Pediatric Diagnostic Reference Levels for Diagnostic and Therapeutic Cardiac Catheterization in Japan

Toru Ishibashi (✉ i_toru_1221@yahoo.co.jp)

Tsuchiya General Hospital <https://orcid.org/0000-0003-4911-866X>

Yasutaka Takei

Department of Radiological Technology, Faculty to Health Science and Technology

Mamoru Kato

Department of Radiology and Nuclear Medicine, Akita Cerebrospinal and Cardiovascular Center

Yukari Yamashita

Tsuchiya General Hospital: Tsuchiya Sogo Byoin

Atsuko Tsukamoto

Department of Radiology, NTT Medical Center Tokyo

Kazuma Matsumoto

Department of Clinical Radiology, Hyogo College of Medicine College Hospital

Hajime Sakamoto

Department of Radiological Technology, Faculty of Health Science, Juntendo University

Takanori Masuda

Department of Radiological Technology, Tsuchiya General Hospital

Osamu Miyazaki

Dept of Radiology, National Center for Child Health and Development

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Abstract

To propose Japanese national DRLs for air-kerma at the reference point ($K_{a,r}$), air-kerma area product (P_{KA}), fluoroscopy time (FT), and number of cine images (CI) for four age groups. We posted a nationwide questionnaire to 132 facilities. Questions focused on identifying the procedure, age, weight, height, $K_{a,r}$, P_{KA} , FT, and CI during diagnostic and therapeutic pediatric cardiac catheterization. For diagnostic cardiac angiography, the 75th percentile values were as follows; $K_{a,r}$: 103, 127, 194, and 351 mGy; P_{KA} : 7.0, 12.3, 14.3, and 47.2 Gy.cm²; FT: 36.8, 30.7, 33.4, and 35.7 min; and CI: 2018, 2313, 2408, and 2016 images for less than one year, 1–5 years, 6–10 years, and 11–15 years respectively. For therapeutic cardiac angiography, the 75th percentile values were as follows: $K_{a,r}$: 146, 209, 130, and 501 mGy; P_{KA} : 7.54, 16.0, 8.35, and 46.0 Gy.cm²; FT: 56.5, 52.0, 49.4, and 52.0 min; and CI: 4075, 4514, 3576, and 5984 images for less than one year, 1–5 years, 6–10 years, and 11–15 years respectively. Our survey of diagnostic and therapeutic cardiac catheterization in Japanese pediatric patients showed that all age-based Japanese 75th percentiles for the $K_{a,r}$, P_{KA} , FT, and CI were higher than in other surveys. Based on the result of our study, it is necessary to establish DRLs for pediatric cardiac catheterization examinations in Japan, in order to optimize the safety of pediatric protocols for diagnostic and therapeutic cardiac catheterization.

Introduction

Fluoroscopy-guided procedures have been used more frequently for pediatric patients in recent years[1, 2]. However, some organs and tissues in children are more sensitive to ionizing radiation and have greater potential to develop malignancies associated with diagnostic medical radiation [3, 4]. According to the UNSCEAR report, estimates of lifetime cancer risk for those exposed as children are uncertain and might be a factor of 2–3 times greater than estimates for a population exposed at all age [5]. The “as low as reasonably achievable” (ALARA) concept emphasizes radiation dose reduction while still maintaining acceptable image quality [6]. It is thus necessary to optimize programs for radiation safety, as well as characterizing dose, x-ray image quality, imaging systems and measurement of patient doses related to diagnostic and therapeutic cardiac catheterization in the pediatric population.

One possible solution for optimal determination of diagnostic and therapeutic radiation doses, establishment of a local diagnostic reference level (DRL), is currently under consideration in several countries[7–10]. A certain level of control is necessary for radiation exposure of patients, therefore, the International Commission on Radiological Protection (ICRP) has recommended the use of DRLs [11]. However, these have not yet been evaluated for pediatric cardiac catheterization in Japan. Furthermore, according to ICRP publication 135, there are no current national DRL values for pediatric interventional radiology or interventional cardiology anywhere in the world[12].

The purpose of this study was to conduct a nationwide questionnaire survey concerning air-kerma at the reference point ($K_{a,r}$), air-kerma area product (P_{KA}), fluoroscopy time (FT), and number of cine images (CI) during diagnostic and therapeutic cardiac catheterization in Japanese pediatric patients, and to propose national DRLs for four pediatric age groups—less than one year, 1–5 years, 6–10 years, and 11–15 years. This research may represent the first national DRL report published anywhere in the world.

Materials And Methods

This retrospective study was approved by Tsuchiya General Hospital review board; in-formed consent was waived. And institutional review board approval was not required for this retrospective nationwide questionnaire study. We

sent questionnaires to 132 facilities using conventional post and the e-mail system of the Japanese Society of Radiological Technology. We subsequently received responses by post and e-mail. The survey period was from March 2017 to August 2017.

We also searched the NGC (National Guideline Clearinghouse) and NICE (National Institute for Health and Care Excellence) for clinical guidelines and performed exhaustive searches of PubMed and CiNii. In addition, we performed Internet searches for similar information. Keywords used within the search were “Japan”, “Japanese”, “diagnostic reference level” and “pediatric” (Fig. 1).

Survey items and data analysis

The quantities for the $K_{a,r}$, P_{KA} , FT, and CI were obtained for the questionnaire. $K_{a,r}$ is expressed in Gy. $K_{a,r}$ is the air kerma at a point in space located at a fixed distance from the focal spot (see Patient entrance reference point) cumulated from a whole x-ray procedure. P_{KA} is expressed in $Gycm^2$. P_{KA} is the integral of the air kerma free-in-air (i.e. in the absence of backscatter) over the area of the x-ray beam in a plane perpendicular to the beam axis. The accuracy of the displayed value is $\pm 35\%$ [13]. FT and CI were collected from the displayed values on the Angio device.

For each patient, the identified procedure, age, weight, height, body mass index (BMI), $K_{a,r}$, P_{KA} , FT, and CI were registered. Data were extracted from the patient dose reports produced by the dose reporting system at the end of each procedure. Data for all procedures were divided into two groups (diagnostic and therapeutic) and four age groups that ranged from less than one year, 1–5 years, 6–10 years, and 11–15 years, as was done in previous papers[7–9]. From these data, we extracted the minimum, 25th percentile, median, 75th percentile, and maximum value using the boxplot method. In addition, we compared the 75th percentile in the diagnostic and treatment groups using Mann-Whitney's U test, with $P < 0.05$ regarded as representing a significant difference. Statistical analyses used the free statistical software EZR, version 1.33 (<http://www.jichi.ac.jp/saitama-sct/SaitamaHP.files/statmedEN.html>)[14]. We also investigated fluoroscopy and exposure rates used in diagnosis and treatment. In addition, we examined characteristics of hospitals, vendors, equipment age, and number of analog and digital units.

Results

Among the 132 facilities to which the questionnaires were sent, 43 facilities (33%) responded. Hospital characteristics were as follows: national hospitals (21 facilities), public hospitals (14 facilities) and others (8 facilities). X-ray imaging system vendors were Philips Medical Systems (116 units), Canon Medical Systems Corporation (111 units), Siemens Medical Systems (105 units) and Shimadzu Corporation (1 unit). The total number of units was 333. And equipment age was as follows: less than 5 years (126 units), 5 to less than ten years (176 units), and 10 years or greater (31 units). All imaging units were flat panel detectors for a digital system.

At each facility, we collected up to 10 cases. In total, 333 patients were available for data analysis for both diagnostic cardiac catheterization ($n=276$), at ages less than one year ($n=62$), 1–5 years ($n=137$), 6–10 years ($n=45$) and 11–15 years ($n=32$); and therapeutic procedures ($n=57$) at ages less than one year ($n=7$), 1–5 years ($n=31$), 6–10 years ($n=11$) and 11–15 years ($n=8$). We also accepted blank $K_{a,r}$ ($n=4$), P_{KA} ($n=63$) and CI ($n=39$) values because some angiographic devices cannot display some of these values. Therefore, blank values were

excluded at the time of analysis. The diagnostic and treatment populations were also treated as separate populations.

Patient demographics

The 75th percentiles for diagnostic angiography are shown in Table 2 for those aged less than one year, 1–5 years, 6–10 years and 11–15 years, respectively. Table 3 shows the minimum, 25th percentile, median, 75th percentile, and maximum values for $K_{a,r}$, P_{KA} , FT and CI with therapeutic angiography.

The 75th percentiles for therapeutic angiography are shown in Table 3 for those aged less than one year, 1–5 years, 6–10 years, and 11–15 years. The diagnosis showed that $K_{a,r}$ and P_{KA} tended to increase with age increasing, but no treatment was observed. In addition, FT and CI were age-independent in both diagnosis and treatment.

Table 4 contains Mann-Whitney U test comparisons of the 75th percentiles for diagnosis and treatment. The diagnostic and therapeutic populations were similarly distributed and comparable. There were no significant differences for $K_{a,r}$ and P_{KA} between the diagnostic and therapeutic procedures. However, the FT of therapeutic procedures (55 minutes) was 1.7 times greater than that for diagnostic procedures (32.7 minutes), and the CI of therapeutic procedure (4132 images) was 1.8 times that of diagnostic procedures (2265 images); there were also significant differences in the FT and CI on comparison of diagnostic and therapeutic procedures ($P < 0.05$).

Fluoroscopy Rate and Exposure Rate for Diagnostic and Therapeutic Procedures

The most commonly used fluoroscopy rate for each institution where diagnostic procedures were performed was 7.5 pulses/sec followed by 15, 10, 6, 6.25 and 3 pulses/sec. For diagnostic procedures, the commonest exposure rate was 30 frames/sec, followed by 15, 60 and 25 frames/sec (Fig. 2a-b).

For therapeutic procedures, the fluoroscopy rate at most institutions was 7.5 pulses/sec followed by 15, 10 and 6 pulses/sec. The most commonly used exposure rate during therapeutic interventions was 30 frames/sec, followed by 15, 25, 7.5, 60 and 1 frames/sec (Fig. 2c-d).

Discussion

A great benefit of recent advances in non-invasive examination using modalities like echocardiography, cardiac CT and MRI is that the number of indications for diagnostic cardiac angiography has decreased in comparison with the past. Nevertheless, reliable and detailed measurement of blood flow, vascular resistance and blood pressure still depends on invasive angiography.

According to ICRP publication 135, there are no current national DRL values for pediatric interventional radiology or interventional cardiology. Several countries have tried to establish local pediatric DRL values for interventional procedures[12]. There are however no studies that attempt any form of qualitative synthesis (Fig. 1). Therefore, our study may be the first instance in the literature of large-scale, national DRL research applied to pediatric interventional cardiology.

The present nationwide survey found that the radiation dose used in pediatric diagnostic and therapeutic cardiac catheterization was much higher than reported in previous literature[7–10]. As compared with previous reports, radiation dose was remarkably high: from 2 to 4 times greater in those aged 1 to 5 years and 1.2 to 4.5 times greater in those aged 6 to 15 years (Fig. 3, 4). There are several possible reasons for such obvious differences. First,

Ubeda's et al., who investigated DRL in Chile and Costa Rica and determined 75th percentile values for diagnostic and interventional cardiac catheterization, based their findings on results from just a single center in both countries. In this study, all equipment for Chile, Costa Rica, and Spain was from the same manufacturer. In contrast, our DRL data originate from equipment from various manufacturers. Therefore, the acquisition parameters, SID, frame and pulse rates, and added filtration used by the device differ. We have not performed detailed analyses, but this is one possible cause for the higher DRL in Japan. The present study included 43 facilities from an entire nation in which there might be a wide range of dose settings within each hospital.

Second, in addition to variation in dose settings, results might be influenced by other factors including a wide variety of angiography units from many vendors, the size of the field being irradiated, soft line elimination filters, bed height, and source image distance. In other words, while 75th percentile values were 2–3 times higher than in the articles referred to above, our result might fundamentally reflect a national reference level.

Third, Japan is in a unique situation regarding control of radiation exposure, as there are very few medical physicists in the entire country. Radiological technologists thus need to play the role of medical physicists in managing the radiation dose.

Comparing diagnostic and therapeutic interventions, Ubeda's results were similar. In this study there were no significant differences for $K_{a,r}$ between the diagnostic and therapeutic procedures.

However, the $K_{a,r}$ (189 mGy) of treatment procedures was 1.3 times the $K_{a,r}$ (142.1 mGy) of diagnostic procedures, and $K_{a,r}$ tended to be higher than the diagnosis.

In addition, it is necessary to consider diagnosis and treatment separately when formulating DRL because significant differences are found for FT and CI.

A further observation is that many facilities use the same fluoroscopy rates (7.5 pulses/sec) and exposure rates (30 frames/sec) for both diagnostic and therapeutic cardiac catheterizations. Previous reports describe fluoroscopy rates and exposure rates of 10–15 pulses/sec and 10–30 frames/sec[15], almost the same as in the present survey.

Among various methods used for exposure dose reduction, decreasing fluoroscopy rates and exposure rates is thought to be one of the most effective techniques during cardiac catheterization[16, 17]. It is necessary to use fluoroscopy rates and exposure rates in a manner that is appropriate to the patient's specific diagnosis and individual status.

In addition to delays in establishing DRLs for cardiac angiography, national guidelines regarding clinical examinations used for decision making in diagnosis of and drug therapy for pediatric patients with congenital heart disease and cardiovascular disorders have only recently been published[18]. Compared to other countries, acquisition of diagnostic guidelines and national DRLs may be somewhat late; we therefore hope that establishing DRLs for cardiac catheterization will quickly lead to national dose regulation.

Our study has some limitations. First, national DRLs are usually determined by the accumulation of data from many cases. For each age group in the diagnostic cardiac catheterization group, the number of cases was large 26 to 137 and we therefore consider the values to be reliable. However, the number of cases for therapeutic cardiac catheterization (excluding ages 1–5), for which DRL data are available, is small, and may therefore be less reliable. We intend to examine more cases in the future. More detailed data may also be derived where missing values are

present using multiple imputation of values. Second, we did not evaluate individual cases or diseases. Further evaluation will therefore be necessary to take into account differences between diagnostic and interventional radiology (IVR) procedures. Third, kV, mA, pulse duration and frame duration values were not collected, nor were details of any additional filtering. Also, pediatric exposure doses by age were evaluated. However, pediatric DRLs recommend the use of weight categories, rather than age bands[19]. DRLs presented as a function of patient weight rather than weight categories. Therefore, it is necessary to further analyze using weight categories. Fourth, fluoroscopy rate and exposure rate are programmable techniques, and may therefore vary across the different protocols programmed into fluoroscopic units. Therefore, fluoroscopy and exposure rates were not collected. However, the device manufacturer, inch size, number of fluoroscopic pulses, and number of imaging frames were specified for each case. Fifth, there are numerous patient factors that influence the derivation of DRLs in interventional procedures, unlike in general radiography. These patient factors may include variable patient anatomy (e.g., body habitus, vascular tree variations, blood vessel diameters), lesion variability, and factors related to operator and equipment. These factors may all play a role in DRLs. Finally, we did not evaluate the images acquired at cardiac catheterization for vascular enhancement and subjective image quality.

Conclusion

Our survey of diagnostic and therapeutic cardiac catheterization in Japanese pediatric patients showed that all age-based Japanese 75th percentiles (at ages less than one year, 1–5 years, 6–10 years, and 11–15 years) for the $K_{a,r}$, P_{KA} , FT, and CI were higher than in other surveys. To promote the optimization of diagnostic and therapeutic cardiac catheterization involving pediatric protocols, it is therefore necessary to establish DRLs for pediatric cardiac catheterization examinations in Japan.

Abbreviations

air-kerma at the reference point ($K_{a,r}$)

air-kerma area product (P_{KA})

fluoroscopy time (FT)

cine images (CI)

diagnostic reference level (DRL)

International Commission on Radiological Protection (ICRP)

Declarations

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Conflicts of interest/Competing interests , Availability of data and material, Code availability,

Authors' contributions : Not applicable

Ethics approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the Institutional Review Board (IRB) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This article does not contain any studies with animals performed. This retrospective study was approved by Tsuchiya General Hospital review board (No. E160530-2).

Consent to participate, Consent for publication

Consent to participate and Consent for publication was obtained from all individual participants included in the study.

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Tables

Table 1 Median (range) values of number, height, weight and body mass index (BMI) for each age group (N=333).

Age	Height (cm)	Weight (kg)	BMI (kg/m ²)
<1 year (n=69)	61.3 (46.5-88.5) [56.0-67.0]	5.8 (2.7-11.8) [4.2-7.0]	15.1 (10.9-29.5) [13.4-16.3]
1–5 years (n=168)	85.7 (54.0-138.4) [74.8-5.9]	11.7 (3.8-29.0) [8.9-13.9]	15.7 (10.7-26.8) [14.7-16.6]
6–10 years (n=56)	120 (67.5-151) [112-134]	23.9 (7.4-42.4) [19.0-28.6]	16.2 (10.8-22.5) [15.0-17.1]
11–15 years (n=40)	146 (62.9-170) [143-155]	41.8 (6.1-81.5) [35.6-48.2]	19.2 (14.5-34.7) [16.6-20.6]

Median (range)

[IQR]

Table 2 The minimum, 25th percentile, median, 75th percentile, and maximum values for $K_{a,r}$, P_{KA} , FT, and CI for diagnostic protocols in four pediatric age groups.

		Age	n	Minimum	25th percentile	Median	75th percentile	Maximum
$K_{a,r}$	[mGy]	<1 year	62	8.9	36	58	103	358
		1-5 years	134	11	36	80	127	329
		6-10 years	45	19	79	129	194	385
		11-15 years	31	11	109	161	351	1047
P_{KA}	[Gy.cm ²]	<1 year	44	0.1	1.8	4.3	6.96	62.1
		1-5 years	115	0.9	3.7	6.3	12.3	39.4
		6-10 years	35	1.9	6.3	10.9	14.3	61.3
		11-15 years	26	0.6	11.2	19.4	47.2	110.1
Fluoroscopy time	[min]	<1 year	62	5.3	15.6	22.9	36.8	89.4
		1-5 years	137	4.2	15.2	20.9	30.7	99.0
		6-10 years	45	5.5	14.3	22.5	33.4	54.4
		11-15 years	32	1.0	15.8	26.2	35.7	73.8
Cine images	[counts]	<1 year	51	168	1100	1538	2018	4336
		1-5 years	126	273	1199	1582	2313	4304
		6-10 years	43	888	1392	1720	2409	9004
		11-15 years	27	28	1312	1758	2016	3590

Table 3 The minimum, 25th percentile, median, 75th percentile, and maximum values for $K_{a,r}$, P_{KA} , FT, and CI for therapeutic protocols in four pediatric age groups.

		Age	n	Minimum	25th percentile	Median	75th percentile	Maximum
K_{a,r}	[mGy]	<1 year	7	23	34	47	146	173
		1-5 years	31	23	54	98	209	608
		6-10 years	11	17	19	40	130	237
		11-15 years	8	29	50	111	501	595
P_{KA}	[Gy.cm²]	<1 year	7	1.2	1.4	1.8	7.54	9.7
		1-5 years	25	1.8	4.3	6.1	16.0	105.9
		6-10 years	10	1.1	2.6	3.5	8.35	16.8
		11-15 years	8	7.1	10.0	18.2	46.0	73.5
Fluoroscopy time [min]		<1 year	7	19.3	20.4	40.0	56.5	78.4
		1-5 years	31	13.8	23.5	37.5	52.0	121.9
		6-10 years	11	7.4	10.0	18.0	49.4	63.9
		11-15 years	8	9.9	13.0	30.8	52.0	64.0
Cine images	[counts]	<1 year	5	1827	2417	3278	4075	4264
		1-5 years	28	562	1490	2478	4514	8216
		6-10 years	8	295	614	819	3576	4976
		11-15 years	6	288	410	2100	5984	8292

Table 4 Comparison of 75th percentile for K_{a,r}, P_{KA}, fluoroscopy time and cine images for diagnostic and therapeutic procedures

	Present study					Ubeda et al. (2015)				
	Diagnostic		Therapeutic			Diagnostic		Therapeutic		
	n	75th percentile	n	75th percentile	<i>p</i>	n	75th percentile	n	75th percentile	<i>p</i>
K _{a,r} [mGy]	272	142.1	57	189	<i>0.588</i>	200	31.4	317	43.1	<i>0.01</i>
P _{KA} [Gy.cm ²]	220	13.8	50	13.5	<i>0.938</i>	200	2.8	317	2.47	<i>0.131</i>
Fluoroscopy time [min]	276	32.7	57	55	<i>0.0001</i>	200	15.9	317	20.6	<i>0.001</i>
Cine images [counts]	247	2265	47	4132	<i>0.0009</i>	200	1101	317	892	<i>0.001</i>

Figures

Figure 1

Literature search flowchart.

Figure 2

Distribution of fluoroscopy rates and exposure rates for diagnostic and therapeutic protocols a Fluoroscopy rate: Diagnostic [pulses/sec] b Exposure rate: Diagnostic [frames/sec] c Fluoroscopy rate: Therapeutic [pulses/sec] d Exposure rate: Therapeutic [frames/sec]

Figure 3

Comparison by age of median $K_{a,r}$ for all pediatric procedures in this study, compared with other surveys

Figure 4

Comparison by age of median PKA for all pediatric procedures in this study, compared with other surveys