Individual dose reconstruction

In accordance with the recommendations of the International Commission on Radiological Protection (ICRP)[15] and Directive 96/29/EURATOM,[16] radiation dose to workers was expressed as effective dose. Staff dosimetry was obtained by a thermo luminescent dosimeter, with monthly measurement. The dosimeter was located under the lead apron, at the waist, or over the chest. Dosimeter results were converted to effective dose as suggested by the ICRP.[17] Generally, personal dosimeter services provide monthly estimates of Hp,[10] the dose equivalent in soft tissue at 10-mm depth, which is usually compared with the limit of the effective dose, set by ICRP at 100 mSv in 5 years[18] and usually used as 20 mSv/year.

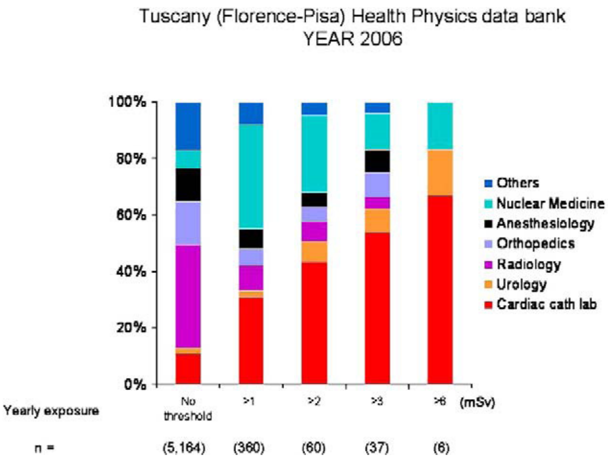
Calculation of risk

To calculate cumulative risk of stochastic effects, we used the age and gender-dependent risk factors from the multiplicative model recommended in the most recent report from the Biological Effects of Ionising Radiation Committee VII (BEIR VII) for (fatal and nonfatal) cancer.[19] Currently, in the risk model for low-level exposures, a linear relationship between dose and risk is used. According to these estimates, it is predicted that for 100 mSv effective doses in adults, approximately 1 individual in 200 would develop fatal cancer, and 1 in 100 would develop fatal or nonfatal cancer.[19] The attributable lifetime risk of radiation-induced cancer for all members of the population may be estimated by multiplying the effective dose in milliSievert by the fatal cancer coefficient of 5.5×10^{-5} for the whole population and by 4.1×10^{-5} for adult workers. Because we dealt with a population of adult workers, we used the latter coefficient.[19] According to BEIR VII estimates for lifetime attributable risk (LAR) of cancer incidence and mortality, receiving 2 mSv per year from ages 18 to 65 (48 years working time) represents (number of cases per 100,000 exposed persons) 612 for men and 859 for women (incidence) and 340 for men and 478 for women (mortality). Thus, for a population of 50% males and 50% females, these values would be 736 (incidence) and 409 (mortality). Thus, according to BEIR VII, the total cancer incidence receiving 2 mSv/y from 18 to 65 should be 1 in 136 and the total mortality 1 in 245 workers.

Statistical analysis

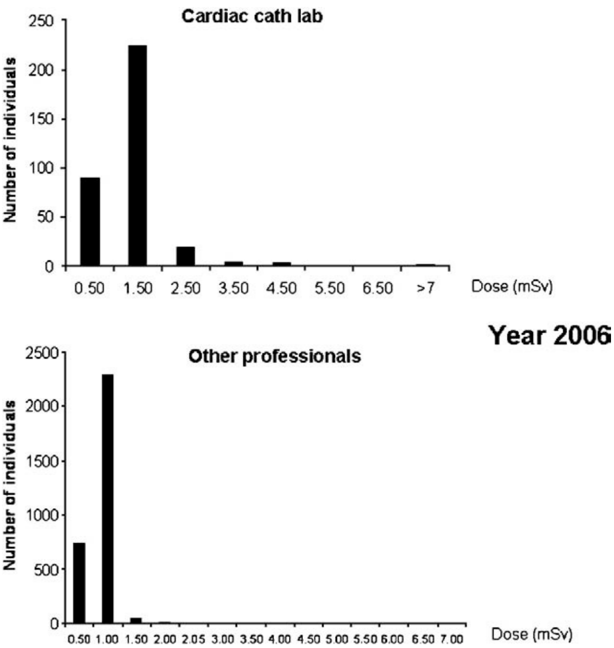
Data were expressed as median, 25 to 75 percentiles, and range for nonnormally distributed values. Linear regression and Pearson correlation were used to assess the relationship between cumulative radiological effective dose and age. The Kruskal-Wallis test was performed to determine any significant differences among the groups.

Figure 1



Bar histograms showing proportions of yearly dose exposure in all medical staff censored in Tuscany Health Physics Department (Pisa and Florence) for the year 2006. The histograms refer to the overall population of hospital workers broken down by specialties and increasing levels of exposure (from no threshold, far left histogram, to exposure >6 mSv/year, far right histogram). The proportion from cardiac catheterization laboratory workers rises with progressively higher exposure threshold.

Figure 2



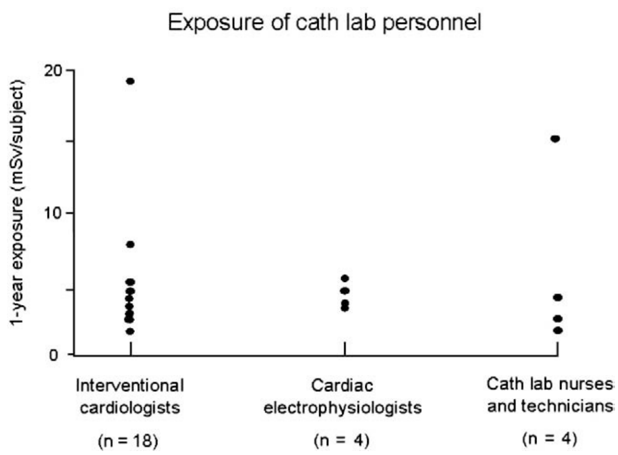
Bar histograms showing the yearly (2006) individual dose exposure (in mSv, x-axis) and the number of cardiac catheterization laboratory workers (upper panel) and other professionals (lower panel) with radiation exposure (y-axis).

The statistical analyses of the data were performed with SPSS (version 11.0, SPSS Inc, Chicago, IL). A P value <.05 was considered significant.

Results

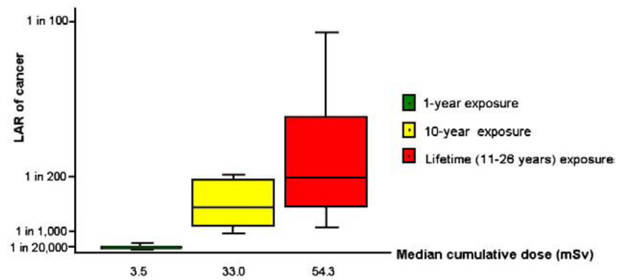
For the total population of 5,164 workers, we assessed the yearly exposure as distributed throughout the medical specialties. Cardiac catheterization laboratory workers represented 67% of workers with yearly exposure >6 mSv and 31% of those with exposure >1 mSv (Figure 1). When the full population of cardiac catheterization laboratory personnel is considered, the exposure levels are relatively low and comparable with those of other specialties with radiation exposure (Figure 2). The 2006 dose exposure of the 26 cardiac catheterization laboratory workers with exposure >2 mSv was divided according to subspecialty and professional role (Figure 3). Interventional cardiologists (median 3.3, range 2.0-19.6 mSv/y) and cardiac electrophysiologists (median 4.3, range 3.5-6.1 mSv/y) have high and comparable, professional exposure, and nurses and technicians may show similar values (median 2.6, range 2.0-14.9 mSv/y, P = NS vs the other groups). Cumulative doses (and corresponding risks) are shown in Figure 4 at 3 discrete time points in the natural history of a high-volume cardiac catheterization laboratory worker: at 1 year (for 26 cardiac catheterization laboratory workers with 2006 dose exposure >2 mSv), at 10 years (for a subset of 15 workers who reached this milestone: $P < .0001$ vs 1 year exposure), and lifetime (for the same 15 workers with exposures longer than 10 years, ranging from 11 to 25 years; $P = .001$ vs 10 year exposure). For these 15 subjects with a more complete lifetime dosimetric history, the median individual effective dose was 46 mSv (interquartile range 24-64). There was a significant correlation between cumulative radiological effective

Figure 3



Exposure in the year 2006 (on y-axis) for the 26 workers with exposure >2 mSv/year.

Figure 4



Box-and-whiskers plot showing the median dose exposure (in mSv, x-axis) and the calculated LAR of cancer (y-axis) for catheterization laboratory workers at 3 different time points of their dosimetric natural history in a busy professional life. The box represents the interquartile range that contains the 50% of values. The whiskers are lines that extend from the box to the highest and lowest values, excluding outliers. A line across the box indicates the median. All of the 26 Tuscany cardiac catheterization laboratory workers with exposure >2 mSv in year 2006 are shown at 1-year exposure (green box); a subset of 15 workers is shown at 10 years (yellow box); the same 15 workers with cumulative (11-25 years) professional exposure reconstruction are shown in the red box.

dose and age ($r = 0.73$, $P < .001$) or years of catheterization laboratory activity ($r = .47$, $P = .02$). The median value of risk of fatal cancer was 1 in 384. The median risk of (fatal and nonfatal) cancer (BEIR 2006) was 1 in 192 (interquartile range = 1 in 137-1 in 370).

Discussion

In contemporary medical practice, catheterization laboratory workers comprised most of those with high levels of exposure. For the most experienced (and most exposed) staff working in the cardiac catheterization laboratory, with a range of exposures in between 2 and 5 mSv per year, a typical cumulative 15-year radiological exposure around the equivalent of 50 mSv is associated with a nonnegligible LAR of cancer in the order of magnitude of 1 cancer in 200 exposed subjects. This applies, however, only at the individuals with the highest exposure, the tip of the iceberg. When the full spectrum of catheterization laboratory workers are considered (not only those with the very highest exposure), the exposure levels are fully comparable with those of other specialties with radiation exposure.

Comparison with previous studies

Very variable estimated effective doses to patients can be found for coronary intervention[5,6] and cardiac electrophysiological[20-23] procedures, with higher values reported for coronary stenting and ablation procedures (around 15 to 25 mSv, ranging from 2 to 60 mSv) and lower values for diagnostic procedures such as coronary angiography or electrophysiologic study (around 3 to 5 mSv, ranging from 1 to 20 mSv). Regarding medical personnel, the rates of risk of death for cancer for both kind of procedures (electrophysiologic procedures and interventional cardiology) depend on the radioprotection measures of the professionals and the radiation dose to the patients, and a wide range of values can be found in the literature. A few microSieverts per electrophysiology[20] and similar values for catheterization procedures,[24-27] with a risk per procedure of developing a fatal cancer of the operator in the 1 in 500,000 to 1 in 1,000,000.[27] In reality, with a 100 μSv exposure per procedure,[20,27-30] the risk of cancer (fatal and nonfatal) would be after BEIR in the range of 1 in 100,000 per procedure. However, it should be highlighted that the lack of a good radioprotection policy could increase occupational doses (and risk of cancer) in a factor of 10.[31]

The professional risk in perspective

The risks from continuous occupational exposure peaks in the seventh, eighth, and ninth decade of life.[32,33] The risk compares favorably with many other occupations. Working in agriculture is associated to 320, in construction to 227, in mines to 167 days of lost life expectancy.[34] An occupation with <1 fatality per 10,000 workers per year is considered a safe occupation by the National Council of Radiological Protection.[35] The risk of the average interventional cardiologist/radiologist is below this risk throughout the radiologist's career, up to a career of 40 years,[36] if the basic radiation protection rules are followed. Only after working >40 years would the annual radiation risk exceed the risk level now considered safe by the National Council on Radiation Protection. However, this overall reassuring picture should be integrated with some prudent concern if we consider, as we probably should, lifetime (not only annual) risk, and fatal and nonfatal (not only fatal) cancer risk. Safety discussion should also consider the spectacularly growing population of highly exposed staff, not only the “average” exposure of catheterization laboratory people, which may have a highly heterogeneous activity within the same catheterization laboratory. For highly exposed personnel with 5-mSv yearly exposure, lifetime extra risk for (fatal or nonfatal) cancer after 20 years of professional life is in the range of 1 in 100. Although this exposure remains well below the dose limit of occupational exposure, consisting of an effective dose of 20 mSv in a year averaged over a period of 5 years,[15] it can neither be considered negligible or harmless.[37]

Uncertainties in risk estimates

At present, both the radiology community[38-40] and advisory bodies[1,15,19,35] are well aware of the carcinogenic effect of low-dose ionizing radiation used in medical diagnostic testing—as well as the degree of approximations and uncertainties in current risk estimation, that is, risk can be 2 to 3 times higher or lower than current estimates.[19] Nevertheless, these estimates represent the best available scientific evidence and should be considered benchmark values for both the scientist and the clinician.[38-40] The threshold of conclusive epidemiological evidence linking radiation and cancer is at 50 mSv—a threshold that only some of the most active cardiac catheterization laboratory workers trespass with the working exposure alone, and a significant number of professionals are still not using their personal dosimeters on a regular basis[37,41] and more cases of high doses between professionals could not be included in the official data basis. Recent epidemiologic and cytogenetic data corroborate the available risk estimates, reducing the room of uncertainty.[32] Health professionals exposed to low dose radiation, as for instance interventional cardiologists or radiologists with an average exposure of 4 mSv/year, show a 2-fold increase in circulating lymphocytes of chromosome aberrations and/or micronuclei, which represent surrogate biomarkers of cancer risk and intermediate end points of carcinogenesis.[42-44] Therefore, the available risk estimates should not be considered either perfect or precise, but certainly reliable for all practical purposes of radiation protection of both patients and physicians.

Study limitations

A primary limitation is that the wearing of radiation badges is subject to the user's capacity of remembering to put the badge on, and we did not have an estimation of the compliance for wearing of radiation badges. It is known that one third of catheterization laboratory staff is negligent in wearing the dosimeters,[31,41,45-47] which may represent a source of significant underestimation of calculated risk. Moreover, we recruited our occupational dose data from Tuscany (Pisa and Florence) Health Physics Department. There are recognized, wide variations in national and even regional practice, depending on radiation protection measures taken, medical specialization, typology and number of procedures, legal and regulatory framework. Staff doses to catheterization laboratory staff can vary by a factor of 10 within a given hospital[41] and by a factor of 12 between hospitals.[48] An additional limitation is that we have evaluated doses under the apron (chest or waist). It is a common practice in radioprotection to directly compare Hp^{10} with the limit of the effective dose.[49] Wearing an additional dosimeter at collar level above lead apron would provide an indication of the head (eye) dose and a better approximation (combined with under apron dosimetry) of the whole body dose.[18] However, ICRP report 85 (2001) states that "a single dosimeter worn under the lead apron will yield a reasonable estimate of effective dose for most instances"[15]—although on the basis of recent evidences, the possibility of an underestimation of dose, with a variable multiplying factor ranging from 1.5 to 7,[50] cannot be excluded. Finally, our risk estimates were derived from population estimates and did not include diagnostic radiation exposure applied on the worker as a patient.[51,52] Many environmental and genetic factors may modulate the individual vulnerability to oncogenic effects of radiation, and the next step is to translate epidemiological estimates to tailored risk assessment on the basis of gene polymorphisms and personalized biomarker evaluation, for instance with micronuclei and/or chromosome aberrations in peripheral lymphocytes, which are an intermediate end point and a long-term predictor of cancer.[32]

Conclusions

The number of interventional radiological (and especially cardiological) procedures has been increasing during the last years. The number of involved professionals (cardiologists, nurses, and technicians) is also substantially increasing. The highest doses to staff (and to patients) are usually recorded in these laboratories. With current staff exposure levels, professional risk cannot be considered negligible, for the most exposed personnel workers in the cardiac catheterization laboratories, whereas the exposure level of the full spectrum of catheterization laboratory participants is acceptably low and comparable to those of other specialties with radiation exposure. However, a wide margin for optimization aimed to reduce patient and staff doses exists. The quest for optimization is one of the aspects, and probably not the least important, to assess the quality of the catheterization laboratory. Most recent professional guidelines on interventional cardiology of the American Heart Association/American College of Cardiology clearly state that "the responsibility of all physicians is to reduce the radiation injury hazard to their patients, to their professional staff and to themselves."[53] The assessment of radiation exposure is also "a required part of the safety outcome in every trial that includes fluoroscopy-based interventions or radiation-based imaging," as recently recommended by the European Heart Rhythm Association in the design of future trials on atrial fibrillation.[54] The challenge ahead is to implement guidelines and recommendations into everyday clinical practice. This should remodulate the current dose exposure of our most experienced interventional cardiologists on a more sustainable trajectory.

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