doi.org/10.15392/2319-0612.2026.2277
Braz. J. Radiat. Sci., Rio de Janeiro
2026, 14(1) | 01-17 | e2277
Editor: Prof. Dr. Fernando Roberto de Andrade Lima
Editor: Prof. Dr. Bernardo Maranhão Dantas
Editor: Prof. Dr. Alfredo Lopes Ferreira Filho
Submitted: 2023-03-27
Accepted: 2025-08-24

Retrospective study of radiation exposures during interventional cardiology procedures performed at the University Cardiovascular Center of Uruguay

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Abstract: The number of interventional cardiology procedures has increased rapidly during the last decades. Fluoroscopic X-ray procedures, such as coronary angiography and percutaneous transluminal coronary angioplasty, are considered the largest source of medical occupational exposure, either for patients or operators, causing deleterious health effects. In this respect, several modifications in classical interventional cardiology procedures as well as the incorporation of radiation protection protocols for reducing radiation exposure have been developed. To adequately know the success in the application of these changes, the reference values of radiation exposure for different interventional cardiology procedures should be established. For this purpose, a retrospective, cross-sectional and descriptive study was carried out at the University Cardiovascular Center from the Faculty of Medicine (University of the Republic) of Uruguay between 2018 and 2020, with the aim to know the frequency of procedures performed as well as the average of delivered radiation dose, the fluoroscopy time and the Kerma-rea product for every interventional procedure. Urgent angioplasty procedure was the most frequent interventional procedure performed, producing the highest exposure level of occupational radiation workers and patients. It was established for the first time in Uruguay reference levels for the three most frequent interventional cardiology procedures using the third quartile of radiation exposure parameters employed (Total dose delivered, Kerma-area product and fluoroscopy time). Reference values obtained were in agreement with the ones found at international level.

Keywords: interventional cardiology, percutaneous transluminal coronary angioplasty, urgent angioplasty, delayed angioplasty, cineangiocoronariography.

BJRS
BRAZILIAN JOURNAL OF RADIATION SCIENCES

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Estudio retrospectivo de la exposición a las radiaciones ionizantes durante procedimientos de cardiología intervencionista realizados en el Centro Cardiovascular Universitario del Uruguay

Resumen: El número de procedimientos de cardiología intervencionista ha aumentado rápidamente durante las últimas décadas. Los procedimientos de fluoroscopía con rayos X, como la angiografía coronaria y la angioplastia coronaria transluminal percutánea, se consideran la mayor fuente de exposición médica ocupacional, ya sea para pacientes u operadores, causando efectos nocivos para la salud. En este sentido, se han desarrollado diversas modificaciones en los procedimientos clásicos de cardiología intervencionista así como la incorporación de protocolos de protección radiológica para reducir la exposición a la radiación. Para conocer adecuadamente el éxito en la aplicación de estos cambios se deben establecer los valores de referencia de exposición a la radiación para diferentes procedimientos de cardiología intervencionista. Para ello se realizó un estudio retrospectivo, transversal y descriptivo en el Centro Cardiovascular Universitario de la Facultad de Medicina (Universidad de la República) del Uruguay entre 2018 y 2020, con el objetivo de conocer la frecuencia de procedimientos realizados, así como el promedio de la dosis de radiación administrada, el tiempo de fluoroscopia y el producto Kerma-rea para cada procedimiento intervencionista. El procedimiento de angioplastia urgente fue el procedimiento intervencionista realizado con más frecuencia y produjo el mayor nivel de exposición de los trabajadores y pacientes a la radiación ocupacional. Se establecieron por primera vez en Uruguay niveles de referencia para los tres procedimientos de cardiología intervencionista más frecuentes utilizando el tercer cuartil de los parámetros de exposición a la radiación empleados (Dosis total administrada, producto Kerma-área y tiempo de fluoroscopia). Los valores de referencia obtenidos coincidieron con los encontrados a nivel internacional.

Palavras-chave: cardiología intervencionista, angioplastia coronaria transluminal percutánea, angioplastia urgente, angioplastia diferida, cineangiocoronariografía.

1. INTRODUCTION

Since the advent of interventional procedures based on catheterization, the number of interventional cardiology (IC) procedures has increased rapidly, due to the fact that they are less invasive procedures that reduce hospitalization time in relation to traditional surgery, greatly reducing their costs [1,2]. IC is a heart catheterized procedure that using fluoroscopy X-ray as guidance in order to provide visualization of hearth chambers, valves or blood vessels, turning it as one of the medical specialties that requires greater use of a radiant source [3,4]. Actually, fluoroscopic procedures are considered the largest source of medical occupational exposure [5]. Around 12% of all radiological examinations correspond to interventional cardiac procedures, which correspond up to 50% of the total collective effective dose of radiation [6,7]. The fact that during the interventional procedures, catheters, guidewires, and other devices are visualized and guided using fluoroscopy in real time, the exposure to ionizing radiation become unavoidable. Therefore, invasive coronary interventions imply radiation exposure, both to the patient and the operator. Patient exposure to X-rays during IC procedures is high and can have deleterious effects, including skin and eye damage, and may cause certain types of cancer [8]. Although, interventional cardiologists use protective tools, the dose received by the operator from scattered radiation become more important when complicated interventional procedures are carried out [9,10]. Long-term exposures to low energy ionizing radiations can also produce deleterious health effects, such as skin burn, premature cataract formation, early carotid atherosclerosis, as well as an increasing risk for developing cancers with a disproportionate incidence of left-sided brain tumors [11-15]. Coronary angiography and percutaneous transluminal coronary angioplasty are now widely performed routinely. Whatever the interventional procedure used, physicians should be based on the ALARA radiation principle: "as low as reasonably achievable". In this respect, there is a strong interest in developing radiation protection

protocols for reducing radiation exposure during interventional procedures [16]. Because of that, regional differences can be found regarding technical variations, equipment or complexity of the patients that can produce a variation in the times and doses of radiation employed per interventional procedure. In this respect, Uruguay has been a pioneer in the use of the radial approach, with the right radial approach being the one of choice in all catheterization centers in our country instead of the left radial approach [17]. There are local reports that account for differences in the irradiation dose between the left and right radial approaches, but there are still no reference values established at the national level in this respect. Therefore, the present study seeks to determine the national reference levels of radiation exposure in patients undergoing interventional cardiology procedures (diagnostic coronary angiography and coronary angioplasty) based on data obtained from the University Cardiovascular Center.

2. MATERIALS AND METHODS

A retrospective, cross-sectional and descriptive study was carried out at the reference public University center ("Centro Cardiovascular Universitario", CCVU, Clinical Hospital, Faculty of Medicine, University of the Republic, Montevideo, Uruguay) between 2018 and 2020 [18-20].

The following parameters were taken into consideration: a- The frequency of interventional cardiology procedures performed, b- The frequency of procedures performed by each occupationally exposed worker, c-Average of cumulative air kerma at the patient entrance reference point ($K_{a,r}$) by type of interventional procedure, d-Average fluoroscopy time by type of interventional procedure, and e-Average Kerma-area product (P_{KA}) by type of interventional procedure [21]. A Siemens Artis Zee 2011 angiograph (Munich, Germany) was used.

2.1. Data collection

To obtain parameters of radiation exposures during different hemodynamic procedures, diagnostic and therapeutic procedures that were performed on patients older than 18 years, between January 2018 and December 2020, were included. Only the following interventional procedures were included in the present study: cineangiocoronariography (CACG), urgent angioplasty (CACG+PTCA, cineangiocoronariography plus percutaneous transluminal coronary angioplasty) and delayed angioplasty (PTCA, percutaneous transluminal coronary angioplasty).

Data related to age, sex, and type of interventional procedure performed with every patient were obtained from the coded reports of the interventional procedures. The use of repository data was authorized by the Board of the University Cardiovascular Center (CCVU). Likewise, the following data on exposure to ionizing radiation were taken: $K_{a,r}$ [22], P_{KA} and fluoroscopy time (FT).

2.2. Reference levels

Reference radiation dose values represent a guide for optimizing radiation protection in Interventional Cardiology, since it gives clinical benefits for patients and minimize radiation exposures to operators. Therefore, the dose reference values or DRLs can be used to perform corrective actions for hemodynamic procedures [23].

To determine reference values for all parameters of radiation exposures employed in the present study, such as $K_{a,r}$, K_{AP} and FT, an interquartile range was performed and the third quartile (Q3) of every radiation exposure parameter were taken as the reference value [23-25].

2.3. Statistical analysis

For an adequate analysis, a database was prepared and for statistical calculations, the STATA v.15.0 software (Collage Station, Texas, USA) was used.

Data normality was evaluated and compared by applying parametric or non-parametric tests according to results obtained. The normality of the quantitative variables was studied with the Kolmogorov-Smirnov test. In case of non-normality, non-parametric tests were used, setting a significance level of $p<0.001$.

3. RESULTS

3.1. Distribution of interventional cardiology procedures

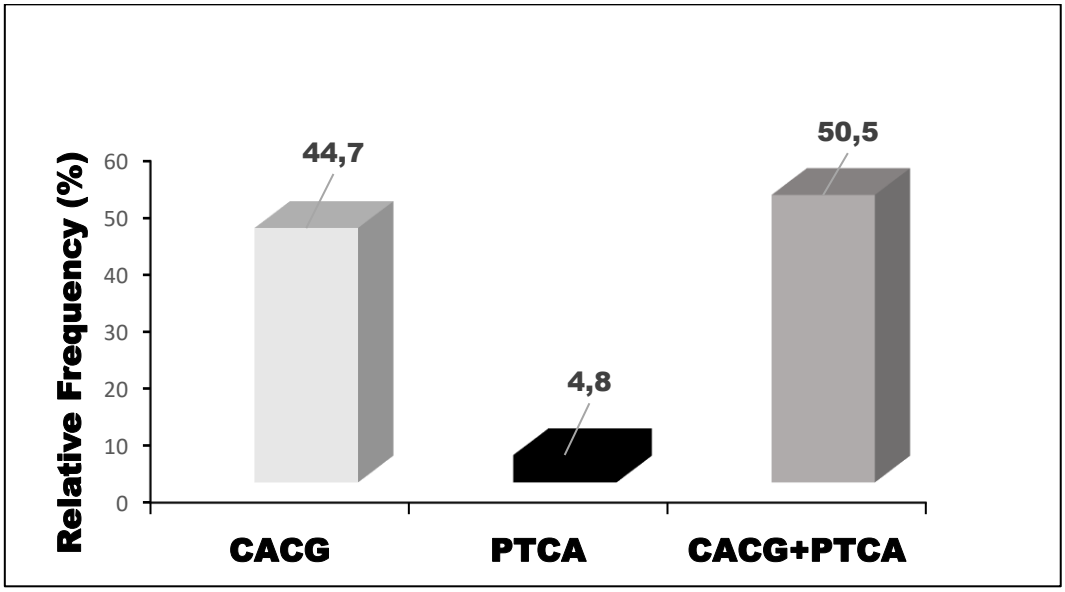
Between January 2018 and December 2020, 2074 patients were admitted to the CCVU, whose annual distribution did not differ much among these years, although there is a decrease a in the year that COVID-19 pandemic began (Table 1).

Table 1: Distribution per year of the total interventional cardiology procedures occurring between January 2018 and December 2020 at the CCVU

	2018	**2019**	**2020**	**TOTAL**
Number of Interventional Cardiology Procedures (%)	676 (35.6)	739 (32.6)	659 (31.8)	2074

Figure 1 shows the frequencies of every interventional cardiology procedure that was performed by 24 interventional cardiologists working during this period of time at the University Cardiovascular Center. The urgent angioplasty (CACG+PTCA) has been the most frequent interventional procedure performed (1047, 50.5%,), followed by the cineangiocoronariography (CACG, 927, 44.7%). The delayed angioplasty (PTCA, percutaneous transluminal coronary angioplasty) was developed in minor proportion during this period of time at CCVU (100, 4.8%).

Figure 1: Distribution of every interventional cardiology procedure. CACG=cineangiocoronariography; PTCA=percutaneous transluminal coronary angioplasty; CACG+PTCA=urgent angioplasty.



3.2. Parameters of exposure to ionizing radiation

Table 2 shows the median and interquartile range for the parameters of exposure to ionizing radiation used in this work.

Table 2: Levels of radiation exposures (Median and interquartile range) assessed for every interventional cardiology procedure. CACG=cineangiocoronariography; PTCA=percutaneous transluminal coronary angioplasty; CACG+PTCA=urgent angioplasty. IQR=interquartile range.

	CACG Median (IQR)	**PTCA Median (IQR)**	**CACG+PTCA Median (IQR)**	***p* value**
Cumulative air kerma (mGy)	667 (396.5-1266.5*)	941.2 (446.2-3136.8*)	1532.5 (873.8-2842*)	< 0.001
Kerma-Area Product (Gy/cm²)	31.1 (18.9-48.2*)	30.0 (15.8-52.0*)	61.3 (36.5-98.3*)	< 0.001
Fluoroscopy time (min)	5.7 (3.5-9.5*)	6.1 (3.4-9.5*)	12.1 (8.0-19.5*)	< 0.001

(*) these values represent the third quartile (Q3) from the interquartile range, which have been taken as the reference values for every parameter employed to evaluate radiation exposure.

3.3. Reference levels

The sample analyzed was sufficient to generate reference values of radiation exposure to different interventional procedures. The third quartile (Q3) of the interquartile range was used as the reference value of radiation exposure for every parameter employed to determine

radiation exposure in every interventional cardiology procedure. Q3 values are highlighted in Table 2 with asterisks.

Tables 3 and 4 show the reference levels of exposure to ionizing radiation for urgent angioplasty (CACG+TAC) and cineangiocoronariography (CACG) obtained from several studies, where it can be observed that our reference values are within expectations. Since we provide data from only one center belonging to the University, there would be a trend towards longer times of radiation use, however, this is not reflected in the international comparison.

Table 3: Comparison of the reference levels of Kerma-area product (KAP or DAP) in Gy*cm^2 and fluoroscopy time (FT) in minutes (min) for cineangiocoronariography (CACG).

Authors	N	FT (min)	K_{AP} or DAP (Gy.cm^2) [25]		
			Media	Median	Q3
Present study	927	5.7	-	31.1	48.2
González-López et al. [31]	95	5.8	29.1	21.7	38.7
Kim et al. [32]	361	4.7	67.6	54.7	75.6
Humagain et al. [33]	166	11.4	40.7	-	-
Simantirakis et al. [34]	2572	6.0	53.0	-	-
D`Helft et al. [35]	967	4.3	37.9	30.6	41.7
Georges et al. [36]	2384	6.3	79.5	63.0	
Sapiin et al. [37]	176	-	48.6	37.0	59.6
Tsapaki et al. [38]	195	6.5	47.3	39.1	60.4
Vaño et al. [39]	288	-	66.5	45.7	69.3

Table 4: Comparison of the reference levels of Kerma-area product (KAP or DAP) in Gy*cm^2 and fluoroscopy time (FT) in minutes (min) for urgent angioplasty (CACG+PATC).

Authors	N	FT (min)	K_{AP} or DAP (Gy.cm^2) [25]		
			Media	Median	Q3
Present study	1047	12.1	-	61.3	98.4
González-López et al. [31]	50	14.6	76.7	63.4	92.4
Simantirakis et al. [34]	1899	18.0	129.0	-	-
D`Helft et al. [35]	463		78.3	58.1	83.6
Georges et al. [36]	1108	14.0	170.5	141.0	-
Sapiin et al. [37]	70		153.0	103.0	189.5
Tsapaki et al. [38]	97	12.2	68.0	58.3	80.7
Van de Putte et al. [40]	62		60.6	56.8	80.6
Subban et al. [41]	715	25.0	26.9	15.7	41.5
Broadhead et al. [42]	214	12.4	77.9	61.1	100.6
Vaño et al. [39]	45	-	87.5	66.7	122.3

4. DISCUSSION

The fact that the exposure to low doses of ionizing radiation can cause health effects on radiation workers, as it was clearly stated for interventional cardiologists in the clinical evaluation of the prevalence of radiation-associated lens changes in a group of cardiology professionals [26], initiated in the frame of an IAEA program called RELID (Retrospective Evaluation of Lens Injuries and Dose), determine the importance of controlling the reference values for the most frequent interventional cardiology procedures as well as to implement radiation protection routine protocols, including periodic ophthalmologic examination.

4.1. Distribution of interventional procedures and parameters of exposures

The total number of interventional procedures performed was 2074, and there was no significant difference between 2018 and 2019, in which 676 and 739 procedures were performed, respectively. However, there was a reduction in the total number of interventional procedures up to 659 in 2020, most probably due to the COVID-19 pandemic situation. It is worth to mention that the CCVU (University Cardiovascular Center, Faculty of Medicine, University of the Republic) represent the reference Center in Uruguay for Cardiology studies. These studies are only carried out at the CCVU for all national posgraduate students as well as for many students coming from the Region.

Urgent angioplasty procedure was the most frequent interventional procedure performed (50.5%) in the CCVU between 2018 and 2020, which was associated with a higher level of exposure of occupational radiation workers and required more fluoroscopy time. The values of the Kerma-area product for this type of procedure are within the range established in Europe [27]. In this respect, the urgent angioplasty (CACG+PTCA) procedure generated the highest delivered dose, more than the double of the dose delivered by the cineangiocoronariography (CACG) procedure. By the same token, fluoroscopy time and Kerma-area product were half for CACG and PTCA (percutaneous transluminal coronary angioplasty) with respect to CACG+PTCA. The complexity of the urgent angioplasty procedure with respect to the cineangiocoronariography and the delayed angioplasty procedures can explain differences found in all parameters for exposition to ionizing radiation [28].

4.2. Reference levels

The three interventional procedures evaluated in this study are the most frequently performed in our country. The most frequently delivered irradiation dose in hemodynamic procedures was around 1 Gy with an interquartile range between 0.5 Gy to 2.5 Gy, while the

K_{AP}, also known as the dose-area product (DAP), was located in the vicinity of 45 Gy*cm^2 produced in a fluoroscopy time of around 9 minutes (data not shown). Besides, it can be observed that all three parameters of radiation exposure were significantly higher for the urgent angioplasty (CACG+PTCA) than for delayed angioplasty (PTCA) or the cineangiocoronariography (CACG).

The third quartile (Q3) was employed as the reference level for each parameter of exposure to ionizing radiation. As seen in Table 2, our results are similar to the ones found in international studies. Regarding diagnostic procedures (CACG) Vañó et al. [18] and Zotova et al. [29] found a median of 45.8 Gy*cm^2 and 21.0 Gy*cm^2, respectively; while the median value of the KAP obtained in the present study was 31.1 Gy*cm^2, indicating that our data are comparable with the ones generated in other interventional cardiovascular centers. Regarding therapeutic procedures (CACG+PTCA or PTCA), Aroua et al. in Switzerland [30] and Zotova et al. in Bulgaria [29] found reference DAP values of 260 Gy*cm^2 and 140 Gy*cm^2, respectively, while in the present study it was 98 Gy*cm^2. In Europe, more complex therapeutic procedures are performed due to the fact that they have technology that allows them to address more complex coronary lesions (such as, complex bifurcations, chronic occlusions or severe calcification), therefore higher PDA values can be expected in European centers of interventional cardiology. Delayed angioplasty (PTCA) was included in the present study, a therapeutic procedure where prior planning stands out and therefore less procedure time is expected. The reference values proposed for the PTCA procedures are shown in Table 2, where it can be seen that the DAP (KAP) value is similar to the one obtained for CACG procedure (52.0 and 48.2 Gy*cm^2, respectively), being approximately half of the value found for the CACG+ATC procedure (98.3 Gy*cm^2). Reference values in the parameters for determining exposures to ionizing radiation for CACG [31-39] and CACG+PTCA [31, 34-42] procedures, obtained from different interventional cardiovascular centers all over the world are presented in Tables 3 and 4, respectively, together with values observed in the present study, which are clearly within the range of international values.

5. CONCLUSIONS

Urgent angioplasty was the most frequent interventional cardiology procedure performed at the University Cardiovascular Center of Uruguay between 2018 and 2020, which was associated with the highest level of exposure of patients and occupationally exposed workers, requiring longer fluoroscopy time.

The present work constitutes the first report of reference doses for interventional cardiovascular procedures in Uruguay, which will contribute to optimize interventional cardiology procedures and improve radioprotection.

ACKNOWLEDGMENT

This work was partially supported by the University Cardiovascular Center (CCVU, Faculty of Medicine, University of the Republic of Uruguay).

FUNDING

This work was funded by the Technical Cooperation (TC) IAEA Project (URU6042).

CONFLICT OF INTEREST

All authors declare that they have no conflicts of interest.

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