

# Characteristics of interventional cardiologists and their work practices for the study on radiation-induced lens opacities based on the methodology developed by ELDO—preliminary results

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## ABSTRACT

Preliminary results of the Polish epidemiology study on eye lens opacities among interventional cardiologists (ICs), based on the methodology proposed by ELDO (epidemiological studies of radio-induced cataracts in interventional cardiologists and radiologists: methodology implementation), are presented. The aim of the study is to test the hypothesis concerning the excess risk of cataract in the group of ICs. The first results concern the study population characteristics, including the most important confounding factors for cataract, as well as a detailed description of the work practices in interventional cardiology needed in order to reconstruct the cumulative eye lens dose. The data from 69 ICs and 23 controls collected based on the general medical questionnaire and the occupational questionnaire (for ICs only) were analyzed. The mean age of ICs and of the control group was 41 and 44, respectively, while the mean duration of work for exposed physicians was 9 years. The analysis of the data from the occupational questionnaire concerning the procedures performed, the use of various access routes, as well as radiation protection tools (eye lens glasses, ceiling suspended transparent shield, etc.) are also presented. On the basis of this information and additional assumptions about the doses per procedure (as well as reduction factors for various types of radiation measures), the cumulative doses to the eye lens of ICs were evaluated. They ranged up to 1.55 Sv and 0.4 Sv for left and right eye, respectively; however, the dose to only 3% of ICs exceeded the new threshold for development of eye lens opacities (0.5 Gy) proposed by the ICRP.

## INTRODUCTION

The lens of the eyes is one of the most radiosensitive tissues in the body [1]. Ocular ionizing radiation exposure results in characteristic, dose-related, progressive lens changes, leading to opacification or clinical cataracts [2].

Cataract associated with ionizing radiation is well known from experimental studies and has been demonstrated in humans by studies among survivors of the Hiroshima and Nagasaki atomic bombs [3]. Additionally, cataract is a frequent side-effect of radiotherapy, and increased frequency of cortical cataracts has been observed among radiation-exposed groups [4].

Recent studies indicate that the threshold for cataract development is likely lower than the current guidelines of 2–5 Gy, perhaps even less than 0.5 mGy; radiation cataractogenesis may in fact be more accurately described by a linear, no-threshold model [5]. Additionally, radiation-induced cataracts have been observed in various exposed populations at doses lower than expected.

Few epidemiological studies on radiation lens opacities among interventional cardiologists (ICs) and radiologists, the most exposed of the health professionals [6–7], have confirmed the increased risk of cataract in this group. However, none of these national studies were able to establish the dose–response relationship for radiation-induced

lens opacities due to the lack of accurate assessment of cumulative eye lens doses and poor statistical power of the study.

In order to prepare the large-scale European survey that will answer the fundamental questions concerning the deterministic or stochastic character of cataract, the ELDO project was launched. Its idea was to develop, on the basis of the experiences from national surveys (the French O'CLOC study and the Finnish study), the methodology for a European epidemiology study on radiation-induced lens opacities. The proposed methodology included, in particular, the detailed questionnaire containing general and medical information (general questionnaire), the protocol for inclusion and exclusion criteria, the improved retrospective assessment of the eye lens doses on the basis of two independent methods (the occupational questionnaire, and results from whole-body measurements when the dosimeter was worn above the apron) and the protocol concerning the performance of the ophthalmological examination.

The following step was to test and validate this new methodology by implementing it in the national epidemiological study. The relevant project concerning Polish ICs was launched under the DoReMi project (EVAMET (Epidemiological pilot study on radiation-induced cataract in interventional cardiology – validation of methodology study) and NIOM (Nofer Institute of Occupational Medicine) grant. The aim of the study is also to test the hypothesis that ICs have an increased risk of cataracts as compared with an unexposed reference group. The preliminary findings from the Polish study are presented in this paper. They include the first analysis of the data collected on the basis of general and occupational questionnaires concerning characteristics of the study population and work practices in interventional cardiology.

## METHODS

### Study approval

The Nofer Institute of Occupational Medicine Bioethical Committee Board approved the study (Resolution No 16/2013(date: 05.11.2013)), and written informed consent was obtained from all subjects before their participation.

### Study population

The study population will consist of a group of exposed individuals (ICs chronically exposed to X-rays) and a group of non-exposed physicians. All individuals gave their written consent to participate in the study.

Only cardiologists with at least 10 years of practice in interventional cardiology or at least 40 years old (for controls) will be included. Subjects with a history of personal medical radiation exposure (radiotherapy, brain scans) will be excluded from both groups. The groups will be matched for age and sex. All participants will be asked during interview questions about demography, lifestyle (consumption of alcohol, tobacco), and risk factors for cataracts (age, diabetes, myopia, steroids etc.).

### Occupational questionnaire

A specific section of the questionnaire for the exposed group focuses on occupational history, including a precise description of the procedures (type, frequency, access type) and working methods concerning the use of radiation protective tools. As the practices have been changing with time, all information was collected for a specific

periods (working decades). These data will be used first to assess the eye lens doses accumulated during the whole working history of the ICs and then to classify subjects into 'exposure level' groups according to the above dose estimates.

### Eye examination

Eye slit lamp examinations for all participants will be performed to detect cataracts, even in the early stages. To assess the lens opacities, the Lens Opacities Classification System III (LOCS III) classification is going to be used. The data from eye examination, however, will not be presented in this paper.

## RESULTS

### Study population

In Poland, we have recruited 69 ICs and 23 unexposed physicians. Both cardiologists and the control group were recruited directly in cardiac medical centers from the region of Lodz or during cardiologist conferences.

The subjects characteristic are presented in Table 1. The mean age was 41 and 44 in the IC group and the control group, respectively, and 80% of the cardiologists and 83% of the controls were males. Most of the study participants (70% of the exposed group and 57% of the unexposed group) were overweight or obese ( $BMI \geq 25 \text{ kg/m}^2$ ). The mean BMI of the ICs was  $26 \text{ kg/m}^2$ , and it was  $25 \text{ kg/m}^2$  in the control group. The duration of work as an IC was  $\sim 9$  years ( $SD = 6.49$ ). Current smoking was declared by 12% of cardiologists and 22% of subjects from the control group. The average number of cigarettes smoked per day was 11 in the exposed group and 12 in the control group (Table 1). Diseases such as diabetes, high cholesterol level, high blood pressure, gout and cancer were diagnosed and treated in 3%, 14%, 16%, 1% and 1% of ICs, respectively. The subjects from the control group declared only high cholesterol level (22%) and high blood pressure (13%) as diseases diagnosed and treated.

Eye diseases (cataract, glaucoma, macular degeneration) affected relatives of ICs (22%, 6% and 0%, respectively) and were also declared among relatives of subjects from the control group (26%, 4% and 9%, respectively) (Table 1).

Regarding medical examinations, the most frequently declared were CT of the head. More than 20% of both ICs and controls took at most one head CT examination.

There were no statistically significant differences between the ICs and the control group (Table 1).

Based on inclusion criteria for the recruited ICs and controls ('10 years of practice' or 'at least 40 years old', respectively), only 43% of subjects from the study group and 61% from the control group could be included in the cohort. This result partly reflects the higher study participation rate of younger people, who are more willing to participate and interested in the study results.

### Data from the occupational questionnaire

The occupational questionnaires have been filled in by 54 ICs so far.

There were two types of procedures included in the occupational questionnaire: coronary interventions (CIs) like angiography (CA); angioplasty (PTCA); coronary chronic total occlusion (CTO); valvuloplasty; and electrophysiology procedures like pacemakers and implantable cardioverter defibrillators (PM and ICDs), cardiac resynchronization therapy (CRT and CRT-D), radiofrequency ablation

**Table 1. Characteristics of the study population**

Subject characteristics	Interventional cardiologists (n = 69)	Controls (n = 23)	P
Age mean ± SD (range)	41 ± 7.73 (28–63)	44 ± 9.43 (27–59)	0.22
Sex n (%)			0.79
female	14 (20.29)	4 (17.39)	
male	55 (79.71)	19 (82.61)	
BMI (kg/m <sup>2</sup> ) n (%)			0.37
<25	21 (30.43)	10 (43.48)	
≥25	48 (69.57)	13 (56.52)	
mean ± SD (range)	26 ± 3.43 (18–34)	25 ± 3.08 (19–33)	
How many years have you been working as an interventional cardiologist or radiologist? mean ± SD (range)	9 ± 6.46 (1–29)		
Last ophthalmological examination (months previous) mean ± SD (range)	30.92 ± 36.11 (3–192)	34.65 ± 43.10 (4–194)	0.27
Have you EVER smoked regularly?			0.38
Yes	8 (11.59)	5 (21.74)	
No	61 (88.41)	18 (78.26)	
Number of smoked cigarettes per day mean ± SD (range)	10.67 ± 6.96 (3–20)	12 ± 6 (1–20)	0.44
Diseases diagnosed and treated			
Diabetes	2 (2.90)	0 (0)	
High cholesterol level	10 (14.49)	5 (21.74)	0.61
High blood pressure	11 (15.94)	3 (13.04)	0.99
Gout	1 (1.45)	0 (0)	
Cancer	1 (1.45)	0	
Eye disease among relatives			
Cataract	15 (21.74)	6 (26.09)	0.87
Glaucoma	4 (5.80)	1 (4.34)	0.99
Macular degeneration	0 (0)	2 (8.70)	
Have you had one of the following treatments?			
Eye surgery	1 (1.45)	1 (4.34)	0.86
Eye injury	5 (7.25)	2 (8.70)	0.97
Uveitis	2 (2.90)	0 (0)	
Implantation of an artificial lens of the eye	0 (0)	0 (0)	
Steroid taken ever			0.33
Yes	15 (21.74)	8 (34.78)	
No	54 (78.26)	15 (65.22)	

Continued

Table 1. Continued

Subject characteristics	Interventional cardiologists (n = 69)	Controls (n = 23)	P
<b>Medical examination</b>			
head CT	16 (23.19)	5 (21.74)	0.99
neck CT	4 (5.80)	3 (13.04)	0.61
head PET-CT	0 (0)	0 (0)	–
neck PET-CT	0 (0)	0 (0)	–
<b>Diagnostic examination or treatment with radio-nuclides</b>			
Yes	4 (5.80)	2 (8.70)	
No	65 (94.20)	21 (91.30)	0.97
<b>Cerebral angiography</b>			
Yes	0 (0)	0 (0)	
No	69 (100)	23 (100)	
<b>Have you ever had an interventional radiology/cardiology procedure?</b>			
Yes	0 (0)	0 (0)	
No	69 (100)	23 (100)	
<b>Have you ever undergone medical interventions with fluoroscopy of the head?</b>			
Yes	1 (1.45)	0 (0)	
No	68 (98.55)	23 (100)	

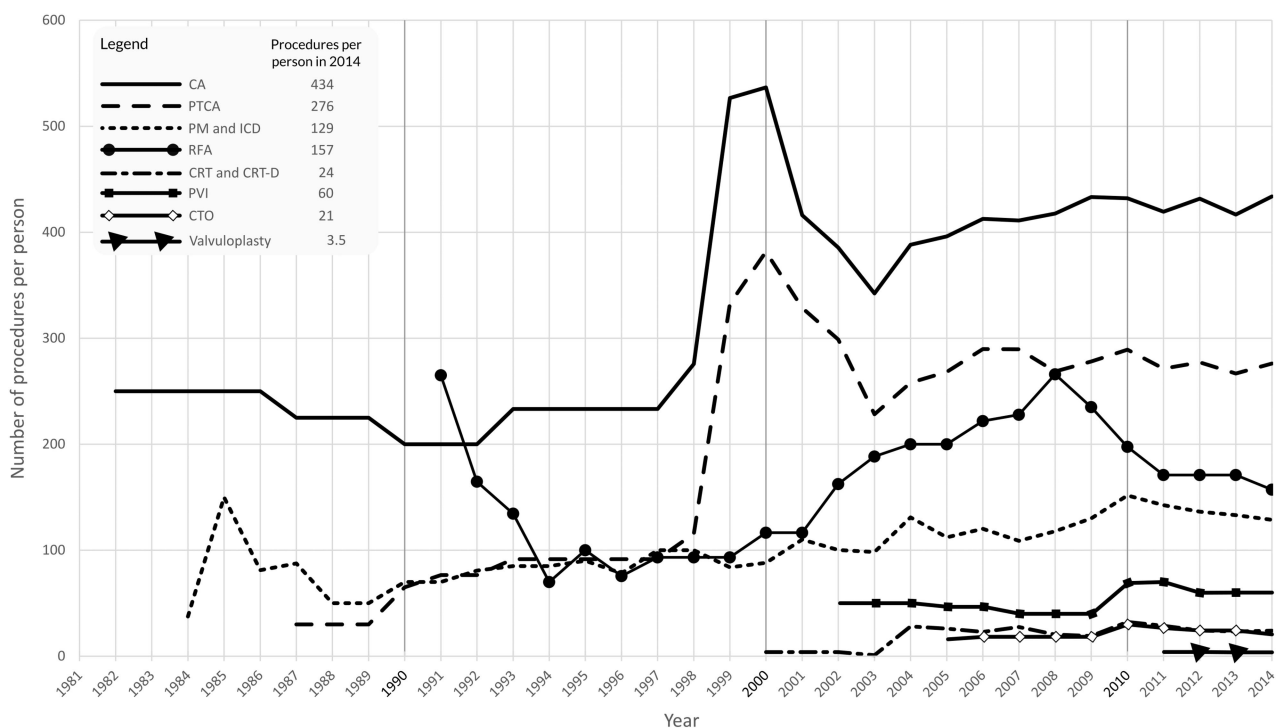


Fig. 1. Trends over the time in the mean annual number of procedures.

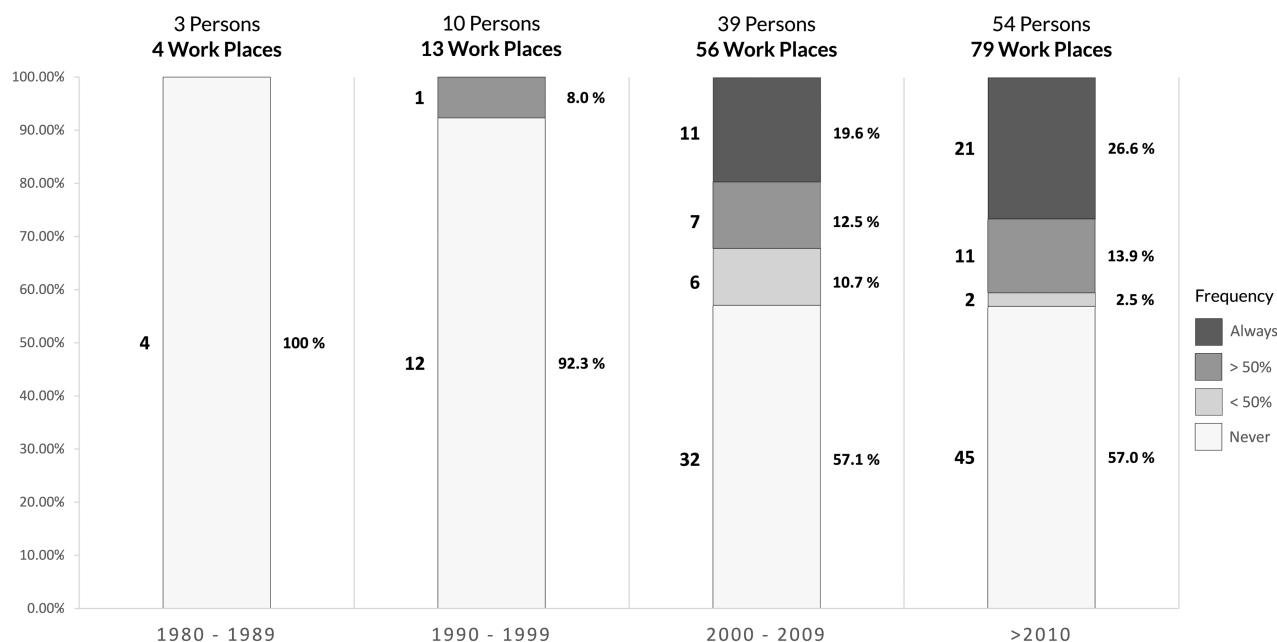


Fig. 2. Trends over time in the use of lead glasses.

(RFA), and pulmonary vein isolation (PVI) for atrial fibrillation ablation. According to the data collected (cf. Fig. 1), the most frequently performed procedures, for all decades, are CIs and, among these, CA and PTCA. CTO procedures appeared later (around 2005) and are rather rare (20 procedures per year in 2014).

Up to now in our database there are only a few cases of valvuloplasty procedures. Regarding electrophysiological procedures, the mean number of procedures per cardiologist does not exceed 160 (for RFA). It is also seen from the figure that PVI is a relatively new procedure (the starting year of the practice declared in questionnaires is 2002).

The access route (the place of insertion with the catheter) for CI procedures has been changing during recent decades in Poland. Till the end of nineties femoral access only was used, whereas at present, the radial one is predominant. Sporadically, brachial access was also used. For the analyzed electrophysiology procedures, the kind of access has not changed with time and depended only on the very procedure. The femoral approach has been used for RFA and PVI, and the direct one for the remaining procedures (PM and ICD, CRT/CRT-D).

Five cardiologists declared the use of the C-arm unit with over-couch X-ray tube and under-couch image intensifier; four of them used it during PM and ICD procedures, and one during PTCA procedures. No one has declared the use of bi-plane systems.

Protective measures used by physicians to reduce doses to the eye lens were eye lead glasses and ceiling lead glass. Figure 2 shows the use of the former in various working places over various periods.

Lead glasses became available and popular at the beginning of the new century. Ceiling protection is now commonly used in CA, PTCA and CTO procedures (in 90% of procedures it is always used); on the other hand, it is less frequently used during electrophysiological procedures: in 50% and 26% of PVI and RFA procedures, respectively. Finally, some cardiologists claim to use it during PM/ICD and

CRT/CRT-D procedures, although the access to the operating field might be difficult (Fig. 3).

On the basis of the information from the occupational questionnaire and the dose distributions for single procedures of a given type collected in the NIOM database (partially published in the paper [8]) the doses cumulated (CD) in left and right eye lenses were evaluated for each individual. For this purpose an additional assumption was made regarding the correction factors for the use of eye lead glasses (3-fold reduction), the ceiling shield (2.3-fold reduction), X-ray tube above the patient table (4-fold increase) and femoral access (2-fold reduction). In general, for the coronary ICs (19% of ICs), the doses estimated were much higher than those of the electrophysiologists (81% of the IC group). For the former, the maximum evaluated cumulative dose was 1.55 Sv to the left and 0.36 Sv to the right eye lens, while for the latter the maximum evaluated cumulative dose was 0.24 Sv for the right eye lens and 0.095 Sv for left one. Seventy-five percent of physicians both from coronary ICs and electrophysiologists received for the most exposed eye lens, doses below 0.41 Sv and 0.05 Sv, respectively; both values are lower than the new threshold for the development of lens opacities.

## DISCUSSION

The possible risk factors for cataract in the study population were examined. The comparison between the IC and control groups showed no statistically significant differences for the various characteristics included in the study (age, sex, smoking, steroids, diabetes, etc.). Many risk factors were associated with cataracts. Age is the strongest determinant of cataract occurrence, though the effect appears stronger for nuclear opacities than for the other types [9]. Other risk factors for both cortical and posterior subcapsular cataracts include diabetes and steroid use, while smoking increases the risk of nuclear and posterior subcapsular cataracts [10]. Currently, special attention is paid to

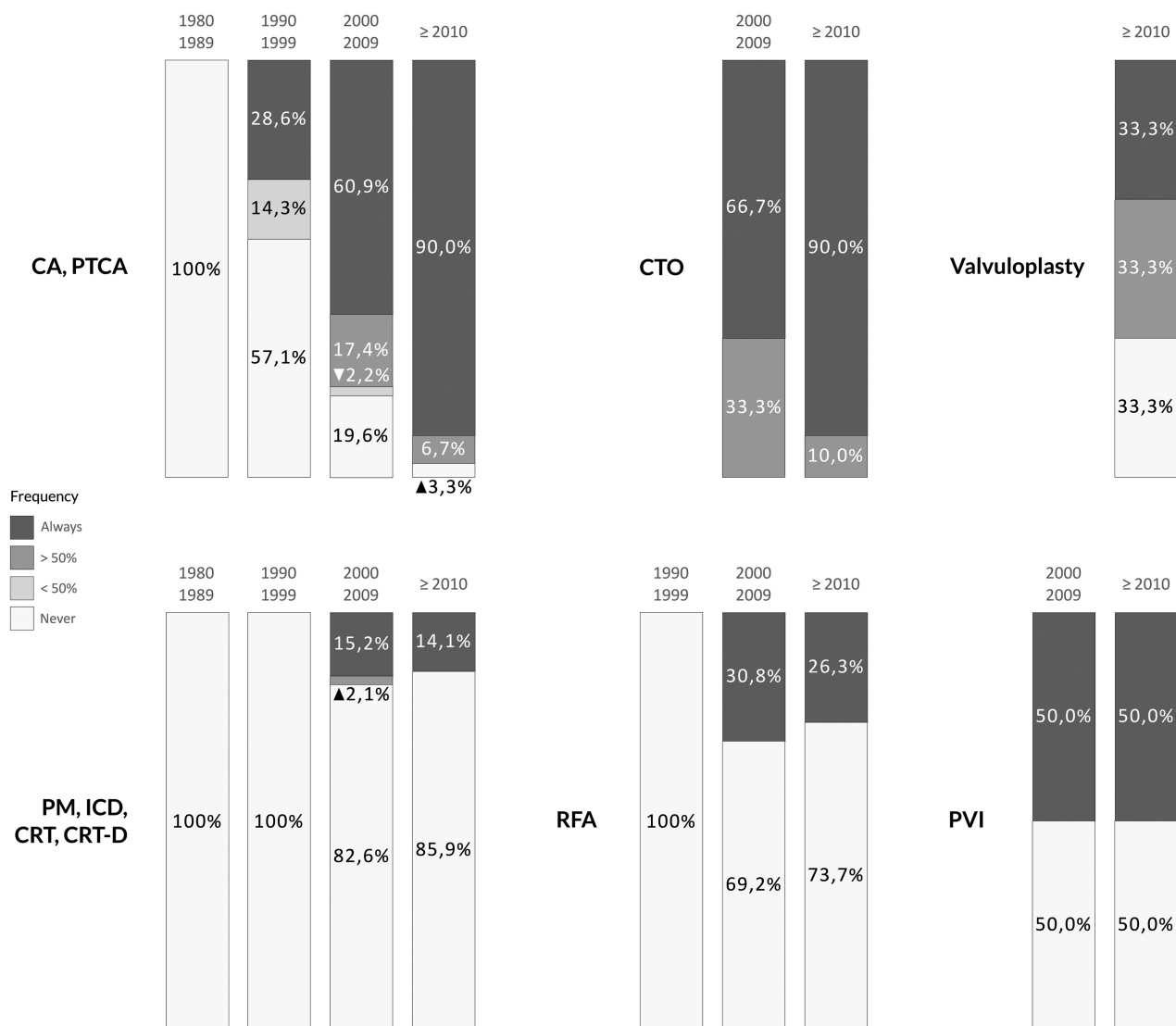


Fig. 3. Trends over time in the use of ceiling suspended lead glasses during various types of procedures.

systemic diseases and the use of medications. Associations of high prevalence of cortical cataract with hypertension, abnormal obesity [11], gout duration of more than 10 years, and arthritis [12] have been observed. A myopia of 1 diopter or more is related to nuclear cataracts [13]. Another issue is CT scans of the head, during which the eye lenses are irradiated indirectly or directly. The doses to the eye lenses reported by various authors range from 25 mGy up to 100 mGy [14, 15]. Although the risk of eye lens injury from brain CT is still unknown, some study results indicate that opacities are significantly associated with CT scans of the head. Other authors conclude that there is a significant increase in the risk for cataract in cases of three or more diagnostic examinations in the region of the head and neck [16].

Analysis of the Polish data shows that inclusion criteria, such as age and duration of work, might be important factors influencing significantly the final cohort size. Comparison of the Polish data with the corresponding data from the French survey [6] shows that the mean age at the time of interview (in years) was lower in the Polish study (41 for Polish ICs, but ~51 for French ICs). Due to this difference,

the cumulative duration of IC activity in years was, as expected, also lower for the Polish ICs (9 for Polish ICs vs ~22 years for French ICs); consequently, the cumulative doses in the eye lens were much lower (18% of the coronary ICs and 0% of the electrophysiologists were above the ICRP lifetime threshold for early opacities (500 mGy) vs 28% and 19% in the French study, respectively).

As the starting point in evaluation of the cumulative eye lens doses, the data (doses per procedures and correction factors for the use of radiation protection measures) from the Polish database were assumed. The choice of the input data used will have an influence on the level of the cumulative eye lens doses and therefore needs validation. A measurement program has already been performed in order to validate the methodology, and its results will be presented in future papers.

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