FIRST LOCAL DIAGNOSTIC REFERENCE LEVELS FOR FLUOROSCOPICALLY GUIDED CARDIAC PROCEDURES IN ADULT PATIENTS IN CHILE

by

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The goal of this study was to generate the first values of local diagnostic reference levels for a range of fluoroscopically guided cardiac diagnostic and therapeutic procedures in adult patients in Chile and to compare radiation dose levels with others presented in the literature. The dosimetric data collection period was conducted over the whole of 2020. The local diagnostic reference levels were calculated as the 75th percentile of patient dose data distributions for kerma area-product values. The sample of collected clinical procedures (480) was divided into diagnostic and therapeutic procedures. The kerma area-product differences found between diagnostic and therapeutic procedures were statistically significant. The local diagnostic reference levels were 81.6 Gy cm^2 and 166.9 Gy cm^2 for fluoroscopically guided cardiac diagnostic and therapeutic procedures, respectively. A comparison of our results with results found in the literature for the last 10 years, showed that there are no published papers for hospitals in Latin America and the Caribbean. It becomes urgent to be able to carry out more research of this type, given that the health reality between countries on different continents is very different. While in some the establishment of diagnostic reference levels is a legal obligation, in others it is a matter of good or bad will.

Key words: interventional cardiology, adult, diagnostic reference level, radiation dose

INTRODUCTION

The fluoroscopically guided procedures in cardiology are used for diagnosing and treating abnormal coronary arteries, cardiac dysrhythmias, congenital and valvular heart diseases, and other vascular interventions [1]. However, the duration and complexity of fluoroscopic exposures for each procedure are multifactorial, can produce high patient doses, and therefore require special attention to protect the patient from radiation injuries such as skin burns, cardiovascular tissue reactions, or radiation-induced cancer [2-4].

For proper management of radiation dose in patients undergoing fluoroscopically guided cardiac procedures, the International Commission on Radiological Protection (ICRP) has recommended the use of diagnostic reference levels (DRL), described as a tool useful for good practice, as an aid in optimization he management of patient dose and hence in optimizing of radiation protection taking into account the clinical benefits for patients. Median patient dose values deriving from the procedures performed in a particular room can be compared with local or national DRL to identify whether the median values obtained for that room are higher or lower than existing DRL, and thereby decide whether any corrective actions might be necessary. This comparison of local practice data with the existing DRL values is the first step in optimizing protection and can be used for patient dose audits [5].

Unlike European countries (which follow the Directive 2013/59/Euratom) [6], Chile and much others countries in Latin America and the Caribbean still have not incorporated in their radiological protection legislation [7, 8] the implementation of quality assurance programmes, including the establishment of DRL for fluoroscopically guided procedures in cardiology. However, the goal of this study was to generate the first

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values of local DRL for a range of fluoroscopically guided cardiac diagnostic and therapeutic procedures in adult patients and to compare radiation dose levels with others presented in the literature.

MATERIALS AND METHODS

A retrospective study was conducted at the Haemodynamics department of Dr. Ernesto Torres Galdames Hospital, Chile. The recruitment period was from January 2020 to December 2020.

An angiography X-ray system (Allura Xper FD20; Philips Healthcare, Best, the Netherlands), installed in 2013 was used in the survey. This angiography system was equipped with a flat panel detector, with a generator of 100 kW at 125 kV. Three fluoroscopy modes were available: low, medium, and high dose. Each mode was configured in pulsed mode at 7 or 15 pulses per second. Cine mode was typically used at 15 frames per second. The system had eight fields of view (15 cm, 19 cm, 22 cm, 27 cm, 31 cm, 37 cm, 42 cm and 48 cm in diagonal). The exam protocols could be pre-programmed with X-per Settings. The distance from isocentre to the floor was 107 cm and the focus-to-isocentre distance was 76 cm. The system was equipped with an internal flat ionization chamber to measure kerma area-product, P_{ka}, or dose-area product values [9] and cumulative air kerma at the patient entrance reference point, $K_{a,r}$, [10]. The total P_{ka} and $K_{a,r}$ for each procedure were corrected by calibration and mean attenuation factor, derived from the table and mattress attenuation measured for the X-ray beam qualities used in this system for paediatric procedures [11].

The methodology to collect patient dose data and calculate local DRL was the same as used in previous papers, but adapted to adult procedures [11, 12] and aligned with the latest ICRP recommendations [5]. The sample of collected clinical procedures was divided into diagnostic and therapeutic procedures. The following data were extracted manually by the operators from patient dose reports produced by the Philips X-ray system at the end of each selected procedure: procedure identification, patient age, gender, weight, height, P_{ka}, $K_{a,r}$, and fluoroscopy time (FT). The total P_{ka} and $K_{a,r}$ values were corrected by the attenuation factor of the table and the mattress for the frontal C-arm.

The Mann-Whitney test (99 % confidence level) was used to compare median P_{ka} values for the two procedure groups (diagnostic and therapeutic). This non-parametric comparison procedure tests hypotheses and it is used to find differences between two independent samples that are not necessarily normally distributed. The STATA 14 software was used [13].

RESULTS

Table 1 shows the anthropometric characteristics of the subjects.

Table 2 summarises the mean, median, and 75th percentile values for P_{ka}, $K_{a,r}$, and FT for all procedures.

Table 3 shows 75th percentile P_{ka} values for diagnostic and therapeutic procedures reported in this paper compared with those reported in similar surveys.

DISCUSSION

Although for some regions of the world establishing DRL may be routine and publishing the values of a single-center does not present much novelty, this work provides such baseline data that may be helpful for those establishing DRL for the fluoroscopically guided cardiac diagnostic and therapeutic procedures in adult patients according to the reality of the health of the countries in Latin America and the Caribbean.

Table 1 shows the anthropometric characteristics of the subjects. Dose monitoring was performed for 480 fluoroscopically guided cardiac diagnostic and therapeutic procedures in adult patients. Median patient height, weight, and BMI values were similar for diagnostic and therapeutic procedures groups. The influence of weight on the increment of radiation dose is

Table 1. Sample size, *n*, median (range) values of height, weight, body mass index (BMI), and age by type of procedures

Procedure	*n*	Height [cm]	Weight [kg]	BMI [kgm^{-2}]	Age (in years)
Diagnostic	252	165.5 (140.0-194.0)	76.0 (45.0-134.0)	27.2 (17.6-46.8)	66.0 (24.0-92.0)
Therapeutic	228	168.0 (140.0-185.0)	76.0 (45.0-116.0)	27.3 (17.6-46.3)	63.0 (30.0-89.0)
All	480	167.0 (140.0-194.0)	76.0 (45.0-134.0)	27.3 (17.6-46.8)	64.0 (24.0-92.0)

Table 2. Median and 75th percentile values for kerma area product, P_{ka}, cumulative air kerma at the patient entrance reference point, $K_{a,r}$, and FT by type of procedures

Procedure	P_{ka} [Gycm^2]* Median – 75th percentile	$K_{a,r}$ [mGy] Median – 75th percentile	*FT* [min] Median – 75th percentile
Diagnostic	57.1-86.1	597.0- 923.5	3.5-6.0
Therapeutic	108.3-166.9	1299.0-1937.5	11.6-19.6
All	75.3-120.8	856.0-1395.0	6.5-12.4

*Statistically significant differences were found between the diagnostic and therapeutic groups for P ($p < 0.01$)

Table 3. Comparison of 75th percentile P_{ka}a values for adult cardiology reported in this and other papers for diagnostic and therapeutic procedures

Procedure	Study	P_{ka} [Gycm^2]
Diagnostic	Brnic *et al*. (2010) [14]	32.0
	Signorotto *et al*. (2010) [15]	53.0
	Sanchez *et al*. (2011) [16]	41.1
	Compagnone *et al*. (2012) [17]	58.7
	Miller *et al*. (2012) [18]	83.0
	Samara *et al*. (2012) (non-academic centres)[19]	102.0
	Samara *et al*. (2012) (academic centres) [19]	90.0
	Ahmed *et al*. (2013) [20]	25.5
	Cui *et al*. (2013) [21]	43.3
	Simantirakis *et al*. (2013) [22]	53.0
	Crowhurst *et al*. (2014) [23]	58.7
	Uniyal *et al*. (2017) [24]	21.1
	Ngaile *et al*. (2018) [25]	91.4
	Siiskonen *et al*. (2018) [26]	35.0
	Isoardi *et al*. (2019) [27]	33.0
	Kim *et al*. (2019) [28]	47.0
	Rizk *et al*. (2019) [29]	45.0
	Zucca *et al*. (2020) (Standard protocol) [30]	35.0
	Zucca *et al*. (2020) (Noise reduction protocol) [30]	18.0
	This study (2021)	81.6
Therapeutic	Brnic *et al*. (2010) [14]	72.0
	Signorotto *et al*. (2010) [15]	226.0
	Sanchez *et al*. (2011) [16]	83.0
	Compagnone *et al*. (2012) [17]	128.6
	Miller *et al*. (2012) [18]	193.0
	Samara *et al*. (2012) (non-academic centres)[19]	120.0
	Samara *et al*. (2012) (academic centres) [19]	170.0
	Ahmed *et al*. (2013) [20]	69.5
	Cui *et al*. (2013) [21]	299.0
	Simantirakis *et al*. (2013) [22]	129.0
	Crowhurst *et al*. (2014) [23]	129.0
	Uniyal *et al*. (2017) [24]	107.0
	Sciahbasi et al. (2017) [31]	109.0
	Ngaile *et al*. (2018) [25]	129.4
	Siiskonen *et al*. (2018) [26]	85.0
	Isoardi et al. (2019) [27]	94.0
	Kim *et al*. (2019) [28]	171.3
	Rizk *et al*. (2019) [29]	131.0
	Zucca *et al*. (2020) (Standard protocol) [30]	91.0
	Zucca *et al*. (2020) (Noise reduction protocol) [30]	53.0
	This study (2021)	166.9

known for the patient undergoing these procedures [1].

Table 2 summarizes three descriptive statistics for P_{ka}, $K_{a,r}$, and FT for diagnostic and therapeutic procedures groups. As expected, the fluoroscopically guided cardiac therapeutic procedures showed the highest median values for P_{ka} (108.3 Gycm^2) and FT (11.6 minute) in comparison with diagnostic procedures. According to the p-values shown, the P_{ka} differences found between diagnostic and therapeutic procedures were statistically significant. Besides, our $K_{a,r}$ values in groups were below the threshold proposed by the ICRP for deterministic effects on the skin (2 Gy for transient erythema) [2].

The DRL based on P_{ka} quantities (75th percentile as recommended by the ICRP) is useful as a guide to good practice and an optimization aid. Pulses and frames per second (rate), image recording technique, and exposure programme options used should be included [5]. According to Martin [32], the optimization actions should include a review of equipment performance, settings used, and examination protocols. In tab. 2, the values

proposed as local DRL in this survey were 81.6 $Gycm^2$ and 166.9 $Gycm^2$ for fluoroscopically guided cardiac diagnostic and therapeutic procedures, respectively.

A comparison of our results with results found in the literature for the last 10 years, tab. 3, showed that there are no published papers for hospitals in Latin America and the Caribbean, which gives more value to our work. Local DRL values for 75^{th} percentile distributions over all patients undergoing diagnostic and therapeutic procedures in this study are within the data ranges reported in the literature. The range of values for diagnostic and therapeutic procedures was from 18 $Gycm^2$ [30] to 102 $Gycm^2$ [19], and 53 $Gycm^2$ [30] to 299 $Gycm^2$ [21], respectively.

Now that the local DRL values are known and, as a part of the continuous improvement process involved in the principle of protection of radiation, an analysis of how these dose values can be lowered, without compromising image quality should be implemented. One approach could be that, indicated by the ICRP publication 120, which proposes to analyze the clinical management of radiation before, during, and after fluoroscopically guided cardiac procedure [1].

CONCLUSIONS

The values presented in our paper are based on a single specialized center. The local DRL values presented in this survey were 81.6 $Gycm^2$ and 166.9 $Gycm^2$ in adult patients for undergoing diagnostic and therapeutic fluoroscopically guided cardiac procedures, respectively. It becomes urgent to be able to carry out more research of this type, given that the health reality between countries on different continents is very different. While in some the establishment of DRL is a legal obligation, in others it is a matter of good or bad will.

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AUTHORS' CONTRIBUTIONS

C. A. Ubeda: Conception and design of the manuscript. Analysis and interpretation of data for the manuscript. Bibliographic analysis. Drafting the manuscript and revising it critically for important intellectual content. Writing the original draft. Writing-review and editing. Accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Supervision, project administration, funding acquisition. Final approval of the version to be published.

D. I. Martinez: Conception and design of the manuscript. Recollection, analysis, and interpretation of data for the manuscript. Drafting the manuscript and revising it critically for important intellectual content. Writing-review and editing. Final approval of the version to be published.

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ПРВИ ЛОКАЛНИ ДИЈАГНОСТИЧКИ РЕФЕРЕНТНИ НИВОИ ЗА ФЛУОРОСКОПСКИ ВОЂЕНЕ СРЧАНЕ ПРОЦЕДУРЕ КОД ОДРАСЛИХ ПАЦИЈЕНАТА У ЧИЛЕУ

Циљ овог рада је да се прикажу генерисане прве вредности локалних дијагностичких референтних нивоа за низ флуороскопски водених кардиолошких дијагностичких и терапијских процедура код одраслих пацијената у Чилеу, и да се упореде нивои дозе зрачења са онима представљеним у литератури. Период прикупљања дозиметријских података спроведен је током целе 2020. године. Локални дијагностички референтни нивои израчунати су као 75. перцентил дистрибуције података о дози пацијената за вредности производа керме и површине. Узорак прикупљених клиничких процедура (480) подељен је на дијагностичке и терапијске. Разлике производа керме и површине пронађене између дијагностичких и терапијских процедура биле су статистички значајне. Локални дијагностички референтни нивои били су 81.6 Gy cm^2 и 166.9 Gy cm^2 за флуороскопски вођене срчане дијагностичке и терапијске процедуре. Поређење наших резултата са резултатима пронађеним у литератури за последњих десет година, показало је да не постоје објављени радови за болнице у Латинској Америци и на Карибима. Постаје хитно да се спроведе више истраживања овог типа, с обзиром да је здравствена стварност између земаља на различитим континентима веома различита. Док је у некима успостављање дијагностичких референтних нивоа законска обавеза, у другима је то питање добре или лоше воље.

Кључне речи: интервентна кардиологија, одрасла особа, дијагностички референтни ниво, доза зрачења