

INTERNATIONAL PROJECT ON INDIVIDUAL MONITORING AND RADIATION EXPOSURE LEVELS IN INTERVENTIONAL CARDIOLOGY

R.Padovani¹, A.Duran³, C. Lefaure², J. Le Heron², D.L. Miller⁴, M. Rehani², H.K. Sim⁵, E.Vano⁶

¹ Medical Physics Dpt. University Hospital, Udine, Italy

² International Atomic Energy Agency, Vienna, Austria

³ Cardiology Dpt., Montevideo, Uruguay

⁴ Radiology Dpt., Uniformed Services University, Bethesda, USA

⁵ Cardiology Dpt., Kuala Lumpur, Malaysia

⁶ Medical Physics Dpt., S. Carlos University Hospital and Universidad Complutense, Madrid, Spain

Introduction: IAEA has launched the Information System on Occupational Exposure in Medicine, Industry and Research (**ISEMIR**) project. The Working Group on Interventional Cardiology (**WGIC**) started a 3-year activity to assess levels of exposure and methods applied for individual monitoring and to setup an international database of occupational exposures.

Methods: Two worldwide surveys have been addressed to national regulatory bodies (RB) and interventional cardiologists (IC) to collect information and staff doses from a hospital sample.

Results: 200 ICs from 32 countries and 81 RBs from 55 countries responded. Concerning dosimetry: 72% of ICs use personal dosimeters, and 36% always two; 26% knew their doses.

Only 57% of RBs define number and position of dosimeters for the staff monitoring requiring: 40% one dosimeter, 83% dosimeter be worn over the apron and 20% two dosimeters. Less than 40% of RBs could provide doses.

Preliminary doses from 20 hospitals in 15 countries are: mean (maximum) Hp(10) over apron 7.6 (42.3), 6.1 (26.3) and 3.4 (14.6) mSv/y, respectively for hemodinamists, electrophysiologists and nurses.

Conclusions: Survey results proof poor compliance with staff monitoring recommendations in a large fraction of cathlabs, the need for staff monitoring harmonization and staff education. The large majority of IC doses are of poor quality, while those of nurses are generally of acceptable quality. Quality indexes have been developed to identify poor data for the purpose to automatically analyse doses will be provided to the designed and under-development international database.

Key Words: staff exposure, interventional cardiology, ISEMIR, dosimetry

1. Introduction

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) has the mandate within the United Nations system to assess and report the levels, effects and risks of exposure to ionizing radiation from all sources, including the collection of dose data on occupational, public and patient radiation exposure(1). Complementary to the work of UNSCEAR, in 2009 the International Atomic Energy Agency (IAEA) initiated the Information System on Occupational Exposure in Medicine, Industry and Research, referred to as the ISEMIR project. ISEMIR is now undergoing a three-year test period.

The ISEMIR project was established to help to improve occupational radiation protection practice in targeted areas of medicine, research and industry, where non-trivial occupational exposures occur. Within each area, its main objectives are to identify good practices and deficiencies, define actions and

key issues that need to be addressed, and disseminate information and knowledge so as to contribute to the reduction of risk of radiation exposure and facilitate the implementation of internationally agreed upon radiation protection practices.

A final goal is to establish an international database for the regular collection of occupational dose data in targeted areas of radiation use in medicine, industry and research.

Within ISEMIR, the first working group on Interventional Cardiology (IC) was set up to assess radiation protection practice and occupational exposure to workers (cardiologists, electrophysiologists and other staff members) involved in IC. Its main objectives are to gain a worldwide overview of the current situation in this field, identify good practices and deficiencies, and define actions to be implemented to improve occupational radiation protection practice in IC. The Working Group on IC (WGIC) has developed recommendations for harmonizing worldwide monitoring procedures and is setting up a system for regular collection of occupational doses in IC.

This paper reports the results of an international survey of national regulatory bodies on requirements for staff dosimetry and on dose data availability at the country level(2).

2. Materials and methods

In its first year of activity (2009) the WGIC performed an international survey on requirements for staff dosimetry and on dose data availability for IC at the country level, requesting to the radiation protection (RP) regulatory body: number of workers with personal dosimetry, values of occupational doses in the national authority's database, existence of a national guideline for staff monitoring in IC, requirements for specific RP training or certification to perform IC. The questionnaire was sent 191 RP regulatory bodies in 136 countries. Other 2 questionnaires were addressed to chiefs cardiology and interventional cardiologists requiring information on: number and type of equipment, facility and individual workloads, level of compliance with personal monitoring, use of protective tools and type of education in RP. Questionnaires were distributed by cardiology and medical physics professional societies.

In the year 2010 a second large multinational survey aiming to collect individual staff doses and workload has been addressed to IC facilities.

3. Results

Responses were received from 81 regulatory bodies (56 national regulatory bodies and 25 state regulatory bodies), giving an overall country response rate of 40% (Table 1). The responding regulatory bodies have jurisdiction over countries and states whose summed population is about one-quarter of the world's total population. Few responses were received from the regulatory bodies of countries with large populations.

Average results suggest that monitored physicians in IC represent about 40% (700 out of 1907 reported numbers) of all persons in IC being individually monitored.

About 50% of regulatory bodies (40 out of 81) provided some occupational dose data. Of these there was a wide variety of responses, ranging from detailed, accurate dose values to data that were inconsistent and/or ambiguous. It was often necessary to write back to regulatory bodies to obtain more detailed information about their responses.

About half the regulatory bodies (41 out of 81) stated that they were not able to provide occupational dose data for IC, citing the following reasons:

- no central dose register in the country;
- no easy access to the central dose register by the regulatory body;
- regulatory body only has records of doses if they exceed some particular threshold (e.g. investigation or action level);

- no specific classification for interventional cardiologists, or other persons in IC in the database.

Some of the dose data supplied were not suitable for further analysis for the following reasons:

- reported dose data were “contaminated” with doses from other occupational classes and functions, such as interventional radiology;
- corrected and uncorrected doses were mixed – e.g. doses were corrected for wearing position only if they exceeded some threshold, and these corrected values were then entered back into the original database of raw doses;
- reported doses were from a database that contained only doses above some action level.

After excluding dose data for the above reasons, occupational dose data from 29 countries were analyzed. The mean values of the reported country median and country 3rd quartile effective doses for the year 2008 are as follows:

- for those regulatory bodies reporting data for IC physicians as a group, the mean of the country median effective doses was 0.73 ± 0.62 mSv per year, and the mean of the country 3rd quartile effective doses was 1.09 ± 0.69 mSv per year. The results are based on reported monitoring results from 23 countries, for a total of 1432 interventional cardiology physicians.
- for those regulatory bodies reporting data for other professionals in IC as a group, the mean of the country median effective doses was 0.76 ± 0.68 mSv per year, and the mean of the country 3rd quartile effective doses was 1.10 ± 1.09 mSv per year. The results are based on reported monitoring results from 17 countries, for a total of 825 other professionals working in IC.

The similarity in the values of doses reported for the IC physicians as a group and for the other professionals as a group deserves comment. Emphasis has traditionally been placed on the IC physician as being the person with the highest potential for being occupationally exposed. Radiation protection training promotes the use of additional radiation protection tools, such as the ceiling suspended screen, to bring about a lower level of occupational exposure for the physician. The other professionals, such as the theatre nurse, may not be afforded the same access to these additional radiation protection tools, having to rely primarily on the protective apron and distance as the main means of protection. Attention may need to be given to providing additional protective tools for these other professionals if occupational radiation protection in IC is to be truly optimized.

In all cases, annual effective doses remain well below the 20 mSv occupational dose limit, recommended by the ICRP⁽³⁾. Specific dose values for extremities and eyes were not requested. It may be useful to obtain these in the future.

Despite some vetting of the dose data provided, other issues remain. Often personnel who have moved into more administrative duties remain on the monitored list, thus lowering mean doses for that occupational group in the facility. It is very difficult to keep track of the doses for interventional cardiologists who may work in more than one facility, and reported doses may not be total doses across all workplaces. The treatment of doses at the limit of detection may differ from one regulatory body to another – a zero dose may be assigned, or a nominal minimum reporting dose or even some other nominal value. This may affect the statistical analysis, especially the mean values.

But the largest potential shortcoming of the reported results is whether the dosimeters were actually being worn by the interventional cardiologists whenever they were performing IC procedures. The reported annual median effective dose values were lower than expected considering validated data from facility-specific studies^(4, 5, 6, 7, 8), indicating that compliance with continuous individual monitoring is often not achieved in IC. Reasons for non-compliance with monitoring range from simple negligence to deliberate avoidance because of the fear of exceeding some dose threshold that leads to regulatory or administrative investigation (often as a result of an above-the-apron dose value being used as a surrogate for effective dose with no correction). All of these reasons would indicate that the results reported above are likely to be an under-estimate of the real situation.

Concerning requirements for wearing dosimeters, 57% of regulatory bodies (45 out of 79) define the number and position of dosimeters for staff monitoring in IC (Tables 1). Among those regulatory bodies defining the number and position of the dosimeter(s):

- 40% require the use of one dosimeter, worn above the apron (80%), and at the collar level above the apron (50%);
- 20% of regulatory bodies require the use of two dosimeters, worn beneath and above the apron in almost all cases,, except where the second dosimeter was to be used for extremity monitoring;
- 2% of regulatory bodies require the use of three dosimeters, one above and one beneath the apron, and a third finger type dosimeter;
- 38% did not specify their defined wearing position.

Table 1. Number of personal dosimeters mandated by regulatory bodies for IC.

Region	No of RBs mandating the number of dosimeters	Number of dosimeters required:			
		1	2	3	Not specified
Africa	3	1	1	0	1
Asia Pacific	8	0	2	0	6
Europe	19	10	2	1	6
Latin America	2	0	1	0	1
North America	13	7	3	0	3
Global	45	18 (40*)	9 (20)	1 (2)	17 (38)

Analysis of the responses on radiation protection training requirements showed that just over one half of regulatory bodies (41 out of 80) mandated RP training for personnel in order to be able to perform IC procedures. There is a need for many countries to strengthen the regulatory framework for occupational RP in IC.

The question on licensing or certification requirements for persons to be able to perform fluoroscopy in interventional cardiology unfortunately yielded ambiguous results. Analysis of responses and accompanying comments indicated that there was confusion about who needed to be licensed (e.g. the physician or the radiographer), what the licence was issued for (e.g. use of radiation or practice of medicine), and who issued the licence (e.g. radiation protection regulatory body or medical registration body or similar). No meaning results could be concluded, except that there was a spectrum of (radiation protection) licensing systems in use throughout the world, ranging from the physician not needing to have a licence to use radiation in interventional cardiology to the physician needing such a licence.

On the survey results to cardiologists, the convenience sample included nearly 200 cardiologists from 32 countries, and 45 IC facilities from 24 countries from all regions of the world. Concerning the dosimetry aspects of IC:

- 72% of cardiologists claim to always use their personal dosimeter, and 36% always two;
- 26% of cardiologists knew their personal doses.

Concerning requirements for wearing dosimeters, 57% of regulatory bodies define the number and position of dosimeters for the monitoring of staff in IC. Among those requiring the use of personal dosimeters:

- 40% require the use of one dosimeter; of these, 83% require that the dosimeter be worn over the apron and in 50% require that the dosimeter be worn at collar level of the cases at the collar level, above the apron;
- 20% require the use of two dosimeters; of these, 89% require that they be worn under and over the apron;
- 38% did not specify the dosimeter position.

Radiation protection training and certification in radiation protection has a positive effect on:

- the wearing of two dosimeters;

- the use of protective equipment and tools;
- the knowledge of personal and patient doses.

20 hospitals in 15 countries provided staff dose data and individual workload in the second 2010 multinational survey. The mean (maximum) Hp(10) over apron derived from the sample was: 7.6 (42.3), 6.1 (26.3) and 3.4 (14.6) mSv/y, respectively for hemodinamists and electrophysiologists doctors and nurses.

Figure 1 right reports the over apron Hp(10) annual doses for interventional cardiologists, permanent and in training staff, versus the number of interventional cardiac procedures performed in 2009. The great number of unrealistic zero values have been analysed taking into account factors like: dose reporting consistency and dose value consistency. The development of a quality factor has allowed to filter dose data (figure 1 right) obtaining a better relationship of dose values with workload.

Annual over apron Hp(10) doses for nurses and technicians are showing a lower level of exposure of this personnel less correlated with the workload (figure 2). Lower values are explained for the average larger distance of this personnel from the scattering body of the patient and to the different duties of this personnel in the IC facilities.

These results are proving the existence a large exposures in IC facilities and, usually, it is assumed the lens of the eyes dose equal to the dose measured over the apron. Figure 1 shows a large percentage of ICs are receiving annual doses in excess of the new dose limit recommended recently by ICRP.

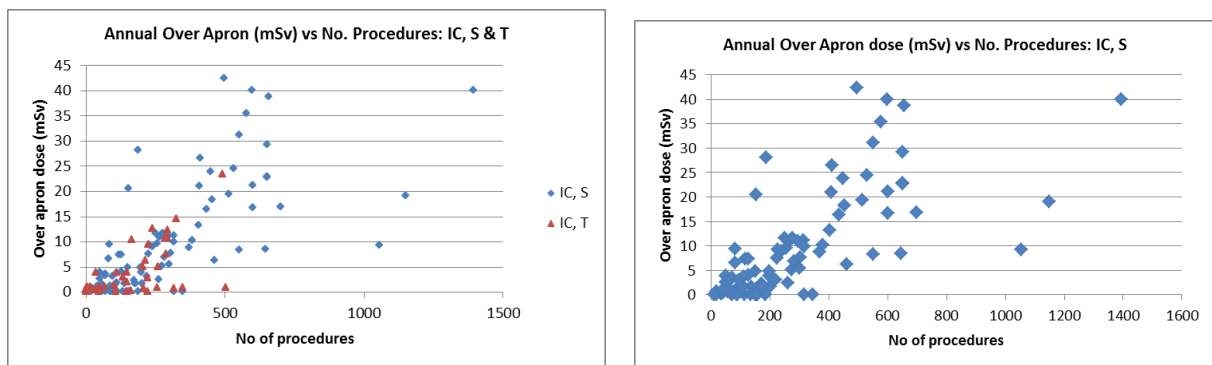


Figure 1. Over apron annual dose versus no. of IC procedures performed in a year for interventional cardiologists (triangle: doses to the staff in training); right: only good quality data.

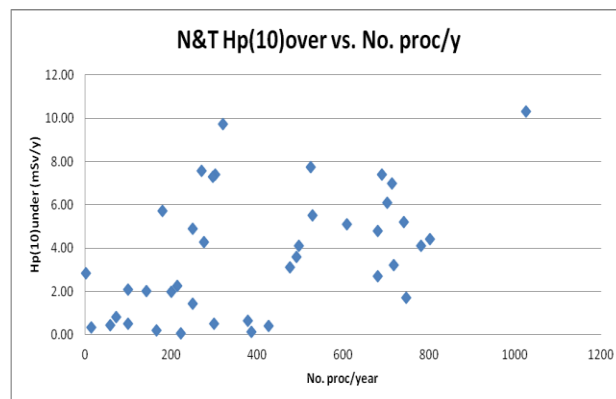


Figure 2. Over apron annual dose versus no. of IC procedures performed in a year for nurses and technicians.

4. Conclusions

This study presents the results of 81 responses from regulatory bodies on staff exposure in IC practice. The results are helping the WGIC of ISEMIR formulate recommendations to improve monitoring methods and facilitate more adequate collection of data at the country level.

Obtaining reliable data on occupational exposures in IC from RP regulatory bodies proved to be difficult. Many regulatory bodies have limited access to these data, and, even if they do have access, the data are often not detailed enough to provide the required information. A further complicating factor is that recorded doses may underestimate true occupational exposure because compliance of IC personnel can be poor, and because an individual's exposures from different IC facilities may not be summed. Alternative strategies for the collection of IC occupational dose data will be utilized when a worldwide database of such information will be available.

Survey results addressed to IC facilities and professionals proof poor compliance with staff monitoring recommendations in a large fraction of IC facilities, the need for staff monitoring harmonization and staff education.

The large majority of IC doses are of poor quality, while those of nurses are generally of acceptable quality. Quality indexes have been developed to identify poor monitoring data for the purpose to automatically analyse doses and this feature will be implemented in the under-development international database.

From the outcome of surveys the WGIC has developed recommendations to support good RP practice and to harmonise monitoring methods. Recommendations have been endorsed by the most relevant regional interventional cardiology societies (SCAI, SOLACI, APSEC & EAPCI)

5. Acknowledgments

One of the authors (EV) acknowledges the partial support of the grant SAF200910485 (Spanish Ministry of Science and Innovation)

6. References

1. UNSCEAR, 2000. *Sources and Effects of Ionizing Radiation*. United Nations Scientific Committee on the Effects of Atomic Radiation Report to the General Assembly with Scientific Annexes, United Nations, New York, NY.
2. ISEMIR - Working Group on Interventional Cardiology. *Report on the questionnaires on occupational exposure in interventional cardiology*. Working material, May 2010 (available from IAEA).
3. International Commission on Radiological Protection. *The 2007 Recommendations of the International Commission on Radiological Protection*. ICRP Publication 103. Ann. ICRP 37(2-4) (2007).
4. Trianni A, Padovani R, Foti C, Cragolini E, Chizzola G, Toh H, Bernardi G, Proclemer A. *Dose to cardiologists in haemodynamic and electrophysiology cardiac interventional procedures*. Radiat Prot Dosim. **117**(1-3):111-115 (2005).
5. Delichas M, Psarrakos K, Molyvda-Athanassopoulou E, Giannoglou G, Sioumdas A, Hatzioannou K, Papanastassiou E. *Radiation exposure to cardiologists performing interventional cardiology procedures*. Eu J Radiol **48**:268-273 (2003).
6. Vano E, Gonzalez L, Guibelalde E, Fernandez JM, Ten JJ. *Radiation exposure to medical staff in interventional and cardiac radiology*. Br J Radiol **71**:954-960 (1998).
7. Karppinen J, Parvianen T, Servomaa A, Komppa T. *Radiation risk and exposure of radiologists and patients during coronary angiography and percutaneous transluminal coronary angioplasty (PTCA)*. Radiat Prot Dosim **57**:481-485 (1995).
8. Bor D, Olgar T, Onal E, Caglan A, Toklu T. *Assessment of radiation dose to cardiologists during interventional examinations*. Med Phys. **36**:3730-6 (2009).