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Interventional cardiologists and risk of radiation-induced cataract: Results of a French multicenter observational study ☆

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ABSTRACT

Background: Interventional cardiologists (ICs) are exposed to X-rays and may be at risk to develop cataract earlier than common senile cataract. Excess risk of posterior subcapsular cataract, known as radiation-induced, was previously observed in samples of ICs from Malaysia, and Latin America. The O'CLOC study (Occupational Cataracts and Lens Opacities in interventional Cardiology) was performed to quantify the risk at the scale of France.

Methods: This cross-sectional multicenter study included an exposed group of ICs from different French centers and an unexposed control group of non-medical workers. Individual information was collected about cataract risk factors and past and present workload in catheterization laboratory. All participants had a clinical eye examination to classify the lens opacities (nuclear, cortical, or posterior subcapsular) with the international standard classification LOCS III.

Results: The study included 106 ICs (mean age = 51 ± 7 years) and 99 unexposed control subjects (mean age = 50 ± 7 years). The groups did not differ significantly in the prevalence of either nuclear or cortical lens opacities (61% vs. 69% and 23% vs. 29%, respectively). However, posterior subcapsular lens opacities, were significantly more frequent among ICs (17% vs. 5%, p = 0.006), for an OR = 3.9 [1.3–11.4]. The risk increased with duration of activity but no clear relationship with workload was observed. However, the risk appeared lower for regular users of protective lead glasses (OR = 2.2 [0.4–12.8]).

Conclusions: ICs, in France as elsewhere, are at high risk of posterior subcapsular cataracts. Use of protective equipment against X-rays, in particular lead glasses, is strongly recommended to limit this risk.

1. Introduction

The wider use of medical imaging involving X-rays as a diagnostic tool and during interventional procedures has led to steadily increasing exposure of medical staff to ionizing radiation, especially in interventional cardiology with fluoroscopically guided procedures [1]. Around 350,000 coronary angiographies and/or percutaneous transluminal angioplasties [2] and close to 100,000 electrophysiological procedures are performed annually in France. These procedures require X-ray use and expose interventional cardiologists to radiation, in particular to the eyes, with doses per procedures that can range from about 10 μSv (micro Sievert) to more than 1000 μSv [3–5] depending on the type of procedure and use of radiation protection equipment. The radiosensitivity of the eye lens to radiation is well known. Although it is commonly accepted that high exposure to ionizing radiation induce lens opacities [6], the current debate includes lower doses with occupational annual dose limit of 20 mSv/year [7,8], which may be in the range of the occupational exposure of unprotected medical staff in catheterization laboratories.

According to their anatomic location, cataract, or presence of lens opacities, can be classified into three main types: nuclear, cortical and posterior subcapsular (PSC) (see Fig. 1). At early stage of cataract, lens changes consist of small dots and vacuoles which, over time, aggregate to form larger opacities. PSC cataract is the least common form, but relatively minor PSC opacities can induce great impact on vision because of its location along the lens visual axis. PSC cataract is commonly associated with ionizing radiation exposure, but some epidemiological studies suggested that the traditional view that PSC opacities are the

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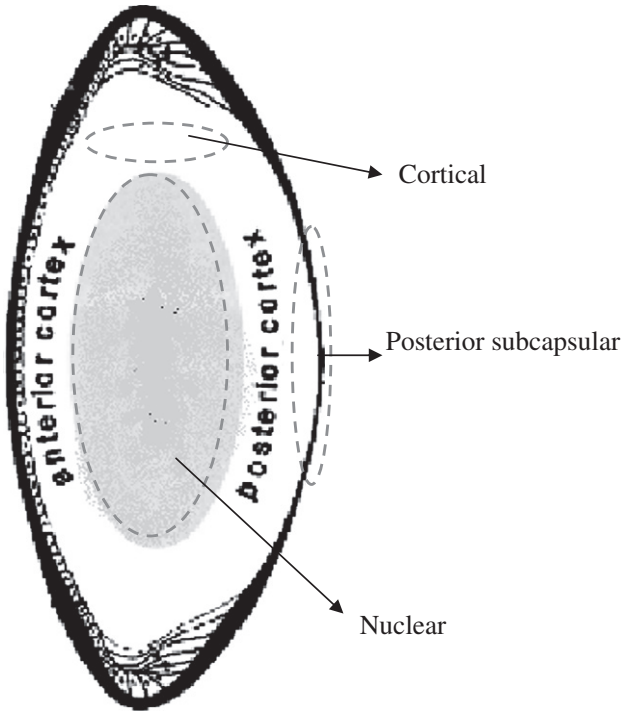

Fig. 1. Location in the eye lens of different types of cataracts.

only type of radiation-induced cataract may be broadened to other type of cataracts [9].

Excess risk of PSC cataract among interventional cardiologists was first suspected in the USA [10] and later observed in some exposed/unexposed studies performed in samples of cardiologist from Uruguay and Columbia [11], Malaysia [12], and from Helsinki [13], suggesting a risk of lens opacities at least twice that of unexposed groups. These studies presented, however, methodological limitations and only focused on PSC opacities whereas other types of cataract may be involved [14]. Moreover, this risk had never been studied in France where cardiologists' workload and radiation protection awareness may be different from previously studied populations.

In this context, the O'CLOC study [15] (Occupational Cataracts and Lens Opacities in interventional Cardiology) was performed in France to screen different types of lens opacities among interventional cardiologists from many French centers and quantify the risk of early cataract among them, compared to an unexposed control group.

2. Materials and methods

The authors of this manuscript have certified that they comply with the principles of ethical publishing in the International Journal of Cardiology.

2.1. Description of the study

The O'CLOC study was a cross-sectional multicenter investigation conducted in France between October 2009 and June 2011 and designed to determine the prevalence and risk estimates of lens opacities among exposed ICs and an unexposed control group [15]. The study was approved by the local ethics commissions: CCTIRS — Advisory Committee on Information processing research in the field of health (advice number 09.079) — and CNIL — National Commission for Computing and Liberties (authorisation number: 909138). Informed consent was obtained from each participant.

ICs from some 40 French centers (public hospitals or private health centers) employing at least 2 ICs were invited to participate in the O'CLOC study. They had to be at least 40 years old and still working in a catheterization laboratory. Exclusion criteria included ever having had computed tomography (CT scan) of the head or cerebral radiotherapy of any sort. Volunteer ICs were interviewed by telephone, based on a questionnaire; to collect individual information. Questions about medical condition asked about smoking status, height and weight (for body mass index, BMI), presence or history of myopia, diabetes, and corticosteroid use (>6 months). Occupational history was investigated by asking them to describe their workload in the cardiac catheterization laboratory (mean number of procedures per week, …) and their use of protective equipment against X-rays (previously reported [15]).

We initially planned to use unexposed non-interventional cardiologists as the frequency-matched unexposed group, but abandoned that idea for three reasons: a too low participation rate, the rarity of truly unexposed occupational activity, and concern about a selection bias among volunteers. Finally, it was decided to recruit unexposed non-medical workers from IRSN (Institute of Radiation protection and Nuclear Safety) as controls. This socioeconomically comparable population had definite recruitment advantages: they were easy to contact by internal emails, would participate at a relatively high rate (IRSN workers were presumably interested in volunteering for an IRSN study), and their age and gender distribution could be controlled more easily. Accordingly, unexposed IRSN workers at the Fontenay-aux-Roses site (France) were invited to participate in the O'CLOC study and required to meet the same initial inclusion criteria. The number of women and the age distribution were restricted, however, to match that of the IC group. Participants were interviewed by telephone to complete the medical part of the questionnaire.

2.2. Eye examination and cataract grading

All participants had an eye examination by an ophthalmologist at their facility, or elsewhere if more convenient. In some cases, ophthalmologists were blind to the exposed status of cardiologist if they didn't know him. For the IRSN controls, an external ophthalmologist who was blind to the exposed or unexposed status of IRSN participants, came to perform the examination at the Fontenay-aux-Roses Centre.

Lens opacities were classified according to their anatomical location (see Fig. 1). The lens of each eye was examined with a slit-lamp after the pupil was dilated, and the LOCS III grading guideline was used [16]: nuclear, cortical, and PSC opacities were graded and scored on an integer scale of one to five or six, based on comparison with reference photographs. At early stage of cataract (stages 1 and 2), lens changes consist of small dots and vacuoles with no impact on visual acuity which, over time, aggregate to form larger opacities (stages ≥ 3) which could be associated with decreased visual acuity, in particular for PSC localizations (explained by the typical morphology obscuring the eye's nodal point and resulting in central visual loss). All three types of lens opacities could appear simultaneously in each eye.

2.3. Outcomes

The studied outcome was the presence or no of lens opacities in either left or right eye, defined as stage ≥ 1. Each type of cataract was considered: nuclear, cortical and PSC.

2.4. Statistical analysis

Categorical variables are presented as percentages and continuous variables as means ± SD. Continuous variables were compared between groups with Wilcoxon tests and categorical variables by the Chi-square or Fisher's exact test, as appropriate. All tests were two-sided. A P-value < 0.05 was considered significant.

The prevalence of lens opacities is presented with its 95% confidence interval (95% CI). The risk of lens opacities was examined with a logistic regression analysis, with the unexposed group of IRSN workers as the reference group. The crude odds ratios (OR) of nuclear, cortical, and PSC stage ≥ 1 were estimated first. Risk factors for cataracts, i.e., age, gender, BMI, myopia, corticosteroid use, and diabetes were considered in the risk estimates. For PSC lens opacities, further analyses were conducted to test the association with the period when subjects began their interventional cardiology practice (1970–1979, 1980–1989, 1990–1999, or ≥2000) and duration of activity (<17, 17–25, >25), with the cumulative number of procedure, and to estimate the potential risk reduction associated with regular use (that is, more than 75% of the time) of lead glasses. All data were analyzed with SAS software (v9.2).

3. Results

3.1. Population characteristics

Of the 526 ICs invited by email or postal mail to participate, in a message specifying an age criterion ≥ 40 years, 131 answered positively and were interviewed by telephone (Fig. 2). For the unexposed group, all 1082 IRSN workers at Fontenay-aux-Roses were contacted by email and after frequency matching criteria for age and sex with the IC group, 128 were interviewed by telephone. A history of head CT scan was slightly more frequent among the 128 unexposed workers than the 131 ICs, but the difference was not significant (16% vs. 8%, p = 0.08), and these individuals were not included based on this exclusion criteria. The number of volunteers who finally did not attend the ophthalmologic examination for personal reasons was in the same range in both groups (14/121 (11%) and 8/108 (7%), p = 0.37). One person in each group could not have their eye lens dilated for medical reasons, and thus could not have an eye examination. Finally, 106 ICs and 99 unexposed IRSN workers were included