



Original paper

Local diagnostic reference levels for paediatric non-cardiac interventional radiology procedures



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ABSTRACT

Purpose: To establish local diagnostic reference levels (DRLs) for non-cardiac interventional procedures in paediatrics.

Methods: The type of procedure, the patient's weight and age and dose-related data from 279 interventions was recorded in a database completed by interventional radiologists, radiographers and technicians of the Medical Physics department. These procedures were classified into 14 categories and 6 weight ranges. Local DRLs were proposed for those ranges in which a sample of at least 15 patients could be gathered and were calculated as the third quartile (Q3) of the air kerma-area product (P_{KA}) values. The Q3 of the fluoroscopy time (FT) and number of digital subtraction angiography (DSA) images were also obtained. Finally, the correlation between P_{KA} and weight was analysed.

Results: Local DRLs are proposed for three types of procedures: hepatic/biliary interventions (5–15 kg, 1304 cGy·cm²; 15–30 kg, 2121 cGy·cm²), sclerotherapy procedures (15–30 kg, 704 cGy·cm²; 30–50 kg, 4049 cGy·cm²; 50–80 kg, 3734 cGy·cm²) and central venous catheter (CVC) procedures (5–15 kg, 84 cGy·cm²). Hepatic/biliary interventions showed a moderate correlation ($r = 0.61$), while sclerotherapy procedures presented a poor correlation ($r = 0.34$) between P_{KA} and weight, possibly due to the P_{KA} dependence on the complexity level. Regarding CVC procedures, a clearly higher correlation was found when the fluoroscopy P_{KA} value was normalised to the FT ($r = 0.85$ vs $r = 0.35$).

Conclusions: The results support the feasibility of establishing DRLs for the most common procedures (sclerotherapy, hepatic/biliary and CVC interventions) despite the small number of paediatric interventions.

1. Introduction

Paediatric interventional radiology (PIR) has become a fast-growing subspecialty which comprises a wide variety of procedures from low radiation dose interventions, such as the insertion of central venous catheters (CVC), to complex interventions involving higher doses such as sclerotherapy procedures [1,2]. PIR differs from adult interventional radiology (IR) in several aspects such as procedural requirements, disease processes, the wide range of weights covered or the radiation exposure awareness [2]. In the case of PIR, the concern for radiation exposure is even greater since paediatric patients are more sensitive to its harmful effects and have a greater risk of developing cancer due to their longer life expectancy [3,4]. Furthermore, recent technological

developments have given rise to more complex interventions [2], resulting in increased patient exposure [5].

The rising trend in the number of fluoroscopy-guided interventional procedures has been noticeable [4,6]. According to a recent report from the European Commission (EC) [7], fluoroscopy and interventional radiology (IR) account for 21% of the medical exposure to the European population, roughly the same as plain radiography (22%). A similar result is reflected in NCRP report no. 160, which indicates that interventional procedures have become the third source of medical radiation in the United States, accounting for roughly 14% of the total [8]. Given that medical exposure already accounts for nearly half of the radiation to the population [9], the development of diagnostic reference levels (DRLs), as a way to comply with the ALARA principle, is necessary.

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Moreover, the new Council Directive 2013/59/Euratom requires Members States to establish DRLs and extends their application to IR procedures [5,6]. However, despite the legal requirement and the deep concern when it comes to paediatric exposure, there are no national DRLs for PIR procedures [4,6]. In fact, the recently published European guidelines on DRLs for Paediatric Imaging points out that for paediatric, non-cardiac interventional procedures, it has not been possible to propose European DRLs due the lack of any (either local or national) DRLs [4]. Considering the elevated radiation doses involved compared to conventional radiology and the high radiosensitivity of the patients treated, establishing DRLs in PIR is imperative.

The major limitation in paediatrics is the lack of data since there are fewer procedures performed. Furthermore, the limited data collected is then analysed in terms of weight or age ranges, making it harder to gather sufficient information to establish local DRLs. However, it may be possible to overcome these problems if enough data were collected within a reasonable period of time.

The aim of this work was to establish local DRLs for PIR procedures, detailing the equipment used, the professionals involved, the data collection and analysis, as well as the difficulties encountered throughout the process. The survey was conducted at La Paz University Hospital (HULP), a large medical institution comprising four specialty hospitals, including a paediatric one which coordinates the European Reference Network for Paediatric Transplantation “TransplantChild” (<https://www.transplantchild.eu>). HULP is also a Spanish reference centre for 25 paediatric pathologies or procedures, including hepatic transplantation (approximately 75% are performed at HULP) and intestinal and multivisceral transplantation [10]. Furthermore, HULP is a leading centre for the treatment of vascular malformations. In summary, the large number of paediatric patients treated (95368 paediatric medical consultations in 2016 and 874 paediatric interventional procedures from 2011 to 2017) gives HULP a unique ability to approach the issue raised by Council Directive 2013/59: setting, when feasible, DRLs for PIR procedures.

2. Materials and methods

Procedure data was collected between November 2016 and May 2018 from the three interventional rooms at our centre where IR procedures are performed, namely rooms 12, 13 and 14 (Table 1). All of the rooms are equipped with Philips Integris Allura systems: Integris Allura MP (2001) in room 12, Integris Allura 15C (2012) in room 13 and Integris Allura Xper FD20 (2008) in room 14.

Regarding the collection of dose-related data, both manual and automatic data recording systems were used. In particular, we made use of the DOLIR [11] automatic dose management software (ADMS) available in two versions: DOLIR 2.1 (used in room 13) allows for data retrieval via DICOM Modality Performed Procedure Step Service (MPPS), which only reports the total air kerma-area product (P_{KA}) [12] per procedure; DOLIR SR (used in room 14) retrieves dose-related information from the Radiation Dose Structured Report (RDSR) generated by the equipment, simplifying the data flow and recording, in addition to the total P_{KA} per procedure, data for every radiation event, projections, focus and field size. On the other hand, the equipment in room 12 was too old to enable automatic data collection since neither DICOM

MPPS nor RDSR are generated. Therefore, radiographers in room 12 collected the dose-related information from the equipment’s console and entered it manually into our database. The effectiveness of the manual collection method was then compared with the automatic method.

Multidisciplinary teamwork played an important role in developing the DRLs, as all the information available was entered into a three-source integrated database fed by interventional radiologists, radiographers and technicians of the Medical Physics department, supervised by a medical physics expert. The 5 interventional radiologists from the IR department (with clinical practice experience ranging from 2.5 to 27 years) registered, among other data, the type of procedure performed according to the usual clinical classification [13]. Due to the broad range of interventions, it was necessary to group them together so as to collect sufficient data to develop DRLs. The classification shown in Table 2 is an initial approach and may be subject to modifications. The interventional radiologists also registered the type of access (femoral, radial, etc.) and X-ray projection for each intervention. Although it is beyond the scope of this study, collecting data from those parameters will allow for the analysis of their impact on the dose. The second source of data was the radiographers who registered the patient weight (PW) and age, as well as sex, room number and height. Radiographers in room 12, where no ADMS is installed, were also in charge of entering dose-related data. Finally, the technicians of the Medical Physics department were responsible for transferring the data retrieved by the ADMS to the database. On those occasions when the ADMS failed to register the dosimetric data, the technicians tried to manually obtain it from the equipment. The whole process was supervised by a medical physics expert.

The data was analysed for the weight ranges proposed in the European Guidelines on DRL for Paediatric Imaging [4]. Furthermore, as in Annex G.2 to the mentioned document, DRLs were only proposed for those procedure types and weight ranges for which a sample of at least 15 patients could be gathered combining data from the three rooms. With a sample size of 15 patients, DRLs can be estimated with a confidence interval of approximately 26% at a 95% confidence level. Furthermore, on the recommendations of the International Commission on Radiological Protection (ICRP) [14] and the EC [4], local DRLs were calculated as the third quartile (Q3) of the P_{KA} values collected from all three rooms. These dose values were verified and corrected on an annual basis using a calibrated Unfors X2 solid-state detector (Raysafe, www.raysafe.com) and radiochromic films (Gafchromic). Additionally, the Q3 fluoroscopy time (FT) and number of digital subtraction angiography images (DSAim) per procedure were obtained, as part of a multiple DRL analysis [4,15,16]. For the sake of completeness, local DRLs were also proposed for the most common age groups [4]. Finally, the correlation between P_{KA} and PW was studied using the Pearson correlation coefficient. All mathematical analysis were performed using the R environment (version 3.4.1, <https://www.r-project.org/>).

3. Results

As shown in Fig. 1, paediatric procedures accounted for approximately 10% of all interventional procedures performed. More than 90% of these were therapeutic procedures, while only 6% were strictly

Table 1

Overview of the facilities available at HULP: room number, X-ray equipment and automatic dose management systems (ADMS). Also indicated are the number of paediatric procedures performed in each room as well as the number of procedures for which the data recording system failed to register the dosimetry information.

Room no.	Equipment	ADMS	No. of procedures	No. of data-collection failures n (%)
12	Philips Integris Allura MP (2001)	Manual	21	2 (9.5%)
13	Philips Integris Allura 15C (2012)	DOLIR 2.1	247	25* (10.1%)
14	Philips Integris Allura Xper FD 20 (2008)	DOLIR SR	11	1 (9.1%)

*23 of those failures could be detected and solved by the technicians of the Medical Physics department.

Table 2

Number of procedures performed over an 18-month period classified by type of procedure and weight range (kg). Only those procedures correctly reported in terms of patient weight, dose data and procedure classification are included. The local DRLs were only established for those cases for which a sample of at least 15 patients sample could be obtained.

Procedure	Weight (kg)						Total
	< 5	5 – < 15	15 – < 30	30 – < 50	50 – < 80	≥ 80	
Hepatic/biliary interventions ^a	1	38	15	7	4		65
Sclerotherapy ^b		9	18	21	16	1	65
CVC ^c	2	21	12	14	14	2	65
Embolisation	1	1	7	2	6	2	19
Diagnostic ^d	1	2	6	1	4		14
PTA ^e		2		3	1		6
Portosystemic shunt			4	1			5
Gastrojejunostomy		1	2	2			5
Lymphography		2		1			3
TIPS ^f				3			3
Vascular recanalisation		1	2				3
Hepatic manometry					1		1
Hepatic biopsy and cavography					1		1
Others		1		1	1		3

^a Including percutaneous transhepatic cholangiography (71%) and portography interventions (29%).

^b Due to venous malformations (95%) and lymphangiomas (5%).

^c Central venous catheter procedures (mainly jugular access).

^d Including arteriography, indirect portography and phlebography.

^e Percutaneous transluminal angioplasty.

^f Transjugular intrahepatic portosystemic shunt.

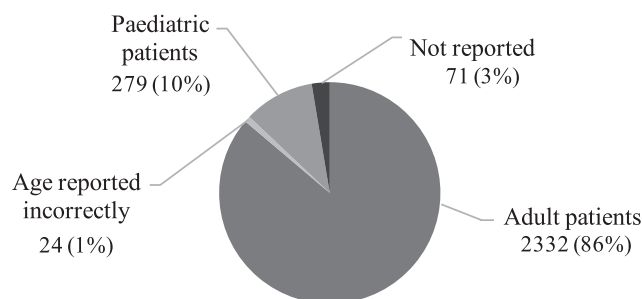


Fig. 1. Number of interventional procedures performed in La Paz University Hospital between November 2016 and May 2018 classified by type of patients.

diagnostic (Fig. 2). For this reason, diagnostic procedures were not further classified into sub-categories. The number of paediatric procedures performed in each room is shown in Table 1, together with the number of errors that occurred during the process of collecting dose-related data. In particular, 23 of the ADMS failures could be solved by the technicians of the Medical Physics department. After all, 21 out of the 279 paediatric records lacked essential information (PW, dose data or procedure classification) and were excluded from the study. An overview of the remaining 258 valid records is presented in Table 2.

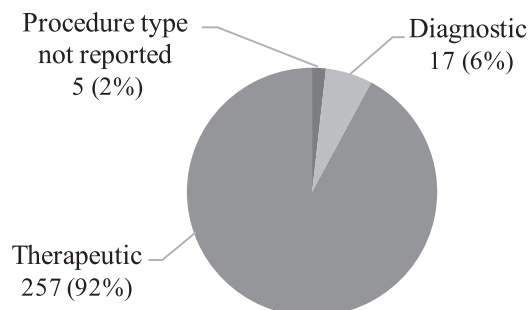


Fig. 2. Number of paediatric procedures performed between November 2016 and May 2018 classified by type of intervention.

There are 3 types of therapeutic interventions that clearly stood out due to the higher number of procedures performed: hepatic/biliary interventions, specifically percutaneous transhepatic cholangiography (PTHC) and portography interventions (71% and 29% respectively); sclerotherapy procedures for venous (95%) and lymphatic (5%) malformations; and central venous catheter (CVC) procedures, mostly with jugular access (therefore not to be confused with peripherally inserted central catheter, PICC). The local DRLs developed for these procedure types are presented in Table 3. The median (Q2) is also included, together with the interquartile range (ratio Q3/Q1), as a measure of the spread of values.

The correlation between P_{KA} and PW is analysed in Figs. 3 and 4 for the above-mentioned interventions. Sclerotherapy procedures showed a poor correlation ($r = 0.34$) while hepatic/biliary interventions presented a moderate correlation between P_{KA} and PW ($r = 0.61$). CVC procedures showed a weak correlation between P_{KA} and PW ($r = 0.35$, Fig. 4a), but a clearly higher correlation between the P_{KA}/FT (understood as fluoroscopy P_{KA} per FT) and PW ($r = 0.85$, Fig. 4b), with a proportionality constant of $0.0301 \text{ cGy}\cdot\text{cm}^2/\text{s}\cdot\text{kg}$. Seven CVC registers with $DSaim > 7$ were excluded from the correlation analysis as they were considered outliers due to their high number of $DSaim$ (the third quartile of the $DSaim$ is one for CVC procedures).

4. Discussion

So far, no European studies have been published on the subject of establishing DRLs for paediatric non-cardiac interventional procedures [4]. In this regard, the values obtained represent the first published DRLs in PIR from a European hospital. The lack of prior studies might be due to the paucity of paediatric data. Even being part of one of the largest national hospitals in terms of the number of paediatric patients treated, we found that only 10% of the non-cardiac interventional procedures performed were paediatric (279 procedures over an 18-month period). This percentage, however, is noticeably higher than the average for well-developed countries (where paediatric cases account for only about 2% of all non-cardiac angiography procedures [17]), supporting HULP in its efforts to establish local DRLs. On the other hand, this lack of paediatric data available could be overcome by conducting a nationwide patient survey; however, the EC has warned

Table 3

Local DRLs proposed, estimated as the third quartile (Q3) of the air kerma-area product (P_{KA}) values ($\text{cGy}\cdot\text{cm}^2$) for the most common weight and age ranges. Also included are the number of patients, the median (Q2) and the interquartile range (ratio Q3/Q1). The same information is given for the fluoroscopy time (FT, in seconds) and the number of digital subtraction angiography images (DSAim).

Procedures		Weight (kg)				Age (years)		
		5 – < 15	15 – < 30	30 – < 50	50 – < 80	1 – < 5	5 – < 10	10 – < 15
Hepatic/Biliary interventions	Sample size	38	15			40		
	P_{KA} ($\text{cGy}\cdot\text{cm}^2$)							
	Q3	1304	2121			1292		
	Q2 (Q3/Q1)	812 (3)	1688 (2)			812 (3)		
	FT (sec)							
	Q3	1163	1359			1175		
	Q2 (Q3/Q1)	876 (3)	864 (3)			672 (3)		
	DSAim							
Sclerotherapy	Sample size		18	21	16		19	26
	P_{KA} ($\text{cGy}\cdot\text{cm}^2$)							
	Q3		704	4049	3734		412	2443
	Q2 (Q3/Q1)		286 (4)	512 (21)	1798 (7)		227 (2)	664 (8)
	FT (sec)							
	Q3		354	447	1398		276	654
	Q2 (Q3/Q1)		249 (2)	237 (3)	652 (5)		198 (2)	252 (3)
	DSAim							
CVC ^a	Sample size	21				21		
	P_{KA} ($\text{cGy}\cdot\text{cm}^2$)							
	Q3	84				107		
	Q2 (Q3/Q1)	67 (3)				67 (4)		
	FT (sec)							
	Q3	204				215		
	Q2 (Q3/Q1)	138 (2)				111 (4)		
	DSAim							
	Q3	1				1		
	Q2 (Q3/Q1)	1				1		

^a Central venous catheter procedures.

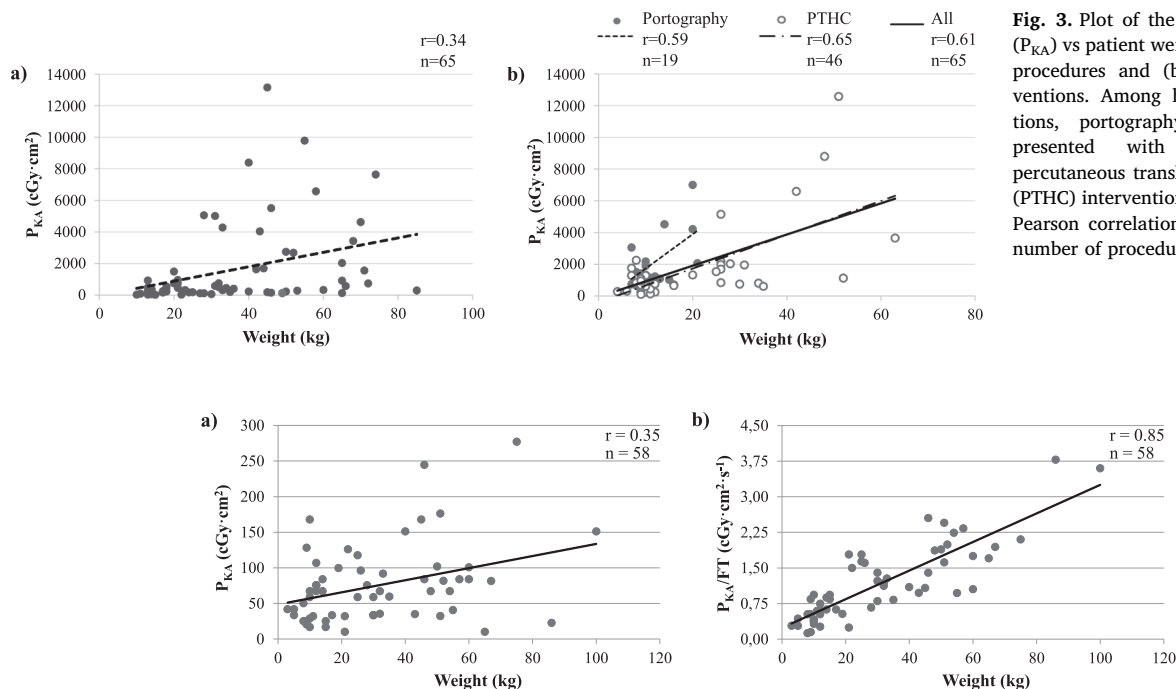
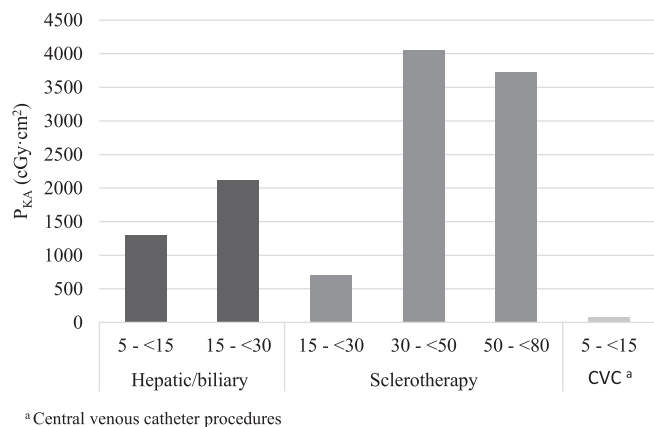


Fig. 3. Plot of the air kerma-area product (P_{KA}) vs patient weight for (a) sclerotherapy procedures and (b) hepatic/biliary interventions. Among hepatic/biliary interventions, portography procedures are represented with solid circles and percutaneous transhepatic cholangiography (PTHC) interventions with open circles. The Pearson correlation coefficient (r) and the number of procedures (n) are indicated.

Fig. 4. (a) Plot of the air kerma-area product (P_{KA}) vs patient weight for central venous catheter (CVC) procedures. (b) Plot of the P_{KA} normalized to the fluoroscopy time (FT) vs patient weight for CVC interventions. The Pearson correlation coefficient (r) and the number of procedures (n) are indicated.



^aCentral venous catheter procedures

Fig. 5. Comparison of the proposed local DRLs, calculated as the third quartile of the air kerma-area product (P_{KA}) values for the different procedure types and weight ranges (in kg).

about the high level of variation found between different centres in the survey conducted as part of the PiDRL project [4].

The second difficulty encountered was related to procedure classification. Although a more specific classification was initially proposed, broader categories were later adopted in order to concur with the classification proposed by the EC document [4]. For example, PTHC and portography procedures were later classified together as hepatic/biliary interventions. Sharing a common classification criteria is imperative for establishing National or European DRLs. In this regard, the classification criteria used in this study must be understood as an initial approximation and may therefore be subject to modifications. On the other hand, even if broader categories need to be adopted in order to make comparison between centres feasible, it could be useful to maintain more specific categories on a local basis since they might allow for more precise evaluation of the dose indicators and might facilitate finding optimisation measures.

Missing data or erroneously recorded data was another issue that we had to face: the patient’s age was either not recorded or was recorded incorrectly in almost 4% of the procedures, and more than 8% of the paediatric procedures were missing some piece of information necessary to establish DRLs (PW, procedure classification or dose-related data). Automating registration by retrieving the patient’s age or the procedure type directly from the RDSR could be an option for reducing the percentage of missing data, although in this study that would only be possible for room 14 where DOLIR SR is installed. Regarding the type of ADMS used (collection via DICOM MPPS or RDSR), no noticeable differences were observed in their performance as the percentage of procedures lacking dose-related data was roughly equal in both

cases. Compared to these, the percentage of mistakes shown by the manual collecting system was only slightly higher, which could be explained by the high-level training of the radiographers in room 12. The use of ADMS, however, simplifies the data collection process and saves time for the professionals involved.

Despite the limitations above-mentioned, local DRLs were established for sclerotherapy, hepatic/biliary and CVC interventions. Among the three, sclerotherapy clearly contributed the most to patient exposure although it is frequently performed on heavier patients. In the 5–15 kg and 15–30 kg ranges, however, hepatic/biliary procedures required higher doses than either CVC or sclerotherapy interventions (Fig. 5). It could be possible to develop DRLs for other weight ranges if the survey was conducted over a longer period of time; nonetheless, it seems difficult to establish DRLs for other type of interventions if weight ranges are to be considered.

The correlation between the P_{KA} and the PW was also studied. A poor dependence of the dose on the PW was observed for sclerotherapy procedures, which could be partially explained by the fact that those interventions are mainly performed on the limbs. On the other hand, CVC procedures showed a poor correlation between P_{KA} and PW and hepatic/biliary interventions presented just a moderate correlation, contrary to what was expected by the EC for interventions in the trunk area [4]. This lack of correlation could be due to the differences in the level of complexity, which might have a higher influence on the patient exposure than PW. In order to illustrate this, two opposed cases were analysed: patient 1 (50-kg, 13 year-old male in room 13) was treated for a localised lesion on the anterior forearm, requiring an overall exposure of 227 cGy·cm²; patient 2 (55-kg, 15 year-old male in room 13) was treat for an extensive low-flow vascular malformation affecting the entire lower limb, with an overall exposure of 9794 cGy·cm². In this regard, the study has been limited by the difficulty in assessing the level of complexity in an objective manner, given the absence of any standardised criteria. An effort should be made to simplify the incorporation of complexity into the analysis, as done by previous authors for a few types of interventions on adults [18–20].

Defining a DRL-curve by presenting the P_{KA} as a function of the PW was suggested by the EC as an alternative way to confront the paucity of data by avoiding the use of weight ranges [4]. This approach has already been implemented by previous authors for plain thorax acquisitions [21] and CT scans [22], which showed a good correlation between the dosimetric quantity and the patient thickness/weight. Alternatively, the EC proposed as a future development for IR procedures [4], the use of the proportionality constant as a single-value DRL for a given procedure type, which has already been applied by some authors for cardiac IR [15,23,24]. However, neither of those approaches could be used in the present work due to the lack of correlation between P_{KA} and the PW.

Table 4

Comparison between the local DRLs obtained at HULP and the local DRLs from 6 centres included in the PiDRL project [4]. DRLs from different centres, when available, are presented separated by comas. The third quartile (Q3) of the air kerma-area product (P_{KA}) values (in cGy·cm²) together with the interquartile ratio (Q3/Q1, presented in brackets) are used in the comparison.

	Hepatic/Biliary		Sclerotherapy		CVC	
	HULP	PiDRL	HULP	PiDRL	HULP	PiDRL ^a
Weight (kg)						
5 - < 15	1304 (3)	–			84 (3)	2 (5), 17 (2), 114 (4)
15 - < 30	2121 (2)	–	704 (4)	41		
30 - < 50			4049 (21)	49		
50 - < 80			3734 (7)	–		
Age (years)						
1 - < 5	1292 (3)	55			107 (4)	2 (4), 17 (2), 114 (3)
5 - < 10			412 (2)	32, 67, 365		
10 - < 15			2443 (8)	88, 51, 225	151 (3)	10 (6), 162 (6), 47 (5)

^a DRLs for peripherally inserted central catheter (PICC) procedures, not CVC (central venous catheters with jugular access).

However, in the particular case of CVC procedures, the reported P_{KA} value could be equated with fluoroscopy P_{KA} (FP_{KA}) since almost no DSA is done (DSAim $Q3 = 1$). A significantly higher correlation was then found when representing the FP_{KA}/FT as a function of the PW ($r = 0.85$, Fig. 4b). The same result was reached by Onnasch et al. [23] and Chida et al. [24] for cardiac catheterisation. This fact raises the possibility of using the proportionality constant (FP_{KA}/FT vs PW) as a secondary indicator for optimisation, which does not require the use of weight ranges. The value found for CVC procedures ($0.0301 \text{ cGy}\cdot\text{cm}^2/\text{s}\cdot\text{kg}$) was comparable to those published by Strauss et al. [25] who calculated the median FP_{KA} per FT and PW for 204 IR procedures, performed using standard technology ($0.045 \text{ cGy}\cdot\text{cm}^2/\text{s}\cdot\text{kg}$) and novel dose-reduction technology ($0.025 \text{ cGy}\cdot\text{cm}^2/\text{s}\cdot\text{kg}$).

Likewise, the DSA P_{KA} per DSAim and PW (understood as a measure of the average dose per image and PW) could be an additional indicator on which to base an optimisation process. However, the use of these indicators requires that P_{KA} values for fluoroscopy and DSA be recorded separately. In the case of room 13, where most of the paediatric procedures are performed, the inability to use DICOM RDSR constitutes a limitation of the study and would hinder a future optimisation process since P_{KA} is recorded by ADMS without distinction between fluoroscopy and DSA.

In Table 4, the results obtained in this study are compared to those found by the EC in the survey conducted as part of the PiDRL project [4]. In the case of hepatic/biliary interventions and sclerotherapy procedures, significantly higher doses have been found for most of the weight ranges for which information is available. However, it has been impossible to analyse the origin of those differences due to the lack of detailed information in the EC document, such as the equipment used in the participating hospitals, the types of procedures included in each category, DSAim or FT. Since HULP is a national reference centre for hepatic transplantation and vascular malformations, it could be argued that complicated cases are often transferred from other hospitals, resulting in higher doses being administered to the patients given the increased complexity of the procedures. In any case, close attention will be paid to future publications in order to assess the suitability of an optimisation process.

5. Conclusions

In this study, local DRLs are established for paediatric non-cardiac IR procedures. The values obtained are highly relevant since they constitute the first published DRLs in PIR from a European hospital. Furthermore, the results support the feasibility of setting local, national or even European DRLs for the three main types of PIR procedures (hepatic/biliary, sclerotherapy and CVC interventions) despite the lack of paediatric data.

On the other hand, weak correlations between P_{KA} and PW were found, probably due to the high influence of the complexity level on the P_{KA} values. In this regard, using weight ranges might not be as useful as it is for conventional radiography. Further studies are needed to assess the impact of the complexity level and to evaluate the best way to take it into account when establishing DRLs in PIR.

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