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Local diagnostic reference levels in diagnostic and therapeutic pediatric cardiology at a specialist pediatric hospital in South Africa

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Abstract

Introduction: Children may be at a higher risk of experiencing the detrimental effects of ionizing radiation arising from medical radiation imaging. Dose optimisation is therefore recommended to provide assurance that their exposure is as low as reasonably achievable. To this end, periodic assessment of dose levels and establishment of Local Diagnostic Reference Levels (LDRLs) in medical facilities is necessary. There is a general paucity in the literature of data pertaining to dose levels in pediatric interventional radiology. This study establishes LDRLs in diagnostic and therapeutic heart catheterization procedures at a specialist pediatric hospital in a resource constrained country.

Material and methods: Dose indicators from actual patient procedures were collected from the archive and analyzed retrospectively to determine the median, 25th, and 75th percentiles of the total Air Kerma Area Product (KAP), Cumulative Air Kerma (CAK), total Fluoroscopy Time (FT), and a total number of Cine Images (CI) of selected interventional procedures. The dose indicators were also age-stratified into five age groups defined by the International Commission on Radiation Protection publication 135. The results were compared to values available from similar studies in the literature to benchmark our dose levels. Local Dose Reference Levels were set as the 75th percentile values.

Results: For diagnostic procedures (n = 80), the 75th percentiles of KAP, CAK, FT, and CI were 4.0 Gy·cm^2, 31.5 mGy, 14.3 min, and 315 frames, respectively and 3.2 Gy·cm^2, 30.5 mGy, 17.5 min, and 606 frames, respectively for therapeutic procedures (n = 143).

Conclusions: The LDRLs from this study did not vary significantly from those published in the literature, suggesting that practices at our center were comparable to international norms. Regular reviews of the LDRLs must be conducted to check that the dose levels do not deviate considerably.

Keywords: pediatric cardiology; interventional; diagnostic reference levels; cathlab.

Introduction

Interventional radiology (IR) is useful in pediatric patients both for the diagnosis and minimally invasive treatment of congenital and acquired conditions. Compared to surgery, IR has the benefits of reduced invasiveness and shorter recovery time.[1] Since the idea of using image guidance for surgical procedures was first mooted in the 1970s, the number and types of procedures have grown so considerably that IR is now a subspecialty, requiring unique imaging equipment, tools, and training.[2] Although IR employs both ionizing and non-ionizing types of radiation for image guidance, the use of Magnetic Resonance Imaging (MRI) and Ultrasound (US) is not as wide as X-ray based Fluoroscopy Guidance.[3,4] Therefore, most IR procedures are Fluoroscopy Guided Interventional (FGI) procedures. Such techniques are potentially high dose and may therefore contribute significantly to the total population exposure from medical radiation.[5]

Using ionizing radiation in medical procedures carries a risk of detrimental side-effects.[6] This risk may be exaggerated in children because of their elevated sensitivity to radiation-induced injury compared to adults.[7] In this regard, the "Image Gently" campaign was initiated[8] to raise awareness of children's vulnerability and to encourage the adoption of imaging practices that would reduce radiation dose in pediatric imaging. Procedures in pediatric radiology must be justified to avoid unnecessary exposures and optimized to minimize the radiation dose to "As Low As Reasonably Achievable" (ALARA). To aid in optimisation, the use of Diagnostic Reference Levels (DRLs) for comparison is recommended.[9] It is a regulatory requirement

Authors' contribution: A – Research concept and design, B – Collection and/or assembly of data, C – Data analysis and interpretation, D – Writing the article, E – Critical revision of the article, F – Final approval of the article.

in South Africa to appoint a qualified Medical Physicist to monitor the total Air Kerma Area Product (KAP), total Fluoroscopy Time (FT), and Cumulative Air Kerma at a Reference Point (CAK) in fluoroscopically guided interventional (FGI) procedures, to establish local DRLs and to review them periodically.[10] Historically, DRLs in FGI were typically reported as KAP and FT. However, it is now common to find the use of CAK and the total number of frames as well in publications.

Center-wide DRLs, designated for local or institutional DRLs are defined as the 75th percentile of the distribution of values of a dose indicator from locally sourced data, while a DRL established for a wider national or regional population is defined at the 75th percentile of the distribution of median values of the indicator.[11] There is an overall shortage of DRL data for pediatric FGI procedures and, to the best of the authors knowledge, no South African DRLs exist. This study establishes institutional DRLs for diagnostic and therapeutic procedures in pediatric interventional cardiology at a specialist pediatric hospital.

Approval to use patient data was obtained from the University of Cape Town's Faculty of Health Sciences Human Research Ethics Committee (REF: 127/2022).

Materials and methods

Fluoroscopy unit

This retrospective study was conducted at Red Cross War Memorial Children's Hospital (RXH), a 272-bed tertiary-level specialist state pediatric hospital in the Western Cape province in South Africa and affiliated with the Faculty of Health Sciences of the University of Cape Town. The review period was from 1 August 2020 to 31 December 2021.

The hospital has a dedicated heart catheterization laboratory equipped with a Philips Azurion Clarity IQ (Philips Healthcare, Eindhoven, The Netherlands) – a biplanar, isocentric interventional cardiology system commissioned in 2020. It has the features typical of a modern, flat panel detector (FPD) fluoroscopy imaging device with software enhancements for dose reduction.[12,13] The exposure protocols were purposefully configured for pediatric imaging. After every procedure, a Radiation Dose Structured Report (RDSR) is generated and saved to the hospital's Picture Archiving and Communication System (PACS). All the quality control tests required by regulations were up to date and well within tolerance limits.[10]

Data acquisition

Radiographers compile procedure-specific data into a spreadsheet and send the records to a Medical Physicist every month. Each record captures the date, patient accession number, name of the responsible physician, name of the radiographer, name of the procedure, KAP, CAK, and FT. For this study, the KAP, CAK, and FT captured over the review period, together with associated patient age and the number of cine images (CI) obtained from PACS were collated and evaluated.

The FGI procedures were classified as diagnostic (Hemodynamic studies and Angiography) or therapeutic [Pulmonary Balloon Valvuloplasty (PBV), Patent Ductus Arteriosus closure (PDA), Aortic Balloon Valvuloplasty (ABV), Pacemaker placement, Atrial Septal Defect (ASD), Ablation, Stenting and Balloon Dilatation)].

Since the system was biplanar, the KAP, CAK, FT, and CI for each procedure were expressed as the sum of the quantities from both tubes. We deemed it unnecessary to correct the dose indices for the presence of patient-support devices in the AP-PA direction. Statistical analyses of values were performed, initially in their binomial classification, and then stratified into five age bands as defined in **Table 1**.

Table 1. Age bands and ranges in accordance with recommendations of ICRP 135.[11]

Band	0	1	5	10	15
Age range	0 to < 1 month	1 month to 4 years	4 to < 10 years	10 to < 14 years	14 to < 18 years

Statistical analysis

The Frequency distributions of diagnostic and therapeutic heart catheterisation procedures are illustrated in pie charts, while the distributions of age-related dosimetric quantities are depicted in boxplots and correlation matrices. Statistical data analyses and the creation of charts were performed with Microsoft Excel (Microsoft Corporation, Redmond, WA, USA) and Python (Python Foundation, Wilmington, DE, USA). The Pearson correlation coefficient test was used to evaluate the degree of correlation amongst the age, KAP, CAK, FT and CI, while the Mann-Whitney U-test compared the differences between diagnostic and therapeutic dose indicators. In all cases, the significance level was set to 5% (where *p*-values < 0.05 indicated that the results were statistically significant). Both tests were performed with the Social Science Statistics online calculator.[14]

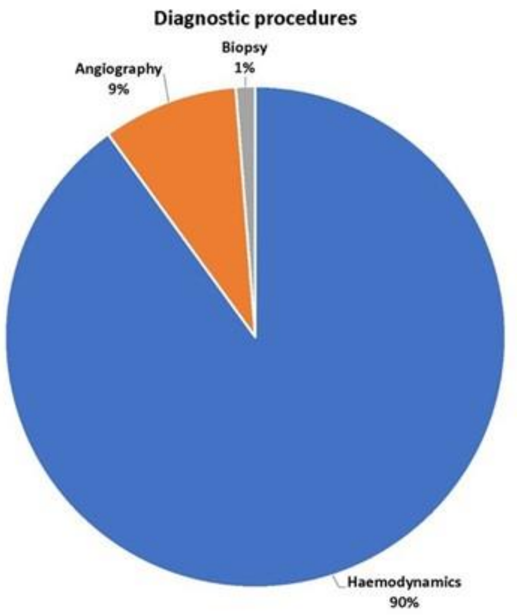
Results

A total of 223 catheterization procedures were recorded over the period under investigation. Eighty of these were diagnostic examinations, while 143 were therapeutic. The median age, 25th, and 75th percentile in years of all the patients encountered were 4.1, 1.9 and 9.8, with minimum and maximum being 0.7 and 17.5 years, respectively. For both classes of procedures, most patients were in the Band 1 age group (N = 36, N = 64 for diagnostic and therapeutic procedures, respectively), while the age Band 0 saw the least number (N = 2, N = 8).

Figure 1 shows the frequency distribution of all procedures. The 75th percentile values for KAP, CAK, FT and CI (proposed as the LDRLs) of all diagnostic procedures were 4.0 Gy·cm^2, 31.5 mGy, 14.3 min and 315, respectively, and those for therapeutic procedures were 3.2 Gy·cm^2, 30.5 mGy, 17.5 min and 606, respectively (**Table 2**). The age-stratified values are also shown in **Table 2**, while **Figure 2** and **Figure 3** illustrate age-stratified boxplots. The correlation amongst age, KAP, CAK, FT, and CI is depicted in **Figure 4**.

The four most common procedures were Hemodynamic studies (N = 71), PBV (N = 50), PDA (N = 46), and ABV (N = 27) and accounted for 87% (N = 194) of the workload. The associated 75th percentile values were: Hemodynamic studies (KAP = 4.0 Gy·cm^2, CAK =31.0 mGy, FT = 14.8 min, CI = 315), PBV (KAP = 6.0 Gy·cm^2, CAK = 51.7 mGy, FT = 20.4 min, CI = 772), PDA (KAP = 2.3 Gy·cm^2, CAK = 21.9 mGy, FT = 15.4 min, CI = 364) and ABV (KAP = 2.8 Gy·cm^2, CAK = 18.0 mGy, FT = 18.0 min, CI = 658) as shown in **Table 3**. The highest and lowest 75th percentile values for KAP and CAK were recorded for PBV (KAP = 6.0 Gy·cm^2, CAK = 51.7 mGy) and ABV (KAP = 2.8 Gy·cm^2, CAK = 18.0 mGy).

Table 4 compares therapeutic and diagnostic dose indices, while **Table 5** compares the results of our paper with those from international studies.



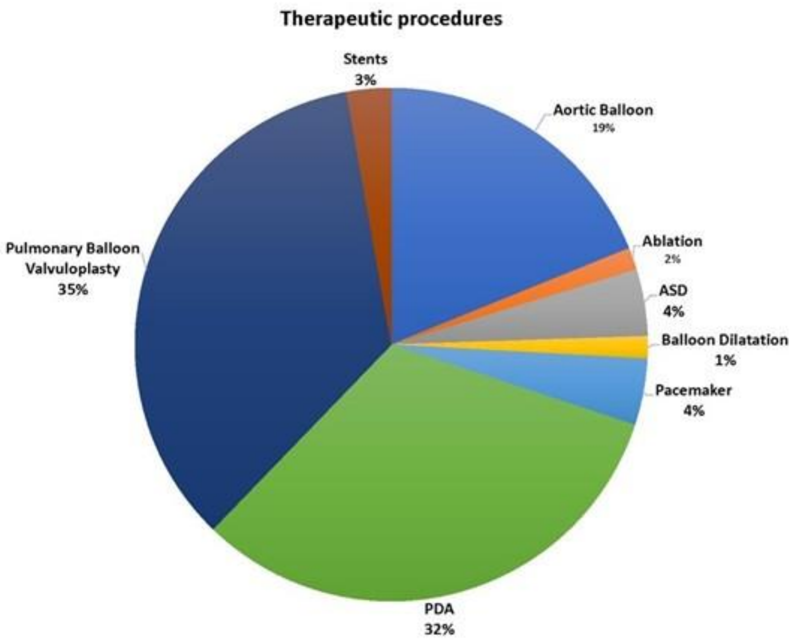


Figure 1. Frequency distributions of diagnostic and therapeutic heart catheterisation procedures. PDA = Patent Ductus Arteriosus Closure, ASD = Atrial Septal Defect.

Table 2. Radiation dose indicators for diagnostic and therapeutic heart catheterizations stated as the median and in parenthesis, the 25th and 75th percentiles. CAK = Cumulative Air Kerma, KAP = Dose Product, FT = Fluoroscopy Time, CI = Cine Image.

Age Group	N	KAP (Gy·cm^2)	CAK (mGy)	FT	CI
All procedures					
All	223	1.3 (0.6; 3.5)	13.3 (6.3; 31.4)	10.1 (6.3; 16.4)	236 (86; 490)
Diagnostic					
All	80	1.3 (0.5; 4.0)	12.9 (6.0; 31.5)	9.9 (6.0; 14.3)	161 (4; 315)
0	2	0.12	1.63	5.90	0
1	36	0.6 (0.3; 1.4)	7.0 (3.3; 13.9)	9.6 (6.1; 13.5)	86 (0; 251)
5	18	3.0 (1.3; 4.1)	26.0 (11.6; 35.8)	13.1 (8.4; 20.3)	167 (109; 267)
10	20	4.3 (1.2; 6.0)	29.1 (11.9; 45.8)	7.1 (4.3; 13.0)	258 (75.5; 474)
15	4	6.0 (1.7;12.5)	45.1 (11.9; 73.2)	12.9 (2.9; 16.8)	256 (62; 441)
Therapeutic					
All	143	1.3 (0.6; 3.2)	13.3 (7.0; 30.5)	10.2 (6.4; 17.5)	294 (156; 606)
0	8	0.6 (0.2; 0.7)	6.6 (4.2; 10.0)	7.7 (3.8; 13.5)	427 (254; 608)
1	64	0.8 (0.4; 1.2)	10.4 (5.0; 16.5)	9.6 (6.3; 15.3)	346 (180; 681)
5	41	2.0 (1.2; 3.5)	16.2 (9.1; 32.4)	11.0 (7.2; 17.6)	265 (159; 663)
10	22	5.3 (1.7; 9.4)	41.0 (11.5; 69.6)	13.4 (5.6; 23.5)	243 (40; 427)
15	8	12.8 (3.0; 54.8)	87.4 (19.4; 411.5)	15.4 (5.1; 35.2)	126 (30; 690)

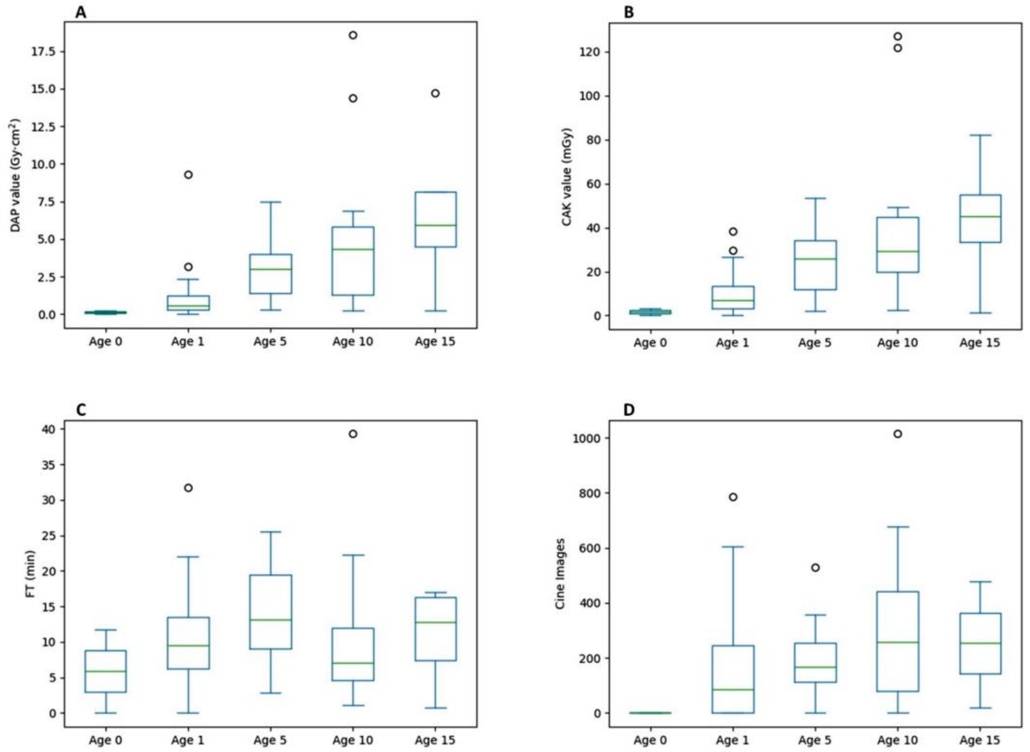


Figure 2. Box plots showing values of (A) total Kerma Area Product (KAP), (B) Cumulative Air Kerma, (C) total Fluoroscopy Time (FT), and (D) number of Cine Images for diagnostic procedures for each age band. Box plot midlines indicate medians, outer lines indicate 25th and 75th percentiles respectively, and whiskers indicate the range of data points excluding outliers represented by blank circles. Outliers are those values lying outside 1.5 times the Interquartile range (IQR) above the upper quartile and below the lower quartile.

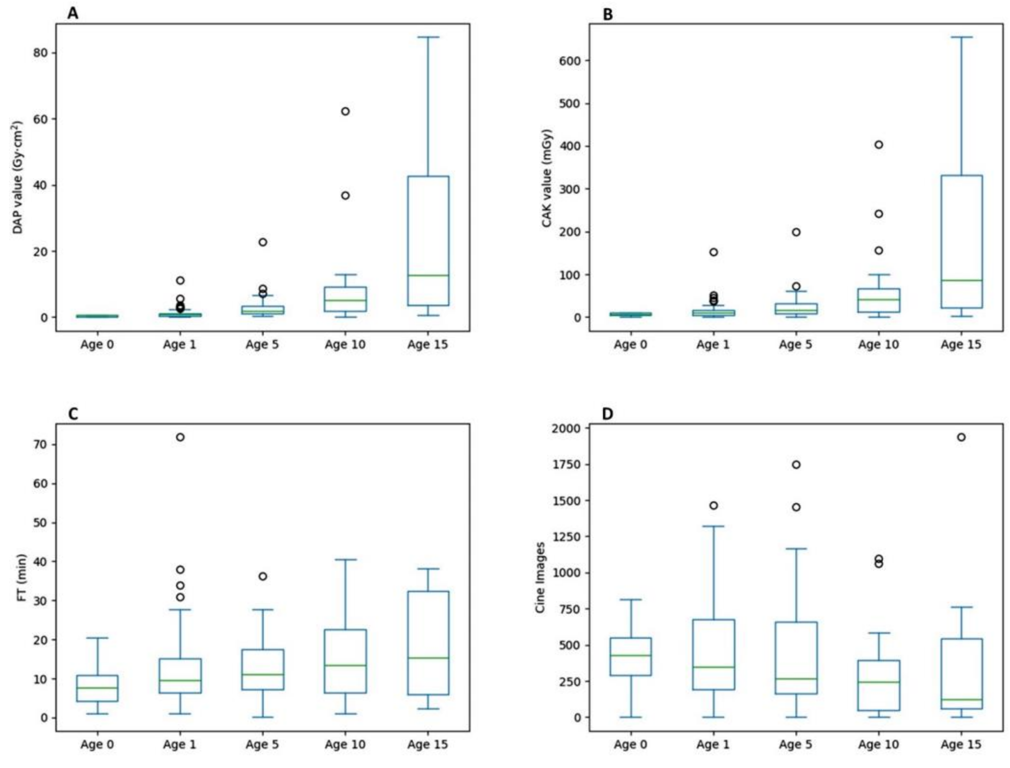


Figure 3. Box plots showing values of (A) total Kerma Area Product (KAP), (B) Cumulative Air Kerma, (C) total Fluoroscopy Time (FT), and (D) number of Cine Images for therapeutic procedures for each age band. Box plot midlines indicate medians, outer lines indicate 25th and 75th percentiles respectively, and whiskers indicate the range of data points excluding outliers represented by blank circles. Outliers are those values lying outside 1.5 times the Interquartile range (IQR) above the upper quartile and below the lower quartile.

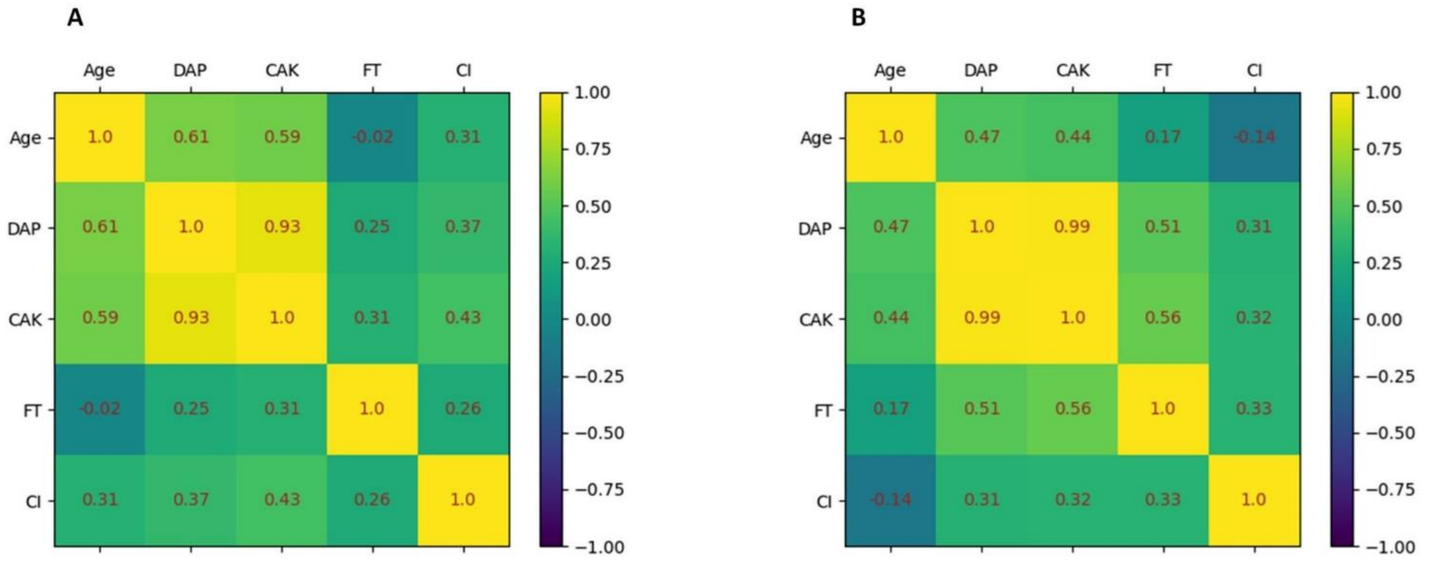


Figure 4. Correlation matrices showing the degrees of correlation between age and values of total Kerma Area Product (KAP), Cumulative Air Kerma (CAK), total Fluoroscopy Time (FT), and number of Cine Images (CI) for (A) diagnostic procedures and (B) therapeutic procedures. The numbers inside the squares are the Pearson correlation coefficient for each value pair.

Table 3. Radiation dose indicators for Haemodynamic study, PDA, PBV, and ABV stated as the median and in parenthesis, the 25th and 75th percentiles. These procedures had the highest frequencies in the study cohort. PDA = Patent ductus arteriosus closure, PBV = Pulmonary Balloon Valvuloplasty, ABV = Aortic Balloon Valvuloplasty, CAK = Cumulative Air Kerma, KAP = Kerma Area Product, FT = Fluoroscopy Time, CI = Cine Image.

Procedure	N	KAP (Gy·cm^2)	CAK (mGy)	FT	CI
Hemodynamics	71	1.3 (0.6; 4.0)	12.3 (6.1; 31.0)	11.2 (6.5; 14.8)	161 (1; 315)
PBV	50	1.7 (0.9; 6.0)	19.0 (10.3; 51.7)	14.7 (9.8; 20.4)	506 (252; 772)
PDA	46	0.9 (0.6; 2.3)	11.7 (7.1; 21.9)	9.6 (6.6; 15.4)	232 (165; 364)
ABV	27	0.5 (0.3; 2.8)	7.7 (4.6; 18.0)	6.6 (5.4; 18.0)	440 (175; 658)

Table 4. Comparison of CAK, KAP, FT, and CI at the 75th percentile for diagnostic and therapeutic procedures. P values were generated using a two-tailed Mann-Whitney U-test with a 0.05 significance level. PDA = Patent ductus arteriosus closure, PBV = Pulmonary Balloon Valvuloplasty, ABV = Aortic Balloon Valvuloplasty, CAK = Cumulative Air Kerma, KAP = Kerma Area Product, FT = Fluoroscopy Time, CI = Cine Images, Q3 = 75th percentile.

	Present study					Ubeda et al.[15]					Ishibashi et al.[21]				
	Diagnostic		Therapeutic		*p*	Diagnostic		Therapeutic		*p*	Diagnostic		Therapeutic		*p*
	N	Q3	N	Q3		N	Q3	N	Q3		N	Q3	N	Q3	
CAK	80	31.5	143	30.5	0.674	200	31.4	317	43.1	0.01	272	142.1	57	189	0.588
KAP	80	4.0	143	3.2	0.841	200	2.8	317	2.47	0.131	220	13.8	50	13.5	0.938
FT	80	14.3	143	17.5	0.002	200	15.9	317	20.6	0.001	276	32.7	57	55	0.0001
CI	80	315	143	606	< 0.01	200	1001	317	892	0.001	247	2265	47	4132	0.0009

Table 5. A comparison of median KAP, CAK, FT, and CI of the four most frequent procedures in this study and median values from the literature. PDA = Patent ductus arteriosus closure, PBV = Pulmonary Balloon Valvuloplasty, ABV = Aortic Balloon Valvuloplasty, CAK = Cumulative Air Kerma, KAP = Kerma Area Product, FT = Fluoroscopy Time, CI = Cine Images.

	PDA		PBV		Hemodynamics		ABV	
	This study	Ubeda et al.[15]	This study	Ubeda et al.[15]	This study	Sutton et al.[22]	This study	Ghelani et al.[23]
N	46	126	50	42	71	18	27	297
KAP (Gy·cm^2)	0.9	0.8	1.7	0.6	1.3	0.16	0.5	14
CAK (mGy)	11.7	-	19.0	-	12.3	1.5	7.7	297
FT (min)	9.6	8	14.7	6.0	11.2	3.7	6.6	25
CI	232	435	506	771	161	-	440	-

Discussion

Over the period of review, more instances of therapeutic than diagnostic procedures were observed (**Figure 1**). This may suggest that alternative means of diagnosis, such as echocardiography or ultrasound, had been used, or that individual patients had multiple follow-up therapeutic procedures. An investigation into these scenarios is the subject for a separate study. The patient records encountered during our review did not include weight and therefore, our DRLs were age-stratified (**Table 2**). Although ICRP Publication 135[11] recommends that pediatric DRLs be weight stratified, it also correctly notes that patient weights may not be readily available and therefore proposes age-stratification in the interim (**Table 1**).

The boxplots in **Figure 2** and **Figure 3** show outliers. Those observed in diagnostic procedures arose when angiography was added to what had initially begun as Hemodynamic studies. The outliers found in therapeutic studies occurred in those instances when procedures were performed by less experienced registrars (resident doctors) instead of a consultant, or by registrars without supervision by a consultant.

Our results confirmed a positive correlation between KAP, CAK and age (**Figure 4**). This correlation was more pronounced in diagnostic than therapeutic procedures with the correlation coefficients comparable in magnitude to the weight vs KAP and CAK coefficients reported by Ubeda et al.[15] We note the limited data in the 0-age band for diagnostic procedures. We opted nonetheless to report the results for completeness. Comparisons with results in the literature are shown in **Table 4** and **Table 5**. The differences between therapeutic and diagnostic procedures were significant for FT and CI, in keeping with the observations of other authors.[15,21]

KAP and CAK are the two dose indicators in radiology that most closely relate to the risk of radiation effects developing in patients. Our results show a strong correlation between these two parameters (**Figure 4**), an observation that is expected since their values are equally affected by exposure technique factors. KAP correlates well with the total energy imparted to the patient during fluoroscopic procedures and is used to estimate the risk of stochastic effects.[16] CAK, on the other hand, is directly proportional to and usually calibrated in terms of the Entrance Surface Air Kerma (ESAK).[17] It is thus well suited for estimating the risk of radiation-induced skin injury, an important consideration in FGI procedures. Such a risk may vary between patients, but a threshold of 2000 mGy CAK was suggested by ICRP publication 85.[18] Results from our study and others demonstrate that typical CAK in pediatric interventional radiology are orders of magnitude less than this threshold. As such, unless a patient is unusually large, or undergoes a series of repeated procedures in short succession involving imaging to the same location of the body, deterministic injuries may be less of a concern in children than the risk of cancer induction.[19]

The FT and CI observed in our results demonstrate weak and moderate, but statistically significant correlations with KAP and CAK in diagnostic and therapeutic FGI procedures, respectively. The coefficients of determination (R^2) in all cases implied that the relationships were not strong in practice. **Table 2** also shows that procedures may have significantly different FT and CI values but still have comparable values of CAK and KAP. In **Table 3**, we observed that CI was directly proportional to the complexity of the procedure: the most complex PBV had the highest median CI (506), followed by ABV (440), PDA (232), and the diagnostic Hemodynamic studies (161). The same could not be said for FT. Some authors, however, state that FT and CI values may be good indicators of the level of skill of performing clinicians.[20] Although we did not investigate this claim, we observed a few outliers that were attributed to inexperience.

Ishibashi et al.[21] proposed Japanese DRLs from a nationwide survey of 132 pediatric facilities. Their dose indicators were expectedly higher than our study owing to the wider variation in equipment and practices. A better agreement is observed when our results are compared to those of Ubeda et al.[15], with LDRLs established for a single-unit facility. The notable differences observed in the number of cine images may be attributed to variations in protocols – the acquisition protocols at RXH tend to use a typical frame rate of 7.5 fps and never exceed 15 fps.

The median dose values for Haemodynamic studies were higher than those published by Sutton et al.[22], although their sample size was smaller. Our PBV median values were also higher than those of Ubeda et al.[15] The median CI was however lower. Finally, our ABV dose indices were significantly lower than the median values reported by Ghelani et al.[23]

In general, the magnitude of dose indices observed in this study suggests that clinical practices at RXH Cathlab are comparable to those of international peers. There is however potential for further dose optimization. More realistic comparisons would be made with other state pediatric centers within the country as the patients are drawn from a similar demographic profile.

Recommendations

The authors recommend that a general directive be issued to compel centers to capture weight data for pediatric imaging procedures – including cardiology, to aid in establishing weight-stratified DRLs as recommended by ICRP Publication 135. In recording the dosimetric data, the patient's identification number, which remains invariant across all radiological examinations must be used instead of the accession number. In that way, any dose arising from follow-up procedures may be properly accounted for. At the time of writing this report, a centralized Radiation Dose Monitor had been installed to autonomously log and archive dose indicators from RDSR files captured at the modality. We recommend that other centers in the country having interventional radiology facilities do likewise to enable seamless and accurate archiving of dose data.

Conclusion

There is a general paucity in dose data in pediatric interventional radiology. The results presented in this paper are an initial attempt at establishing local DRLs in pediatric heart catheterisation procedures. Our DRLs comparable to the results of similar studies available in the literature. Although ICRP 135 recommends that DRLs be stratified in patient weight bands, it is also acceptable to use age stratification where weight data are unavailable. A significant limitation encountered in this study was the small sample size, more so for diagnostic procedures. To the best of our knowledge, no such data have been published in South Africa, and we hope that our results could be used as a benchmark by other pediatric centers in the country wishing to audit their own practices.

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