Radiation Protection Dosimetry Advance Access published November 24, 2016

Radiation Protection Dosimetry (2016), pp. 1–6 doi:10.1093/rpd/ncw339

RESULTS OF RELID STUDY 2014—BUENOS AIRES, ARGENTINA RETROSPECTIVE EVALUATION OF LENS INJURIES AND DOSE

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High levels of scatter radiation in catheterization laboratories may lead to posterior subcapsular opacities in the lens of the staff. The international Retrospective Evaluation of Lens Injuries and Dose (RELID) was performed in Argentina for the first time in 2010 in the context of the congress of the Latin American Society of Interventional Cardiology (SOLACI) and recently, in 2014, was carried out for the second time (SOLACI-CACI 2014). The 2014 study included 115 participants: interventional cardiologists, technicians and nurses. Posterior subcapsular lens changes typical of ionizing radiation exposure were found in 91.5% of interventional cardiologists, in 77% of technicians and in 100% of nurses, according to the Merriam–Focht scale. This RELID study (Argentina 2014) has particular importance since it allowed the follow-up of 10 professionals evaluated in 2010. The results obtained in the study population highlight the importance of the availability and proper use of the elements of radiation protection, as well as staff training.

INTRODUCTION

Situation in the cardiac catheterization laboratories

Among all medical applications of X-rays, hemodynamics turns out to be one of the most complex ones in terms of radiation protection. This is mainly because of the high dose rates for patients and staff, their exposure time, and particularly, due to the inherent characteristics of the professional roles during the intervention.

Dose rates at the point of entry into the patient's skin may range between 15 and 150 mGy h^{-1} in fluoroscopy[1], within normal working conditions and using equipment controlled under a quality control program. A typical diagnostic procedure, such as a coronary angiography, can provide the patient with a reference effective dose of 3.1 mSv (equivalent to some 155 chest radiographs); while a therapeutic procedure, such as a percutaneous transluminal coronary angioplasty, provides a reference effective dose of 15.1 mSv (equivalent to some 755 chest radiographs)[2]. The main source of radiation dose to the worker is the scattered radiation generated in the patient. Consequently, high doses to the patient involve a high dose for staff. The physician performing the intervention (operator) may be exposed to dose rates without protection elements of 0.5–2.5 mSv h^{-1} at head height, of 1–5 mSv h^{-1} at waist height and of 2–10 mSv h^{-1} at legs height[3].

The interventional cardiologist (operator) is the person standing closest to the X-ray tube and to the patient, just 50 cm away on average, while the support staff (technicians and nurses) stay >1 m apart during the procedure. The operator's work requires the physician to remain in front of the patient's bed, leaving her/his left side closer to the point of entry into the patient and to the X-ray tube. Therefore, the doses received are generally higher in the left side than in the right side, as demonstrated in several studies[4]. Dose rates without protective elements are high, and the dose received by the different organs could be significant depending mainly on the use of suitable personal protective equipment and the amount of the performed procedures.

Protective elements and personal dosimetry

The availability, the proper use and the status of the protective elements are essential for the radiation protection of the Personnel Occupationally Exposed (POE). According to Law No. 17,557/67, Resolution No. 2680/68 and their modifications (Regulation concerning the installation and operation of generators X-ray equipment), Basic Safety Standards of the Ministry of Health of Argentina, Point 3.4 'The owner of the facility should contemplate the usage of the most appropriate protection means to prevent that both staff and public receive doses higher than those established'[5]. Protective elements must be available in the service and should be provided by the owner of the facility as required by the regulations. However, the staff concerned are responsible for the correct use of the tools, as well as of their care and cleaning to guarantee their durability.

In the case of catheterization laboratories, the protective elements can be classified into two groups: elements of leaded personal protection (apron, thyroid collar and glasses) and elements of leaded mobile protection (ceiling suspended screens and curtains hanging from the patient bed). In order to protect the lens, it is essential that all the POE wear leaded glasses, and that the operator uses a suspended ceiling screen for trunk and head protection during all the intervention. According to other studies(6), leaded glasses equivalent to 0.25 mm Pb can attenuate almost up to 60% of the scattered radiation that reaches the lens of the interventional cardiologist, 52% in technicians and 45% in nurses. In general, it is estimated that the glasses attenuate at least 50% of the scattered radiation.

Regarding possible high doses received, it is important to use an appropriate dosimetry control and to consider the use of a double dosemeter, as recommended by the US National Council on Radiation Protection and Measurements in its publication NCRP No. 122(7). The use of a double dosemeter (one under the leaded apron on the chest and another outside the apron on the thyroid collar) allows better estimates of both the effective dose and the dose to the lens.

The Argentinean Ministry of Health manifested in 2013 that the operators need to implement the use of a double dosemeter and since then, services began to implement this measure. According to Art. 25 of the Ministry of Health Decree No. 6320/68: 'The person responsible for each facility will provide workers involved with the handling and use of equipment for the generation of X-rays with a dosemeter, which will be used in a way that allows the individualization of doses'(5).

Biological effects of ionizing radiation on the lens

Several studies have shown that the lens is one of the most radiosensitive tissues even in people exposed to low doses of ionizing radiation, including professionals exposed in medical practices(8).

Cataracts caused by ionizing radiation generally differ from those caused by age, and are associated with the posterior subcapsular region(9). The process of opacity by radiation is generated on the lens anterior surface from which germinative epithelial cells begin to migrate to the subcapsular region developing an abnormal proliferation and differentiation. Alterations are generated in the formation and folding of proteins, which implies a possible alteration/modification in the DNA as a primary event responsible for the formation of cataracts(10).

In previous studies, the existence of radiation-induced cataracts in the catheterization laboratories working staff was demonstrated as the accumulated dose due to the X-ray exposure can be elevated(11).

The equivalent dose limit for the lens is currently 150 mSv in a year. In 2011, the ICRP(3) issued a statement (taking into account new epidemiological evidence), in which a new dose limit for workers is recommended: 'an equivalent dose limit for the lens of the eye of 20 mSv in a year, averaged over defined periods of 5 y, with no single year exceeding 50 mSv'(12).

Retrospective Evaluation of Lens Injuries and Dose Study Records

The 'Retrospective Evaluation of Lens Injuries and Dose' (RELID) study was initiated internationally by International Atomic Energy Agency (IAEA) in 2008. This evaluation was first performed on interventional cardiology workers in Bogotá, Colombia(13). In 2010, the study was conducted in Argentina during the congress of the Latin American Society of Interventional Cardiology (SOLACI). In order to continue this work and monitor some of the interventional cardiology professionals that were evaluated in 2010, the study was conducted for the second time in Argentina in the SOLACI-CACI Congress 2014. This study presents the results of this latest study and some recommendations.

MATERIALS AND METHODS

Survey design

This work was performed during the congress of the SOLACI and the Argentine College of Interventional Cardioangiologist (SOLACI-CACI 2014) on 23–25 April 2014 in Buenos Aires. The study was organized by an interdisciplinary group including radiation protection specialists, medical physicists, interventional cardiologists and a group of ophthalmologists coordinated by the ophthalmologist who performed the RELID 2010 study together with a team from IAEA.

The RELID study 2014 in Argentina was the first to re-evaluate lens opacities in professionals 4 y after the first evaluation in the SOLACI-CACI Congress 2010. The implemented methodology and criteria were similar to those used in earlier studies to compare the results, not only with other RELID studies performed in the world, but particularly in those participants evaluated for the first time in 2010 and re-evaluated in 2014 for monitoring.

The participants attended the congress and entered the study voluntarily. Prior to the ophthalmologic examination, each participant completed an informed consent form, a medical record (including previous imaging studies such as CT scans of the head), ophthalmologic evaluations, and another form concerning working conditions with ionizing radiation (years of work on catheterization laboratories, protective elements used and frequency of usage, typical workload in diagnostic and therapeutic practices, use of personal dosimetry, etc.).

A total amount of 151 participants were enrolled for the study, including professionals of both genders within an age range of 23–68 y; 36 of whom were excluded afterwards. Therefore, a total of 115 individuals were included: 47 interventional cardiologists, 53 technicians and 15 nurses; 10 of which were professionals previously evaluated in 2010 (5 interventional cardiologists, 4 technicians and 1 nurse). The exclusion criteria were omission of relevant data on informed consent; lack of complete ophthalmological examination for different reasons; conditions such as diabetes, history of uveitis and/or use of systemic corticosteroids.

The control group was not evaluated specifically for this study, but considered from a previous RELID study that took place in the SOLACI Congress in Bogotá[(14)]. This group comprised 91 volunteers who reported no exposure to relevant ionizing radiation in the area of the head and the neck.

Assessment of lens opacities

Posterior lens changes were evaluated using a slit lamp and a modified Merriam–Focht scoring system[(15)]. This system considers the amount of posterior and anterior opacities, vacuoles and other defects, and describes the severity of lens opacities in subsequent range from 0 to 4.0, with 0.5 increments. A score of 0.5, usually considered pre-cataractogenic, indicates subsequent early changes in the lens that can become opacities in the future. Likewise, a score of 1.0 in either eye is considered an early start of opacity, while a score of 1.5 is considered cataract in progress.

In order to evaluate the subcapsular opacities in each lens associated with ionizing radiation, an ophthalmologic examination was carried out after eye dilation. This evaluation was performed with a double check made by two different professionals. Eye dilation was performed with 2.5% phenylephrine and 1% cyclopentolate. The examination consisted of two complementary techniques: direct illumination (axial view) and retroillumination (sagittal view). The first one facilitates the location of opacities while the second allows a wide field of view of the opaque regions and identification of vacuoles, dots and bone spicules (spokelike) in no visible radial projection oblique direct illumination.

Radiation dose assessment

The radiation dose to the lens was estimated from the number of procedures per week (recorded in the questionnaire) and reference values of dose[(14)]. In those cases in which protective elements were not used, a dose of 0.5 mGy was assumed for the cardiologists and a dose of 0.15 mGy for the technicians and nurses. These reference values correspond to a typical interventional cardiac procedure: 10 min fluoroscopy, 800 cine frames. In procedures in which screens and leaded glasses were used, the applied correction factor was 0.1, and 2 for procedures carried out with radial access.

RESULTS

The results of the RELID study 2014 carried out in Buenos Aires—Argentina are shown in Tables 1–3, corresponding to one different profession each. According to the score of Merriam–Focht[(15)], 86% of the participants had typical subcapsular opacities by exposure to ionizing radiation in at least one of their two lenses. This means that of the 115 professionals evaluated, only 16 did not present opacities attributable to radiation doses in any of their lenses.

In a closer analysis, these tables show that 91% of the interventionists cardiologists (Table 1), 77% of technicians (Table 2) and 100% of nurses (Table 3) presented opacities. However, the average opacity score of participants calculated from the sum of both lenses was higher for technicians (1.07 ± 0.48, Table 2) than for physicians and nurses (0.99 ± 0.42 and 0.8 ± 0.41, Tables 2 and 3, respectively).

Table 1. Results for interventional cardiologists.

Interventional cardiologists	With opacity	Without opacity
47 Professionals	91.49%	8.51%
Mean Merriam–Focht score (±SD)	0.99 ± 0.42	N/A
Cumulative dose lens (Gy ± SD)	6.42 ± 8.42 (0.12–42)	3.17 ± 7.32 (0.53–10)
Average age (±SD)	47.46 ± 10.25 (31–68)	41.25 ± 5.91 (33–47)
Years of work (±SD)	16.78 ± 11.08	11.50 ± 5.07
Use of leaded screen ‘always’	26%	50%
Use of leaded screen ‘sometimes’	23%	0%
Use of leaded screen ‘never’	46%	50%
Use of leaded glasses ‘always’	33%	67%
Use of leaded glasses ‘sometimes’	44%	33%
Use of leaded glasses ‘never’	23%	0%
Use of personal dosimeter	93%	100%
Use of double personal dosimeter	41%	25%

SD, standard deviation.

Table 2. Results for technicians.

Technicians	With opacity	Without opacity
53 Professionals	77.36%	22.64%
Mean Merriam–Focht score (±SD)	1.07 ± 0.48	N/A
Cumulative dose lens (Gy ± SD)	5.41 ± 7.54 (0.0.7–10.08)	1.19 ± 2.02 (0.03–5.25)
Average age (±SD)	39.25 ± 9.67 (23–62)	31.09 ± 8.14 (23–49)
Years of work (±SD)	10.43 ± 8.82	6 ± 5.65
Use of leaded screen 'always'	27%	33%
Use of leaded screen 'sometimes'	14%	25%
Use of leaded screen 'never'	49%	25%
Use of leaded glasses 'always'	12%	8%
Use of leaded glasses 'sometimes'	17%	33%
Use of leaded glasses 'never'	61%	42%
Use of personal dosimeter	93%	64%
Use of double personal dosimeter	28%	18%

SD, standard deviation.

Table 3. Results for nurses.

Nurses	With opacity	Without opacity
15 Professionals	100%	0%
Mean Merriam–Focht Score (±SD)	0.8 ± 0.41	N/A
Cumulative dose lens (Gy ± SD)	3.30 ± 3.67 (0.35–13.50)	N/A
Average age (±SD)	39.64 ± 10.10 (24–55)	N/A
Years of work (±SD)	8.71 ± 5.95	N/A
Use of leaded screen 'always'	7%	N/A
Use of leaded screen 'sometimes'	21%	N/A
Use of leaded screen 'never'	36%	N/A
Use of leaded glasses 'always'	7%	N/A
Use of leaded glasses 'sometimes'	14%	N/A
Use of leaded glasses 'never'	50%	N/A
Use of personal dosimeter	86%	N/A
Use of double personal dosimeter	14%	N/A

SD, standard deviation.

Two participants showed a maximum score of 1.5 for a single lens and a maximum of 3.0 for the sum of both lenses. This result was observed in a single participant: a technician with an average of 10 y of work with ionizing radiation who has not worn leaded glasses.

Of the 43 cardiologists who presented opacities, 6 had them only in the right lens, 11 only in the left lens and 26 had bilateral opacities. In the case of the 53 technicians with opacities, 4 had opacities only in the right lens, 6 in the left and 43 had bilateral opacities.

The estimated retrospective cumulative lens dose was 6.42 ± 8.42 Gy for the cardiologists with opacities and 3.17 ± 7.32 Gy for those without opacities (Table 1). On the other hand, the corresponding estimates were 5.41 ± 7.54 Gy for technicians with opacities and 1.19 ± 2.02 Gy without opacities (Table 2) and 3.30 ± 3.67 Gy for nurses with opacities and 3.30 ± 3.67 Gy for those without opacities (Table 3).

For cardiologists and technicians (Tables 1 and 2), the average age and average years of work were higher in the group of participants with opacities, compared with the group without them.

Table 1 shows that only 26% of the operators with opacities claimed that they were using 'always' leaded screen, while 50% of the group without opacities reported that they 'always' used it. The use of leaded glasses is lower in those with opacities than in ones who did not present opacities (Table 1). In the case of support staff, there was a low percentage of professionals who 'always' or 'sometimes' wore leaded glasses (Tables 2 and 3). A high percentage of operators with opacities use personal dosimetry (93%, Table 1). Although the study population is different, this percentage is higher than in 2010 (48%)[14]. Technicians and nurses with opacities presented a very similar percentage (Tables 2 and 3). A high percentage of participants also reported not having their dosimetry records, and therefore ignoring the dose received.

The comparison between the percentages of professionals with opacities evaluated in RELID 2010 and 2014 is presented in Table 4. The results indicate that in 2010, 50% of the cardiologists presented subcapsular opacities, while in 2014 the percentage was 91%. Regarding the support staff, in 2010 technicians and nurses were analyzed jointly and 41% of them had opacities. In this study, both groups of professionals were analyzed separately, as their jobs' characteristics are different (distance to the X-ray tube and the patient, movement within the room, etc). The results of 2014 indicate that 77% of technicians and 100% of the nurses had opacities. It should be noted that, although the number of people tested in 2010 and 2014 is different, the distribution of

Table 4. Comparison between the percentage of professionals with opacities evaluated in the RELID 2010 [14] and the RELID 2014.

Profession	2010 (n = 127)	2014 (n = 115)
Interventional cardiologists	50%	91.49%
Technicians and nurses	41%	N/A
Technicians	N/A	77.36%
Nurses	N/A	100%

professions is similar in both studies (interventional cardiologists 2010 = 54, 2014 = 47; technicians and nurses 2010 = 69, 2014 = 68).

The re-assessment of the 10 professionals, who participated in RELID 2010, showed that 6 of them had an increase in their score. Five of these six professionals did not show typical opacities or only had a score of 0.5 in a single lens in 2010, while some had a score of 0.5 in both lenses in 2014. The participants reported that protective elements are used in their services. Additionally, it was noted that one of these professionals showed a score of 0 in each lens in 2010, but he had a score of 0.5 in the right lens and 1 on the left in 2014 (a technician with 9 y of interventional work, 26 procedures per week on average, 'always' wears leaded glasses, but has a cataract family history).

DISCUSSION

It has been shown that work with ionizing radiation, even at low doses, can cause subcapsular opacities in the lens[13, 14].

This study shows that 86% of the professionals who participated in the study had posterior subcapsular opacities associated with working with ionizing radiation, compared with the control group taken from a previous RELID study[16], in which only 10–12% of the population presented changes. Technicians, out of the three groups of professionals, were the ones with the lowest percentage of participants with opacities. This could be due to the characteristics of the work of each studied group.

The percentage of professionals with opacities was high compared with the one in the 2010 RELID study[14]. However, the observed opacity scores were not high, except in specific cases. The professional with the highest score accumulated between the two lenses reached a value of 3.0. This finding is striking because, although this professional does not use leaded glasses, he is a technician and has only 10 y experience of working for catheterization laboratories. This is a particular case that should be assessed individually.

The analysis of professionals with the highest opacity in the left lens reflects the characteristics of their work, since all the left side of the body is usually more exposed and therefore receives a higher dose. These results demonstrate the importance of using a leaded screen as well as leaded glasses.

The cumulative dose evidenced in the results should be considered as estimation only, because the values of dose were obtained from the literature and their application depended on each case in particular. Although these estimations are not rigorous, they might be useful to compare with other RELID studies.

The average age and years of work in catheterization laboratories in professionals with opacities indicate a correlation between exposure to radiation and changes in the lens.

The lack of protective elements use or discontinuous use is still an important issue to deal with, and demonstrates the need for constant training of the staff and institutional managers who must provide workers with all necessary protection to safeguard their health. The study has shown that not all services have personal dosimetry, which strengthens the need for training and assistance to institutions. However, it is important to highlight that the population of professionals who use a dosimeter is higher compared with the evaluation in 2010. At the same time and particularly for operators, it is also necessary to implement the dosimetry service, as well as the use of a double dosimeter. Part of the training should focus on understanding the purpose of dosimeter usage, and the knowledge of the individual dose received by operators in each month and year of work.

The comparison of the percentage of professionals with opacities between the 2010 RELID and the one performed in 2014 drew the attention of the authors. However, it should be noted that the study was performed on two different populations (except for the 10 re-evaluated professionals). Again, these results are aimed at the training of professionals, the use of protective elements and possibly the need to implement a quality control program to check the X-ray equipment periodically.

The re-evaluation of those professionals has also been a wake-up call, since 6 of 10 increased the opacity score according to Merriam–Focht system. The case of the technician who did not show opacities in 2010, but presented 0.5 in the right lens and 1 in the left lens in 2014, should be analyzed individually.

CONCLUSION

Interventional cardiology has advanced significantly in recent years. Although the clinical benefits are undeniable, the dose of radiation received by the staff can be really high reaching the thresholds of tissue reactions.

This study together with previous ones have shown that even at low doses of radiation, the lens is one of the most radiosensitive organs.

According to the results and other papers[14, 16] it is recommended to:

- Implement the new equivalent dose limit for the lens of 20 mSv in a year in national regulations.
- Implement and/or strengthen the training programs for all the staff: highlighting the need to use the protective elements and the necessary recommendations to optimize radiation protection and raise awareness of the risks of working with ionizing radiation, as recommended by the ICRP[17] and the European Commission[18].
- Implement leaded protective elements for the lenses in all the laboratories.
- Implement a double dosemeter and personal dosimetry in the professionals who have not been yet individually monitored, and keep a complete record of their dosimetry and working conditions (workload, etc.).

After the RELID study in 2014, IAEA provided in 2015 a slit lamp that allows this work to be in continuous progress; developing evaluation on a new control group to be referred to in this and future RELID studies. Furthermore, other ocular structures that could undergo changes related to ionizing radiation are being studied.

ACKNOWLEDGMENTS

The authors of this study would like to express our sincere gratitude to the Latin American Society of Interventional Cardiology (SOLACI) and the Argentine College of Interventional Cardioangiologists (CACI) for allowing this study, to Eliseo Vañó, PhD for his recommendations, and to the International Atomic Energy Agency (IAEA) and all the colleagues who provided their kind contribution, insight and expertize.

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