KJMS 2026 VOL.8 (1): 151-162

KDU Journal of Multidisciplinary Studies (KJMS)
Volume 8. Issue 1 July 2026
DOI: https://doi.org/10.4038/kjms.v8i1.259

DETERMINATION OF INSTITUTIONAL DIAGNOSTIC REFERENCE LEVELS FOR PAEDIATRIC INTERVENTIONAL CARDIOLOGY PROCEDURES IN SRI LANKA

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ABSTRACT

Determining diagnostic reference levels (DRLs) for paediatric patients undergoing interventional cardiology (IC) procedures is essential, as these procedures involve high radiation exposure and require dose optimization to account for the unique anatomical and tissue characteristics of children compared to adults. Data from Right and left heart cardiac catheterization (RHCC/LHCC), patent ductus arteriosus (PDA) closure, and atrial septal defect (ASD) closure procedures conducted at Lady Ridgway Hospital (LRH) for children in Colombo, Sri Lanka, from April 2023 to April 2025 were collected and grouped based on weight and age, as recommended by the European guidelines in Radiation Protection Report Number 185. A total of 438 procedures were analysed, including 195 ASD closures, 159 RHCC/LHCC, and 84 PDA closures. Institutional DRLs (IDRLs) were calculated for the DRL quantities such as dose area product (DAP), cumulative air kerma (Ka), and cumulative fluoroscopy time (FT) as recommended by the International Commission of Radiation Protection (ICRP). Except for the IDRLs determined based on Ka for 1-<4 years age group in ASD closure and RHCC/LHCC procedures, all other IDRLs were lower than the previously published reference levels. The developed IDRLs can be used by LRH, Sri Lanka, as reference levels to identify unusual situations in case of abnormally low or higher values of these DRL quantities in IC procedures. This study highlights the need for the development of national DRLs for paediatric interventional cardiology procedures in Sri Lanka.

KEYWORDS: Diagnostic Reference Level, Paediatric Interventional Cardiology, Radiation Dose Optimization, Dose Area Product, Air Kerma, Fluoroscopy Time

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1. INTRODUCTION

Interventional cardiology (IC) procedures in paediatric patients is a specialized field of medicine focused on diagnosing and treating congenital or acquired heart conditions using minimally invasive techniques. These procedures require careful attention to radiation safety due to the heightened vulnerability of paediatric patients to radiation related risks and harm (ICRP, 1996). Children are more susceptible to the harmful effects of ionizing radiation because their developing organs and tissue are more sensitive and have a longer lifespan for potential radiation induced damage compared to adults (ICRP, 1996). The main concerns include an increased risk of radiation induced cancers and potential genetic effects, emphasizing the importance of minimizing radiation exposure during medical imaging and interventional procedures (Euratom, 1997; ICRP, 2001; Wagner et al., 1994; Andreassi et al., 2014).

Optimization of radiation exposure in medical settings is crucial to balancing the diagnostic or therapeutic benefits of imaging and interventional procedures with the potential risks associated with ionizing radiation (Ramanathan et al., 2023; Athukorala and Ramanathan, 2025). The primary goal is to adhere to the principle of "As Low As Reasonably Achievable (ALARA)", which emphasizes minimizing radiation doses to the lowest level that still allows for effective clinical outcomes (IAEA, 2018). This approach involves several key strategies. Utilizing advanced imaging technologies equipped with dose reduction capabilities, such as low dose protocols and iterative reconstruction algorithms, helps achieve high-quality images while reducing radiation exposure. Modifying imaging protocols based on patient specific factors, such as age, size, and clinical indication further optimizes radiation dose management (ICRP, 2007). Regular calibration and quality assurance of imaging equipment ensure accurate delivery of dose and maintain consistency in radiation safety practices. Real time monitoring of patient doses during a procedure along with periodic audits using diagnostic reference levels (DRLs) help to ensure compliance with established radiation safety guidelines and identify opportunities for further optimization. The DRL was introduced by the International Commission on Radiological Protection (ICRP) in 1996. It can be established at national, regional, or local levels and serves as a tool to identify unusual situations in case of abnormally low or high values of DRL quantities (ICRP, 1996). The 75th percentile of a dose metric distribution is used as national DRL (NDRL) and the 50th percentile within an institution is used as local DRL (LDRL) or institutional DRL (IDRL) which would not exceed national DRL (Liang et al., 2017).

Developing and establishing DRLs for paediatric IC procedures are essential for optimizing radiation safety in this vulnerable patient population. Paediatric specific DRLs are crucial due to the unique anatomical and physiological characteristics of children compared to adults, including smaller body sizes and varying tissue densities (ICRP, 2017). These levels are determined through comprehensive data collection and analysis across a range of procedures, considering factors such as patient age, weight, procedural complexity, and equipment specifications. By setting and adhering to paediatric DRLs, healthcare providers can standardize radiation dose management, monitor procedural practices, and identify opportunities for dose optimization. This approach not only enhances radiation protection for paediatric patients but also supports ongoing quality improvement initiatives in IC to ensure safe and effective care delivery (Damilakis et al., 2023; European Commission, 2018); Ubeda et al., 2015; Ou-Saada et al., 2020; De Monte et al., 2020).

According to the ICRP recommendations, the air kerma area product (P_{KA})/dose area product (DAP) is considered as the primary dose quantity for setting DRLs for fluoroscopy guided interventional procedures. The air kerma at patient entrance reference point ($K_{a,r}$)/cumulative air kerma (CAK), cumulative fluoroscopy time (FT), and total number of images (cine-frames) acquired (F) are recommended as useful secondary DRL quantities for fluoroscopy guided interventional procedures. The ICRP recommends that data for all suitable DRL quantities, if available, should be tracked for interventional procedures since it aids the optimization process (ICRP, 2007).

Despite the increasing use of paediatric IC procedures worldwide, there are currently no published DRL for paediatric IC procedures in Sri Lanka. Furthermore, limited data are available from South Asian countries, making it difficult to benchmark radiation doses and support dose optimization in this region. Establishing IDRLs is therefore an important first step toward optimizing radiation protection and providing baseline data for future NDRL development.

This paper presents the results of the first patient dose evaluation study conducted over a two year period (April 2023 to April 2025) to determine IDRLs for the most common IC procedures, such as right heart cardiac catheterization (RHCC), left heart cardiac catheterization (LHCC), patent ductus arteriosus (PDA) closure, and atrial septal defect (ASD) closure performed at Lady Ridgway Hospital (LRH), for children in Colombo, Sri Lanka. LRH is one of the three pediatric hospitals in Sri Lanka and manages approximately 60% of these procedures nationwide.

2. METHODS

A retrospective study was conducted at the cardiac catheterization laboratory (Cath lab) of LRH for children in Colombo following approval taken from the hospital authorities and the Ethical Review Committee of the Faculty of Medicine, General Sir John Kotelawala University (RP/2023/05). Paediatric patients (<18 years of age) who underwent IC procedures, such as combined RHCC and LHCC procedures, PDA closure procedures, and ASD closure procedures, between April 2023 to April 2025 were enrolled. Patients weighing >80 kg were excluded. Procedures with incomplete data for any of the selected dose quantities (DAP, CAK, or cumulative FT) were also excluded. Thus, the procedures with missing data for one or more of these variables were excluded from the analysis. The final analytical dataset comprised 438 procedures, including 195 ASD closure procedures, 159 RHCC/LHCC procedures, and 84 PDA closure procedures.

The procedures were performed using a digital single plane Philips Allura Xper FD10 cardiovascular imaging system. Routine quality control (QC) measures ensured that the DAP meter and cumulative air kerma display maintained a variation below 10% in the range of 60-120 kV. Data on procedure type, demographic details (patient age and weight), and DRL quantities (total DAP in Gy.cm^2, cumulative K_a in mGy, and cumulative FT in minutes were obtained from Digital Imaging and Communications in Medicine (DICOM) Radiation Structured Dose Report (RDSR) generated by the X-ray system.

The grouping of patients by body weight (BW) and age was considered for each procedure to determine weight-based and age-based IDRLs in accordance with the recommendations of the European Guidelines on DRLs for paediatric imaging. According to the recommendations, this grouping is necessary since the dose levels significantly vary in children not only by age but also by weight of the children. Therefore, in this study, paediatric patients were categorized into five BW groups: < 5 kg (WG1), 5 - < 15 kg (WG2), 15 - < 30 kg (WG3), 30 - < 50 kg (WG4), and 50 - < 80 kg (WG5) and five age groups: < 1 months (AG1), 1 months - < 4 years (AG2), 4 - < 10 years (AG3), 10 - < 14 years (AG4), and 14 - < 18 years (AG5) as recommended by the European guidelines and the ICRP [(European Commission, 2018), (ICRP, 2017)].

According to ICRP publication 135, DRLs are typically established using the 75th percentile of the median dose values from multiple facilities for national or regional DRLs. However, for local or institutional DRLs, especially for less common examinations where patient numbers are difficult to obtain, institutions may adopt alternative approaches to support dose optimization. In the present study, the available sample size was insufficient to produce a robust estimate of the 75th percentile. Therefore, the median (50th percentile) of the patient dose distribution was used as the institutional reference level to represent typical clinical practice and provide a base line for future optimization. This approach should be considered an interim institutional benchmark rather than a conventional DRL and can be updated as additional data become available.

3. RESULTS

A total of 438 IC procedures were collected, including 195 ASD closure procedures, 159 RHCC/LHCC procedures, and 84 PDA closure procedures. Figures 1 and 2 illustrate the number of patients by body weight and age groups, respectively, for each procedure type. Table 1 presents the mean ± standard deviation (SD) of the study samples based on weight groups, while Table 2 shows the mean ± SD of the study samples based on age groups. Table 3 presents the mean ± SD of the study samples based on weight groups, while Table 4 shows the mean ± SD of the study samples based on age groups.

In addition, categories with an inadequate sample size, based on either body weight (Figure 1) or age group (Figure 2), were not included and are shown as blank in the histograms. In Tables 1 and 2, these categories are indicated by a dash (-). The same convention was followed in Figure 3 – 8.

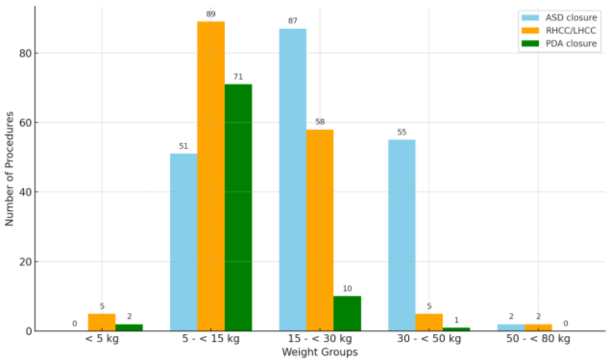

Figure 1: Number of patients for BW groups per procedures type.

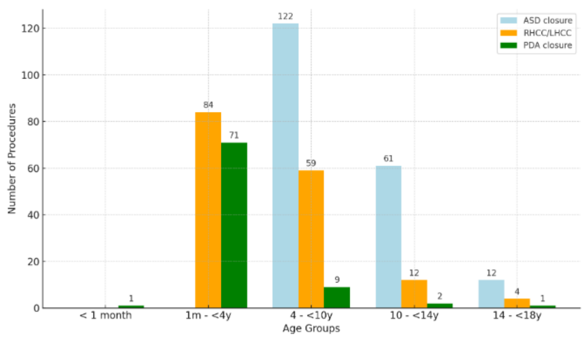

Figure 2: Number of patients for age groups per procedures type.

Table 1: Mean weight ± SD of the study samples based on weight groups.

Procedure	**<5 kg (WG1)**	**5- <15 kg (WG2)**	**15- <30 kg (WG3)**	**30- <50 kg (WG4)**	**50- <80 kg (WG5)**
ASD closure	-	13.7± 0.9	19.4± 3.7	39.5 ±5.2	-
PDA closure	-	8.9± 2.6	-	-	-
RHCC/LHCC	-	9.6± 2.9	20.2± 4.3	-	-

Table 2: Mean age ± SD of the study samples based on age groups.

Procedure	**<1 month (AG1)**	**1 month - <4 years (AG2)**	**4 years- < 10 years (AG3)**	**10 years - <14 years (AG4)**	**14 years - <18 years (AG5)**
ASD closure	-	-	6.2± 1.5	12.1 ±1.2	-
PDA closure	-	1.5± 0.9	-	-	-
RHCC/LHCC	-	1.7± 1.0	6.4± 1.9	-	-

The box plot of DAP for each procedure type based on weight groups is shown in Figure 3. The median DAP value for the WG2 during the ASD closure procedure is 0.40 $Gy.cm^2$ (IQR: 0.32 – 0.47 $Gy.cm^2$); for the WG3, it is 0.56 $Gy.cm^2$ (IQR: 0.33 – 0.73 $Gy.cm^2$); and for the WG4, it is 0.89 $Gy.cm^2$ (IQR: 0.61-1.12 $Gy.cm^2$). For the RHCC/LHCC procedure, the median DAP value for the WG2 is 0.70 $Gy.cm^2$ (IQR: 0.48-0.98 $Gy.cm^2$), and for the WG3, it is 1.71 $Gy.cm^2$ (IQR: 1.10 – 2.29 $Gy.cm^2$). For the PDA closure procedure, the median DAP value for the WG2 is 0.45 $Gy.cm^2$ (IQR: 0.31 – 0.59 $Gy.cm^2$).

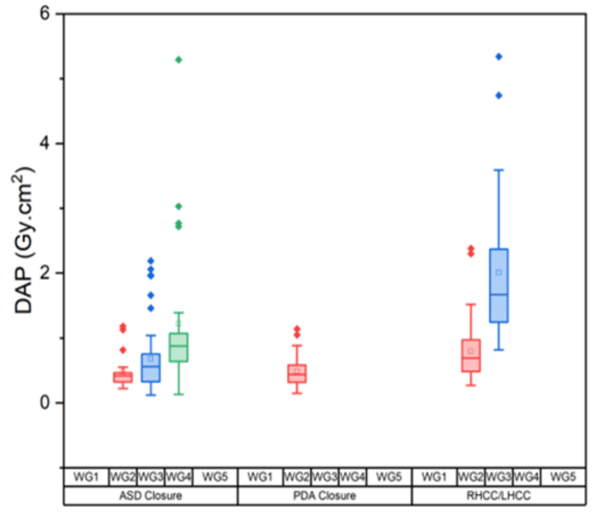

Figure 3: The box plot of DAP for each procedure type based on weight groups.

The box plot of Ka for each procedure type based on weight group is shown in Figure 4. The median Ka value for the WG2 during the ASD closure procedure is 7.91 mGy (IQR: 6.40 – 10.06 mGy); for the WG3, it is 9.49 mGy (IQR: 5.65 – 12.29 mGy); and for the WG4, it is 12.8 mGy (IQR: 9.18 – 18.3 mGy). For the RHCC/LHCC procedure, the median Ka value for the WG2 is 13.0 mGy (IQR: 9.50 – 17.08 mGy), and for the WG3, it is 22.4 mGy (IQR: 14.35– 26.63 mGy). For the PDA closure procedure, the median Ka value for the WG2 is 14.9 mGy (IQR: 10.40 – 22.77 mGy).

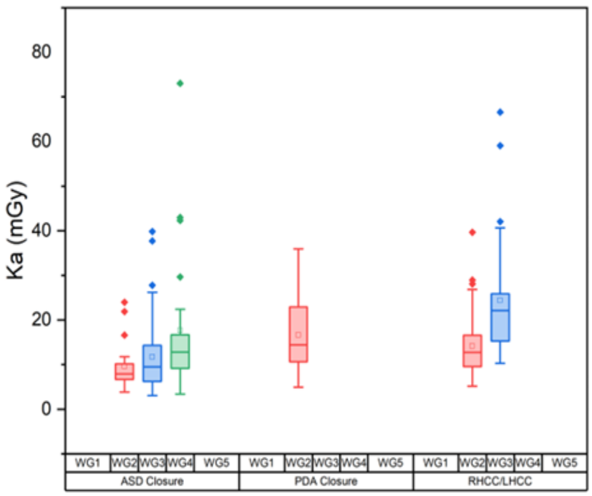

Figure 4: The box plot of Ka for each procedure type based on weight groups.

The box plot of FT for each procedure type based on weight group is shown in Figure 5. The median FT value for the WG2 during the ASD closure procedure is 4.25 minutes (IQR: 3.27 – 5.34 minutes); for the WG3, it is 4.63 minutes (IQR: 2.42 – 5.46 minutes); and for the WG4, it is 4.60 minutes (IQR: 3.26– 6.87 minutes). For the RHCC/LHCC procedure, the median FT value for the WG2 is 3.08 minutes (IQR: 2.08 - 5.08 minutes), and for the WG3, it is 4.77 minutes (IQR: 2.41– 5.18 minutes). For the PDA closure procedure, the median FT value for the WG2 is 3.95 minutes (IQR: 3.18 – 5.13 minutes).

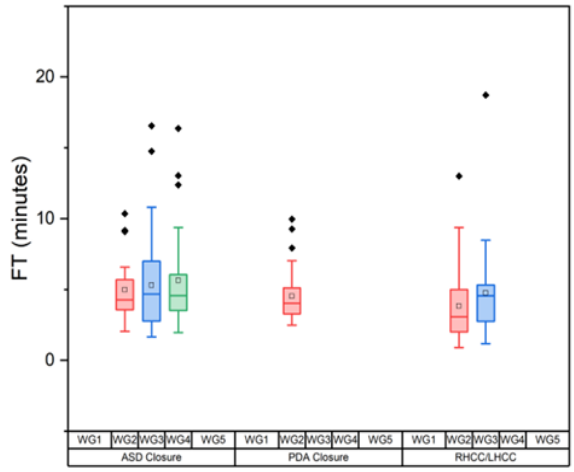

Figure 5: The box plot of FT for each procedure type based on weight groups.

The box plot of DAP for each procedure type based on age groups is shown in Figure 6. The median DAP value for the AG3 during the ASD closure procedure is 0.45 Gy.cm^2 (IQR: 0.32 – 0.65 Gy.cm^2); and for the AG4 is 0.88 Gy.cm^2 (IQR: 0.43 - 1.61 Gy.cm^2). For the RHCC/LHCC procedure, the median DAP value for the AG2 is 0.60 Gy.cm^2 (IQR: 0.45 - 0.91 Gy.cm^2), and for the AG3 is 1.45 Gy.cm^2 (IQR: 1.03 – 2.00 Gy.cm^2). For the PDA closure procedure, the median DAP value for the AG2 is 0.45 Gy.cm^2 (IQR: 0.32 – 0.59 Gy.cm^2).

The box plot of Ka for each procedure type based on age groups is shown in Figure 7. The median Ka value for the AG3 during the ASD closure procedure is 9.00 mGy (IQR: 6.21– 11.57 mGy); and for the AG4 is 13.3 mGy (IQR: 7.16-20.43 mGy). For the RHCC/LHCC procedure, the median Ka value for the

AG2 is 11.0 mGy (IQR: 9.11-15.72 mGy), and for the AG3 is 20.8 mGy (IQR: 12.62 – 24.53 mGy). For the PDA closure procedure, the median Ka value for the AG2 is 14.9 mGy (IQR: 11.01 – 23.13 mGy).

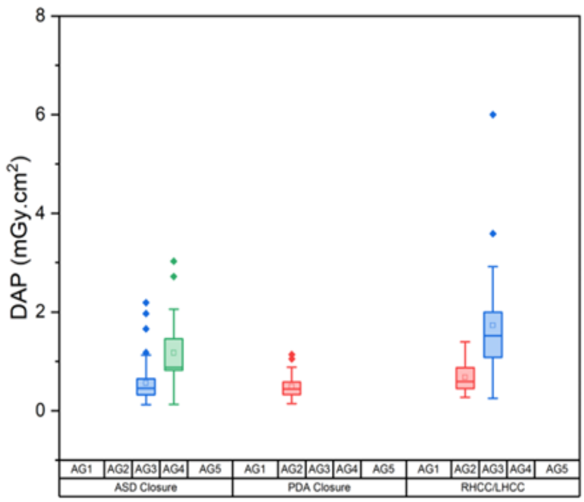

Figure 6: The box plot of DAP for each procedure type based on age groups.

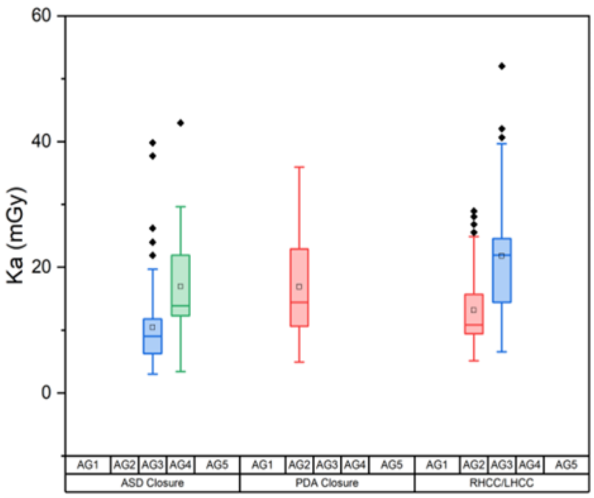

Figure 7: The box plot of Ka for each procedure type based on age groups.

The box plot of FT for each procedure type based on age groups is shown in Figure 8. The median FT value for the AG3 during the ASD closure procedure is 4.28 minutes (IQR: 2.58– 5.38 minutes); and for the AG4 is 4.63 minutes (IQR: 3.23-7.23 minutes). For the RHCC/LHCC procedure, the median FT value for the AG2 is 3.07 minutes (IQR: 2.05-5.19 minutes), and for the AG3 is 3.28 minutes (IQR: 2.70– 5.20 minutes). For the PDA closure procedure, the median FT value for the AG2 is 4.03 minutes (IQR: 3.18–5.19 minutes).

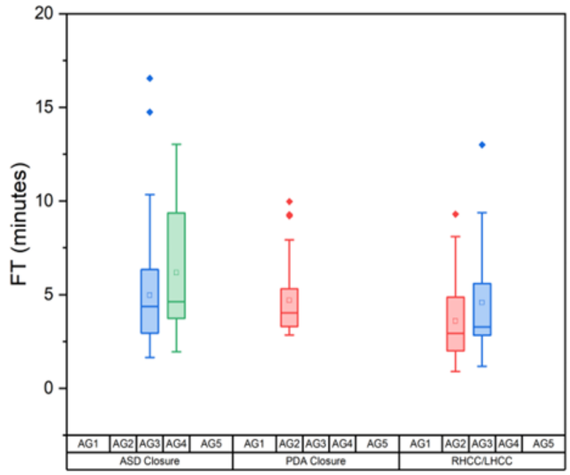

Figure 8: The box plot of FT for each procedure type based on age groups.

4. DISCUSSION

In terms of radiation protection (RP), optimizing patient exposure is a crucial aspect of medical imaging, particularly in IC procedures, as they deliver high radiation doses to patients. Radiation dose received by a paediatric patient during an IC procedure is a significant concern since the cells in children are rapidly dividing, making them more vulnerable than adults to long-term stochastic effects from radiation. DRLs serve as tools for quality assurance and for optimizing radiation doses in diagnostic and/or therapeutic interventional procedures. Therefore, the present study was conducted as the first dosimetric survey aimed at the preliminary estimation of multiple IDRLs for most common IC procedures performed on children, in alignment with the ICRP135 definition of different DRL types, at one of the main paediatric hospitals in Sri Lanka.

Due to limitations in sample size, the study determined IDRLs only for three IC procedures: RHCC/LHCC, PDA closure, and ASD closure. Even for these three procedures, the IDRLs could be determined only for specific weight and age groups and based on limited dosimetric quantities. It was observed that for some procedures, while IDRLs could be determined for certain weight groups, they could not be established for the equivalent age groups, and vice versa.

The study determined the IDRLs for RHCC/LHCC procedure and PDA closure procedures based on WG2 and also based on its equivalent age group (AG2). But for ASD closure procedure it was only able to determine the IDRL based on WG2 (Figure 1 and Figure 2). Since the median and mean ages, 5 yrs and 5.15 yrs respectively, within the WG2 of ASD closure procedure were not consistent with the mid-point of the equivalent age ranges of the European guidelines, it is not possible to use the IDRLs determined for ASD closure procedure based on WG2 interchangeably for its equivalent age group (AG2). This difference between the equivalent age and weight groups are due to the body size differences of Asian and European people.

ure procedure based on WG2 interchangeably for its equivalent age group (AG2). This difference between the equivalent age and weight groups are due to the body size differences of Asian and European people.

Based on the results of the present study, the proposed IDRLs for each procedure with those of published studies are presented in table 3, table 4, and table 5 for WG2, WG3, and WG4 respectively. Table 6, table 7, and table 8 show the IDRLs determined by the present study for AG2, AG3, and AG4 respectively.

According to the comparisons (Table 3, Table 4, Table 5), it was noticed that all the multiple IDRLs determined based on weight by the present study for selected IC procedures are below those of published studies. Further, it was noticed that the IDRL values determined by the present study are very closer to some published studies such as the study done in Italy in 2020, while noticeably lower than some published studies such as the studies done in Chile, Argentina, and Brazil (De Montea et al., 2020; Ubeda et al., 2020; Azcurra et al., 2023; Yagui et al., 2024; Asfora et al., 2024). This difference may be mainly due to the different stratification methods of IC procedures used in the studies. In the study done in Italy, the IDRLs were defined separately for each IC procedure similar to the present study while in the other studies, the IDRLs were determined by classifying the IC procedures into two main types of procedures such as diagnostic IC procedures and therapeutic IC procedures or by considering all IC procedures based on a selected weight group. The observed differences between studies should be interpreted cautiously because methodological differences, including procedure stratification, patient characteristics, and study design, may influence the reported IDRLs. In addition, factors reported in the literature, such as operator experience, imaging protocols, fluoroscopy system characteristics, and procedural complexity, may contribute to inter-study variation. However, these variables were not evaluated in the present study; therefore, their individual contribution cannot be determined.

When the IDRLs determined based on age by the present study are checked with the only published study which has used the similar age group classification, it was found that the IDRLs determined based on K_a for AG2 of ASD closure and RHCC/LHCC procedures in the present study are higher than those in the published study while the IDRL determined using FT is lower than and the IDRL determined using DAP is similar to those in the published study (Table 6). The higher values found in the present study may be due to the different categorization of IC procedure such as diagnostic and therapeutic procedures in the study done in South Africa rather considering the IC procedures separately. All the IDRLs determined for AG3 and AG4 for ASD closure and RHCC/LHCC procedures in the present study are below to the values published in the study done in South Africa (Table 7, Table 8).

r AG3 and AG4 for ASD closure and RHCC/LHCC procedures in the present study are below to the values published in the study done in South Africa (Table 7, Table 8).

Table 3: Comparison of IDRLs determined by the present study with median values of published studies for WG2.

Country	IDRLs for RHCC/LHCC			IDRLs for PDA closure			IDRLs for ASD closure		
	DAP ($Gy.cm^2$)	Ka (mGy)	FT(minutes)	DAP ($Gy.cm^2$)	Ka (mGy)	FT(minutes)	DAP ($Gy.cm^2$)	Ka (mGy)	FT(minutes)
Italy (De Montea et al., 2020) (n=22)				1.9	34.2	5.9			
Chile (Ubeda et al., 2020) (n=77)	2.7	38.6	9.9	2.7	38.6	9.9	2.7	38.6	9.9
Argentina (Azcurra et al., 2023) (n=80)	5.3	78.5	13.3	5.3	78.5	13.3	5.3	78.5	13.3
Brazil (Asfora et al., 2024) (n=108)	3.4	47.7		4.9	91.4		4.9	91.4	
Brazil (Yagui et al., 2024)	2.2			2.7			2.7		
Present study	0.7	13	3.1	0.5	14.9	4.0	0.4	7.9	4.3

Table 4: Comparison of IDRLs determined by the present study with median values of published studies for WG3.

Country	IDRLs for RHCC/LHCC			IDRLs for ASD closure		
	DAP($Gy.cm^2$)	Ka(mGy)	FT(minutes)	DAP($Gy.cm^2$)	Ka(mGy)	FT(minutes)
Italy (De Montea et al., 2020) (n=33)				1.2	9.7	5.6
Chile (Ubeda et al., 2020)	6.9	69	12.0	6.9	69	12.0

(n=64)						
Argentina (Azcurra et al., 2023) (n=85)	10.9	107	12.3	10.9	107	12.5
Brazil (Asfora et al., 2024) (n=61)	3.3	42.2		8.1	124	
Brazil (Yagui et al., 2024)	3.2			5.4		
Present study	1.7	22.4	4.8	0.6	9.5	4.6

Table 5: Comparison of IDRLs determined by the present study with median values of published studies for WG4.

Country	IDRLs for ASD closure		
	DAP (Gy.cm^2)	Ka(mGy)	FT(minutes)
Italy (De Montea et al., 2020) (n=21)	1.7	14.1	5.0
Chile (Ubeda et al., 2020) (n=25)	14.2	97.4	12.9
Argentina (Azcurra et al., 2023) (n=22)	8.5	73.5	8.5
Brazil (Asfora et al., 2024) (n=36)	52.7	361	
Brazil (Yagui et al., 2024)	5.5		
Present study	0.9	12.8	4.6

Table 6: Comparison of IDRLs determined by the present study with the values of published studies for AG2.

Country	IDRLs for RHCC/LHCC			IDRLs for PDA closure		
	DAP(Gy.cm^2)	Ka(mGy)	FT(minutes)	DAP(Gy.cm^2)	Ka(mGy)	FT(minutes)
South Africa (Jonathan & Thembisa, 2022) (n=100)	0.6	7	9.6	0.8	10.4	9.6
Present study	0.6	11	3.1	0.5	14.9	4.0

Table 7: Comparison of IDRLs determined by the present study with the values of published studies for AG3.

Country	IDRLs for RHCC/LHCC			IDRLs for ASD closure		
	DAP(Gy.cm^2)	Ka(mGy)	FT(minutes)	DAP(Gy.cm^2)	Ka(mGy)	FT(minutes)
South Africa (Jonathan & Thembisa, 2022) (n=59)	3.0	26	13.6	2.0	16.2	11.0
Present study	1.5	20.8	3.3	0.5	9.0	4.3

Table 8: Comparison of IDRLs determined by the present study with the values of published studies for AG4.

Country	IDRLs for ASD closure	
	Ka(mGy)	FT(minutes)
South Africa (Jonathan & Thembisa, 2022) (n=42)	41.0	13.4
Present study	13.3	4.6

The present study had some limitations. The IDRL values proposed for PDA closure procedure have not been determined separately for PDA closure using a coil and PDA closure using a device due to the lack of sample size. Further, the present study was unable to determine IDRLs based on the total number of images acquired (F) and for some BW and age groups due to lack of data. Moreover, the present study was unable to propose IDRLs for the IC procedures such as balloon aortic valvuloplasty (BAV), balloon pulmonary valvotomy (BPV), and coarctation of the aorta dilation (COA dilation) which are rarely performed at this hospital due to the time limitation.

5. CONCLUSION

The multiple IDRLs presented in this paper could be used by LRH, Sri Lanka for optimizing the radiation dose given to a paediatric patient during RHCC and LHCC procedures, PDA closure procedures, and ASD closure procedures. Further studies should be carried out by the relevant authorities in the country towards establishing IDRLs and NDRLs for paediatric IC procedures.

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