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Setting up regional diagnostic reference levels for pediatric interventional cardiology in Latin America and the Caribbean countries: preliminary results and identified challenges

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Abstract

The goal of the present study was to propose a set of preliminary regional diagnostic reference levels (DRLs) for pediatric interventional cardiology (IC) procedures in Latin America and the Caribbean countries, classified by age and weight groups. The study was conducted in the framework of the Optimization of Protection in Pediatric Interventional Radiology in Latin America and the Caribbean program coordinated by the World Health Organization and the Pan American Health Organization in cooperation with the International Atomic Energy Agency. The first step of the program was focused on pediatric IC. Dose data from diagnostic and therapeutic procedures were collected between December 2020 and December 2021. Regional DRLs were set as the third quartile of patient dose data (kerma area product) collected in 18 hospitals from 10 countries in an initial sample of 968 procedures. DRLs were set for four age bands and five weight ranges. The values obtained for the four age bands (<1 yr, 1 to <5 yr, 5 to <10 yr and 10 to <16 yr) were 2.9, 6.1, 8.8 and 14.4 Gy cm² for diagnostic procedures, and 4.0, 5.0, 10.0 and 38.1 Gy cm² for therapeutic procedures, respectively. The values obtained for the five weight bands (<5 kg, 5 to <15 kg, 15 to <30 kg, 30 to <50 kg and 50 to <80 kg) were 3.0, 4.5, 8.1, 9.2 and 26.8 Gy cm² for

diagnostic procedures and 3.7, 4.3, 7.3, 16.1 and 53.4 Gy cm² for therapeutic procedures, respectively. While initial data were collected manually as patient dose management systems (DMSs) were not available in most of the hospitals involved in the program, a centralized automatic DMS for the collection and management of patient dose indicators has now been introduced and is envisaged to increase the sample size. The possibility of alerting on high dose values and introducing corrective actions will help in optimization.

1. Introduction

Interventional cardiology (IC) procedures may involve high radiation doses to patients (UNSCEAR 2013). Particular attention must be paid to pediatric patients undergoing these procedures, as children are potentially at greater risk of radiation-induced stochastic effects due to a higher radiation sensitivity of their tissues compared to adult patients (Bacher *et al* 2005, ICRP 2007). Furthermore, they have a longer lifespan in which long-term effects such as neoplasms can develop (Linnet *et al* 2009, UNSCEAR 2013).

The number of fluoroscopy-guided interventional procedures in pediatrics is increasing, especially in IC. In recent decades, pediatric cardiac catheterization has gone from being a primarily diagnostic tool to becoming a therapeutic modality that has substantially improved the prognosis of congenital cardiac malformations (Kim 2017, Kang and Benson 2018). According to a recent report from the United Nations Scientific Committee on Effects of Atomic Radiation Sources and Effects of Ionizing Radiation, the mean frequency of image-guided interventional procedures has significantly increased worldwide during the decade 2008–2018, particularly in high-income countries where this increase was over six-fold. This report also indicates that between 0.2% and 32% of all cardiac angiographies are carried out in pediatric patients (UNSCEAR 2022).

From a radiological protection (RP) perspective, it is essential that IC procedures are justified and optimized in each patient, and this is especially important in pediatrics. To assist in the optimization process concerning medical exposure to patients, the use of diagnostic reference levels (DRLs) has been recommended by the International Commission on Radiological Protection for proper management of radiation dose to patients undergoing fluoroscopically guided procedures (ICRP 2013, 2017). DRLs are described by international commission on radiological protection (ICRP) as ‘*a tool useful for good practice, as an aid in optimization the management of patient dose and hence in optimizing of radiation protection taking into account the clinical benefits for patients*’ (ICRP 2017).

The International Basic Safety Standards (BSSs) for radiation protection and safety of radiation sources cosponsored by eight international organizations include a safety requirement for governments to ensure that ‘*... as a result of consultation between the health authority, relevant professional bodies and the regulatory body, a set of DRLs is established for medical exposures incurred in medical imaging, including image guided interventional procedures [...] and based, as far as possible, on wide scale surveys or on published values that are appropriate for the local circumstances*’ (IAEA 2014). The establishment, use and regular update of DRLs for interventional procedures, in particular for children, was identified as one of the priority actions to enhance radiation protection in medicine (IAEA and WHO 2014). Guidance to support the implementation of the BSS requirements regarding DRLs is provided in a related safety guide (IAEA 2018).

In the last decade, a few papers have been published proposing DRLs for pediatric IC procedures grouped by age or weight groups (Chida *et al* 2010, Vano *et al* 2011, Ubeda *et al* 2012, 2015, 2018, 2020, Verghese *et al* 2012, McFadden *et al* 2013, Barnaoui *et al* 2014, Keiller and Martin 2015, Jones *et al* 2016, Kottou *et al* 2018, Buytaert *et al* 2019, Ishibashi *et al* 2021, Hultenmo *et al* 2021). In most cases, the results refer to experiences from a single hospital.

To our knowledge, no DRL values for pediatric IC procedures have yet been established at regional level in any part of the world. While the European Guidelines on DRLs for pediatric imaging were published in 2018, it was concluded that data concerning patient doses and DRLs for IC procedures were still very scarce in Europe and even scarcer outside Europe. Only some local DRLs were available. In addition, existing studies greatly differ in the methodology and information provided, making comparisons very difficult. It was therefore not possible to suggest European DRLs for pediatric IC (EC 2018).

The goal of the present study was to propose a set of preliminary regional DRLs for pediatric IC procedures for Latin America and the Caribbean countries, classified by age and weight bands. The present work has been carried out as part of the ‘Optimization of Protection in Pediatric Interventional Radiology in Latin America and the Caribbean’ (OPRIPALC) program, which was conceived in 2018, as a joint response of the Pan American Health Organization (PAHO) and the World Health Organization (WHO), in cooperation with the International Atomic Energy Agency (IAEA), to support their member states in ensuring that

radiation exposures of pediatric patients are the minimum necessary during fluoroscopy-guided interventional procedures²³.

2. Materials and methods

The OPRIPALC program is being developed with a series of satellite online activities (mainly due to the COVID-19 pandemic) such as webinars on RP and virtual scientific meetings to agree on the methodology and discuss the preliminary results and optimization strategies.

The Latin America and Caribbean region is made up of 44 countries. In 2020, the estimated total population for this region was approximately 653 million inhabitants. The population of children between 0 and 14 years old was estimated at around 157 million²⁴.

A retrospective case series study (Manterola and Astudillo 2013) was conducted in 18 of the 21 centers that currently participate in the OPRIPALC program, corresponding to 10 countries in Latin America and the Caribbean (see table 1). Pediatric patients undergoing IC procedures were included. Patients with weight ≥ 80 kg were excluded.

The data presented in this paper were collected from December 2020 to December 2021. This work was approved by the ethics committees of the different participating centers in the study.

The x-ray systems used in all hospitals were equipped with an internal flat ionization chamber to measure kerma area product (P_{ka}) or dose area product values (ICRU 2005) and cumulative air kerma at the patient entrance reference point ($K_{a,r}$) (IEC 2010).

Only one of the centers reported explicitly that it performed periodic quality controls including the estimation of the correction factor (calibration derived from the table and mattress attenuation measured for the x-ray beam qualities used in the system) for total P_{ka} and $K_{a,r}$ (Ubeda *et al* 2015). Other centers have so far not reported data on quality control and it is assumed that the validation of dosimetric quantities is part of the periodic maintenance service provided by the manufacturers.

Due to the lack of national DRLs for pediatric IC, the preliminary regional DRLs have been obtained as the third quartile values from the database containing all the collected data, as one of the options suggested by the ICRP in its publication 135 (ICRP 2017). The sample of P_{ka} values collected for clinical procedures in all the involved hospitals was initially divided into two groups (diagnostic and therapeutic) and grouped into four age groups (<1 yr, 1 to <5 yr, 5 to <10 yr and 10 to <16 yr) and five weight groups (<5 kg, 5 to <15 kg, 15 to <30 kg, 30 to <50 kg and 50 to <80 kg).

The initial attempt was to classify the data from different IC procedures but the discrepancies between the different hospitals and countries regarding the nomenclature and the classification criteria of the procedures led to the pragmatic approach of using initially only the two groups of diagnostic and therapeutic IC procedures. The sample size (i.e. the number of procedures per interval of age and weight) was not too large and, as a first step, this approach was considered advisable for grouping the procedures. In the future, with a larger sample size, other approaches may be envisaged.

According to the ICRP (2017), the national DRL values should be used to obtain the regional values. However, this was not possible as national DRLs were not available in the region when the OPRIPALC program was launched. Thus, a practical approach was adopted to derive the regional DRLs. It was decided to collect all the patient data (P_{ka} values, procedures classification, age and weight) in a central database for the region.

Since patient dose management systems (DMSs) were still not available in most of the hospitals involved in the OPRIPALC program, it was decided to initiate the data collection manually. The following data were extracted by the operators from patient dose reports produced by the x-ray systems at the end of each selected IC procedure: type of procedure, patient age, gender, weight, height, P_{ka} , $K_{a,r}$, number of cine series and fluoroscopy time (FT). Tarapacá University in Chile agreed to collect and manage all the data and to host the database. All data were anonymized and processed at the Medical Technology Department of Tarapacá University in Arica, Chile.

The Mann–Whitney test (95% confidence level) was used to compare the values of P_{ka} for the two groups of procedures: diagnostic and therapeutic (including diagnostic and therapeutic procedures combined) for age and weight groups, respectively. This nonparametric comparison procedure tests hypotheses and is used to find differences between two independent samples that are not necessarily distributed normally. Values of $p < 0.05$ were considered statistically significant. The tests were performed with the software SPSS 25.0²⁵.

²³ www.opripalc.org/.

²⁴ www.cepal.org/es/indicadores-demograficos-datos-interactivos?ind=1&lang=es.

²⁵ www.ibm.com/mysupport/s/question/0D50z00006PsEgKCAV/spss-version-25-download?language=es.

Table 1. List of centers and x-ray systems participating in OPRIPALC for different countries.

Country	Center name	X-ray systems (installation year)
ARGENTINA	Pedro de Elizalde Children's Hospital	Philips Integris Allura (2004)
	Santísima Trinidad Children's Hospital	Philips Allura Xper FD10 (2015)
	Italian Hospital of Buenos Aires	Siemens Artis Zee (2009) Philips Allura FD10 (2010) Philips Allura Clarity FD 20 (2015)
BRASIL	Santa Isabel Hospital	Siemens Artis Zee (2012)
BRASIL	University Hospital of the Federal University of Maranhão	General Electric Innova 3100 (2013)
BRASIL	Pequeno Príncipe Hospital	General Electric Innova 530 (2017)
BRASIL	Clinical Hospital of the Federal University of Paraná	General Electric Innova IGS 630 (2012)
CHILE	Luis Calvo Mackenna's Hospital	Philips Allura Xper FD20/15 Clarity (2018)
	Roberto del Rio Children's	Philips Allura FDX 20/20 (2014)
	Santa Maria Clinic	Philips Azurion 7B20 (2018)
COLOMBIA	Valle del Lili Foundation University Hospital ICESI	Siemens Artis Q (2020)
COSTA RICA	National Children's Hospital	Siemens Artis Zee (2016)
CUBA	Cardiocentro pediátrico Nacional	Siemens Artis Zee ^(a)
	William Soler	
	Hospital Metropolitano	
	Instituto Nacional de Cardiología Ignacio Chávez	
	Instituto Nacional Salud del Niño San Borja	
	Instituto Nacional Cardiovascular (INCOR)	
	Instituto de Cardiología Infantil	
ECUADOR	Metropolitan Hospital	Philips Allura Clarity FD 20 (2012)
MÉXICO	National Institute of Cardiology Ignacio Chávez	
	National Institute of Cardiology Ignacio Chávez	Philips Duodiagnost (2005)
PERU	National Institute of Child Health St. Borja	Siemens Artis Zee (2010)
	National Cardiovascular Institute	Siemens Artis Zee Ceiling (2010)
URUGUAY	Children's Cardiology Institute	Philips Allura FD 10 (2018)

^a Information not available.

3. Results

Data from 968 pediatric cardiac procedures were processed during one year, but requested variables were not always provided by all the centers (especially age and weight). Therefore, the final samples were 728 and 685 procedures for age and weight groups, respectively.

Internationally recommended anthropometric parameters were adopted (ICRP 2017, EC 2018). Tables 2 and 3 show the anthropometric characteristics of the patients by age and weight groups, respectively.

Tables 4 and 5 summarize the median and third quartile values for P_{ka} , $K_{a,r}$ and FT for all the collected pediatric procedures (diagnostic and therapeutic) and frequencies by age and weight groups, respectively.

Figures 1 and 2 show a summary of third quartile P_{ka} values (presented as initial regional DRLs for Latin American and Caribbean countries) separated by type of procedure (diagnostic and therapeutic) and for all procedures grouped by age and weight groups, respectively.

Table 6 shows median P_{ka} values by age range reported in this paper compared with those reported in similar surveys (Martinez *et al* 2007, Verghese *et al* 2012, Ubeda *et al* 2012, Corredoira *et al* 2015, Ubeda *et al* 2018, Kottou *et al* 2018, Ishibashi *et al* 2021). Note that the comparison is made for median values and not for DRLs (third quartile) because the third quartile values are not reported in all the papers.

Table 7 shows median P_{ka} values by weight range reported in this paper compared with those reported in similar surveys. Note that the comparison is made for median values and not for DRLs (third quartile) because the third quartile values are not reported in all the referred papers.

Table 8 presents the ten highest values of P_{ka} in the database, which can serve as 'alerts' for quality control and clinical audit purposes, as well as for comparative purposes to inform decisions about potential

Table 2. Sample size (n), median (range) values of height, weight and body mass index (BMI) by age group.

Age group (years)	n	Height (m)	Weight (kg)	BMI (kg m^{-2})
<1	221	0.6 (0.3–0.9)	4.8 (2.1–11.0)	14.6 (7.3–44.8)
1 to <5	252	0.9 (0.4–1.5)	11.0 (5.2–23.0)	15.6 (6.7–44.4)
5 to <10	151	1.2 (0.9–1.5)	23.0 (11.0–54.0)	15.9 (11.0–26.9)
10 to <16	104	1.5 (1.2–1.8)	45.0 (24.0–76.5)	19.3 (14.1–28.7)

Table 3. Sample size (n), median (range) values of height, weight and body mass index (BMI) by weight group.

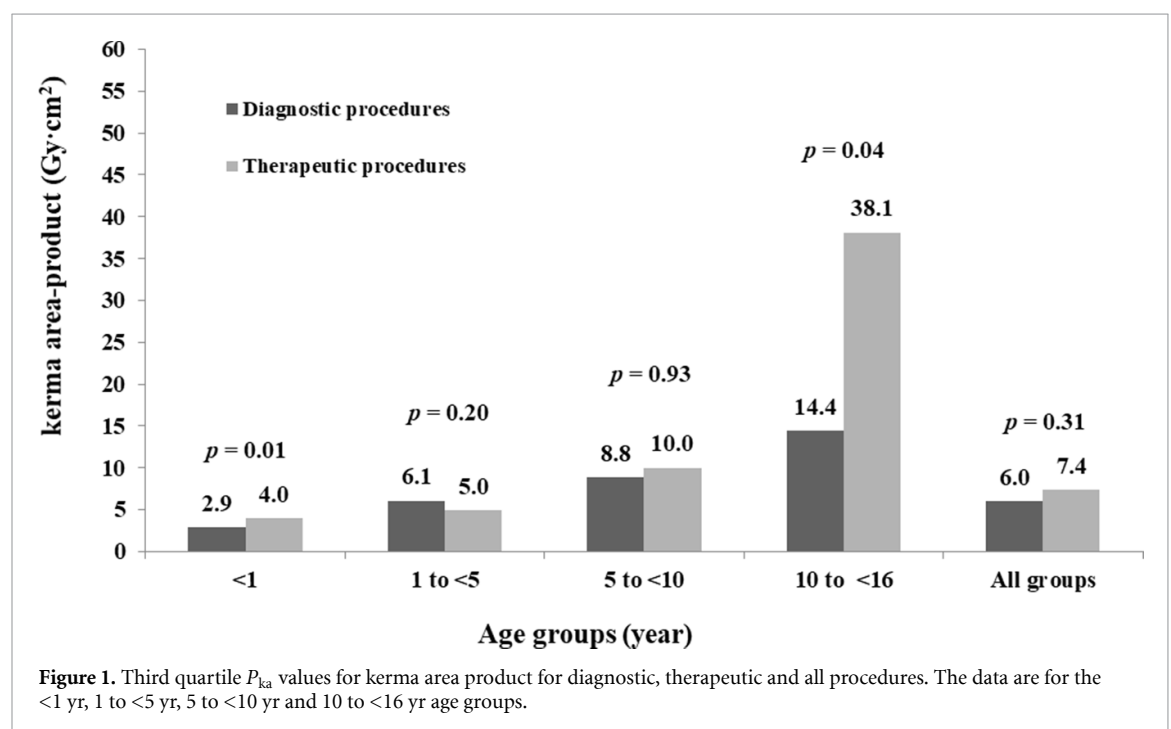
Weight group (kg)	n	Height (m)	Weight (kg)	BMI (kg m^{-2})
<5	116	0.5 (0.3–0.7)	3.8 (2.1–5.0)	13.9 (7.6–44.8)
5 to <15	280	0.8 (0.4–1.3)	9.0 (5.0–14.6)	16.0 (7.4–44.4)
15 to <30	174	1.1 (0.8–1.5)	20.0 (15.0–29.8)	16.0 (11.5–26.0)
30 to <50	79	1.4 (1.0–1.7)	38.4 (30.0–49.5)	18.9 (14.2–38.0)
50 to <80	36	1.6 (1.4–1.8)	55.0 (50.0–76.5)	23.2 (17.1–28.7)

Table 4. Sample size (n), median and third quartile P_{KA} values for kerma area product (P_{ka}), cumulative air kerma at patient entrance reference point ($K_{\text{a,r}}$) and FT by age group.

Age group (years)	n	P_{ka} (Gy cm^2) Median—3rd	$K_{\text{a,r}}$ (mGy) Median—3rd	FT (min) Median—3rd
<1	221	1.9–3.6	36.1–66.3	16.9–30.7
1 to <5	252	2.8–5.5	33.7–62.1	11.3–20.5
5 to <10	151	3.6–9.1	39.7–94.5	10.5–19.3
10 to <16	104	11.5–26.8	80.1–194.0	15.7–24.5

Table 5. Sample size (n), median and third quartile P_{KA} values for kerma area product (P_{ka}), cumulative air kerma at patient entrance reference point ($K_{\text{a,r}}$) and FT by weight group.

Weight group (kg)	n	P_{ka} (Gy cm^2) Median—3rd	$K_{\text{a,r}}$ (mGy) Median—3rd	FT (min) Median—3rd
<5	116	1.8–3.5	34.4–68.0	15.7–28.4
5 to <15	280	2.5–4.4	34.9–59.8	13.7–25.0
15 to <30	174	3.3–7.3	35.3–85.5	10.7–20.1
30 to <50	79	6.2–14.0	46.6–99.9	13.4–21.8
50 to <80	36	23.6–50.8	162.7–251.2	18.1–32.9

**Figure 1.** Third quartile P_{ka} values for kerma area product for diagnostic, therapeutic and all procedures. The data are for the <1 yr, 1 to <5 yr, 5 to <10 yr and 10 to <16 yr age groups.

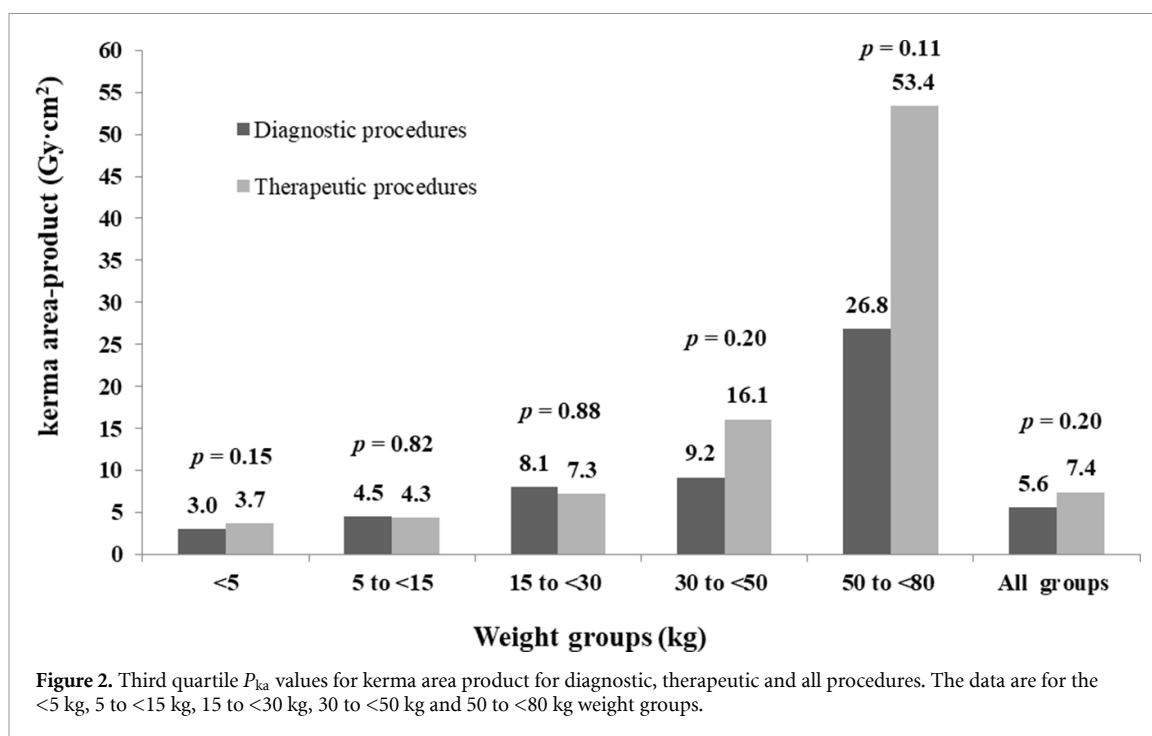


Table 6. Comparison of median P_{ka} values for pediatric cardiology reported in this and other papers (values adapted by the authors of this paper).

Age group (years)	Martinez <i>et al</i> (2007) (Gy·cm ²)	Verghese <i>et al</i> (2012) (Gy·cm ²)	Ubeda <i>et al</i> (2012) (Gy·cm ²)	Corredoira <i>et al</i> (2015) (Gy·cm ²)	Ubeda <i>et al</i> (2018) (Gy·cm ²)	Kottou <i>et al</i> (2018) (Gy·cm ²)	Ubeda <i>et al</i> (2020) (Gy·cm ²)	Ishibashi <i>et al</i> (2021) (Gy·cm ²)	This paper (2022) (Gy·cm ²)
<1	1.9	4.6	0.9	1.8	1.1	2	2.1	4.3	1.9
1–<5	2.9	8.3	1.5	3.1	1.5	3	4.7	6.3	2.6
5–<10	4.5	11.5	2.1	6.0	2.7	7	6.3	10.9	3.6
10–<16	15.4	24.7	5.0	12.1	8.4	14	13.6	19.4	11.5

Table 7. Comparison of median P_{ka} values for pediatric cardiology (in weight bands) reported in this and other papers (values adapted by the authors of this paper). Note that the comparison is made for median values and not for DRLs (third quartile) because the third quartile values are not reported in all the papers.

Weight group (kg)	Buytaert <i>et al</i> (2019) (Gy·cm ²)	Ubeda <i>et al</i> (2020) (Gy·cm ²)	This paper (2022) (Gy·cm ²)
<5	0.6	1.9	1.8
5 to <15	0.7	2.7	2.5
15 to <30	1.9	6.9	3.3
30 to <50	7.1	14.2	6.2
50 to <80	8.7	12.6	23.6

optimization actions. This table shows that the highest $K_{a,r}$ values are under 1000 mGy, which would correspond to a low risk of skin tissue reactions.

4. Discussion

The European Guidelines on DRLs for Paediatric Imaging (EC 2018) suggest that ‘the establishment of a generic DRL for all diagnostic procedures or for all therapeutic procedures might not be appropriate. In particular, for therapeutic procedures, the observed variation of patient doses between different types of procedures suggests the need for procedure specific DRLs.’ However, in the OPRIPALC program, the initial attempt to collect dosimetric data for the different types of therapeutic procedures was unsuccessful since the nomenclature used in the different hospitals and countries was very different and for this reason it was agreed that, in the initial stage of the program, the data would be classified into two groups: diagnostic and therapeutic procedures.

Table 8. Age, weight, FT, kerma area-product (P_{ka}), cumulative air kerma at patient entrance reference point ($K_{a,r}$) for the ten procedures (diagnostic and therapeutic) with higher radiation dose values.

Procedures	Age (year)	Weight (kg)	FT (min)	P_{ka} (Gy·cm ²)	$K_{a,r}$ (mGy)
Diagnostic	7.7	42.0	42.4	102.9	667.0
	12.0	75.2	17.2	61.1	277.1
	0.2	2.1	30.0	55.5	143.0
	15.9	76.0	16.5	52.4	207.2
	7.7	25.5	32.3	45.9	239.4
Therapeutic	10.0	44.0	71.2	174.3	941.5
	3.3	11.0	142.90	110.5	936.6
	11.0	56.0	40.1	90.9	441.9
	13.0	57.6	68.5	89.3	477.6
	14.9	54.0	115.3	78.3	489.2

It should be noted that in figures 1 and 2, the differences for the DRLs in P_{ka} values between diagnostic and therapeutic procedures are statistically significant ($p < 0.05$) only for the age bands of <1 and $10-16$ years and that the differences for the DRLs in P_{ka} values between diagnostic and therapeutic procedures are not statistically significant, for any of the weight bands.

The results of this study show that radiation doses have a very large range (see tables 4 and 5). In tables 6 and 7, with the comparison of median P_{ka} values by age range reported in this paper and others reported in similar surveys, there are large differences but most of the published papers refer to local DRLs, and in this paper the sample is for the full region and the demographic patient data (shown in tables 2 and 3) and the level of optimization in the IC practices in pediatrics may be different.

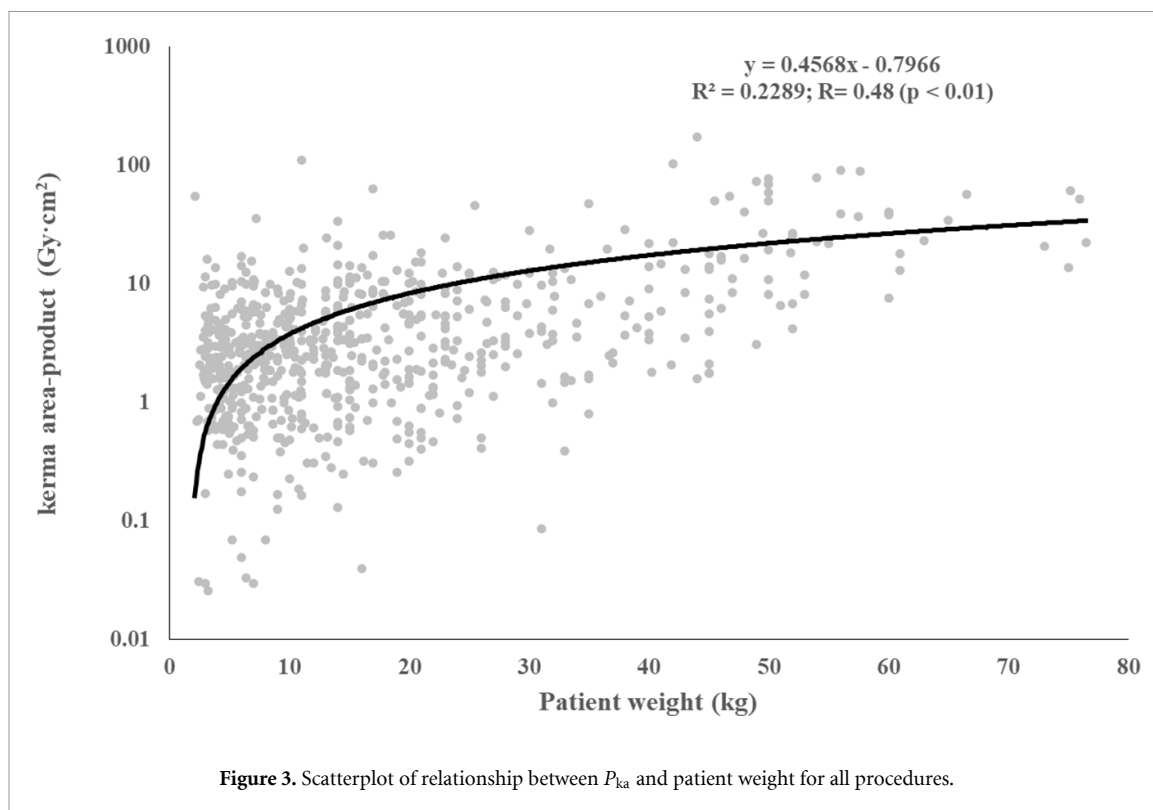
The values shown in table 8 are part of the quality controls included in the OPRIPALC program, as an alert to help detect potential problems related to the use of the x-ray systems or the imaging protocol, as well as to identify the most complex procedures. Usually, these individual procedures are not detected when comparing median values with DRLs, but their identification and review may be useful to improve the clinical practice and the radiation protection of patients. It can be seen that the P_{ka} values included in table 8 are, in general, higher than the DRLs. It is also observed that all the $K_{a,r}$ values exceed the trigger levels to implement clinical follow-up for potential radiation skin injuries (ICRP 2000, 2017). It should be noted that all the values of $K_{a,r}$ in the full database are under 1000 mGy. Currently, with modern x-ray systems and with the increase in RP training for cardiologists and radiation technologists in Latin American and Caribbean countries, the risk of skin radiation injuries in pediatric IC is fortunately low.

Concerning the collection and management of the dosimetric data, the University of Tarapacá has made an agreement with the San Carlos Hospital in Madrid (Spain) to use the DMS 'DOLQA' for the OPRIPALC program (Vano *et al* 2022). This software is expected to increase and facilitate the collection of data for the next steps of the project. The initial experience with one of the hospitals in Chile was successful.

For this initial step, the regional DRLs were derived as the third quartile of all the P_{ka} values in the central database. In a few years, when the sample size will increase (for all the age and weight groups) and some countries may derive their national DRLs, other approaches to estimate the regional DRLs could be considered as suggested by the ICRP (2017). A study conducted in Sweden proposed DRLs for pediatric IC based on procedure type and patient weight (Hultenmo *et al* 2021). The values reported by these authors are much lower than the regional DRLs (values from 18 hospitals and 10 countries) presented in this paper, especially for the lower weight groups. It should be noted that these values correspond to local DRLs obtained in a single center in Sweden, and performed on a high-sensitivity angiographic system allowing low-dose imaging.

Buytaert *et al* (2019) suggest using P_{ka} normalized to body weight as a useful parameter. If P_{ka} and body weight have a clear linear correlation, $P_{ka}/\text{body weight}$ can be used as a single DRL parameter instead of determining different DRLs per weight group. In our case, and based on the regional data collected from 10 countries and 18 hospitals, this approach is not valid (see figure 3) as there are variations of more than a factor of five for the ratio between the DRLs and the weights of the patients in the different age bands.

LIMITATIONS: Some limitations identified during the initial steps of the project are summarized in this section. The calibration/validation of P_{ka} is supposed to be made in some cases by the maintenance services of the x-ray systems and these data need to be collected and analyzed. Unfortunately this is not always well documented and solving this issue will be one of the priorities for the next steps of this regional project. Some hospitals contributed with a small amount of data. The sample used to obtain these preliminary results was not very large, especially when referring to the different age and weight groups. The initial classification of procedures was quite generic. Manual management of the data in this initial phase may have introduced



some mistakes. An analysis of the impact of the procedure complexity and operator experience on patient doses was not performed and would be useful in the next steps.

5. Conclusions

Under an international program (OPRIPALC) supported by the WHO and PAHO with the cooperation of the IAEA, an initial set of regional values of DRLs has been obtained in pediatric IC for diagnostic and therapeutic procedures, by age and weight groups.

In the available sample, it seems that skin doses are low, and the risk of skin radiation injuries will not be a problem in pediatric IC if the x-ray systems used are submitted to a quality control program and the cardiologists are trained in RP.

It is expected that the methodology used and the results obtained will help to improve RP in pediatric IC in the region. Comparison with regional DRL values can give an indication that further optimization may be required for countries whose current national DRLs are above the regional values; it can promote the establishment of national DRLs in countries enrolled in the project (e.g. through awareness raising and capacity building) and can also encourage adoption and use of DRLs as useful tools for optimization in countries where local or national DRLs have not yet been established.

Next steps include the evaluation of DRLs for more specific clinical procedures, the impact of the complexity in the procedures and the evaluation of the optimization actions.

The use of automatic DMSs and their benefits in the collection and management of patient dose indicators is envisaged to increase the size of the samples and to alert on high dose values to introduce corrective (optimization) actions in a short time interval.

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