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Original Article

Simple evaluation method for radiation dose monitoring using fluoroscopic dose rate in cardiac catheterization for pediatric congenital heart disease

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Abstract

Cardiac catheterization is used to diagnose, treat, and monitor the progress of congenital heart disease (CHD). International multicenter trials using database data have been conducted. In these trials, methods of monitoring radiation dose using kerma-area product (KAP) divided by body weight (BW) have been assessed. However, in Japan, dose monitoring methods that take KAP into consideration are not widely used. We aimed to analyze previous reports on the radiation dose received by CHD patients during diagnostic and therapeutic procedures, propose a standard method for monitoring radiation dose in Japan, and ensure that this method will be applicable to database-type data repositories. To evaluate the use of fluoroscopic dose rate (FDR) as a means of monitoring radiation doses, we calculated correlation coefficients for KAP/BW with FDR, FDR/BW, FDR/Height, and the index of FDR and BW in the diagnostic, therapeutic, and total categories. FDR/BW correlated best with KAP/BW, and the coefficients ranged between 0.4 and 0.6. Additionally, correlation coefficients according to age (in days) across all categories were calculated. FDR/BW was a reliable index to compare Japanese and international data. We therefore propose the use of FDR/BW as a standardized method for monitoring stochastic effects related to radiation dose. Calculating this statistic is easy, and future database research may facilitate inter-center comparisons.

Keywords: Fluoroscopic dose rate, Congenital heart disease, Interventional radiology, Radiation dose monitoring, Radiation dose management

1. Introduction

Cardiac catheterization is used to diagnose, treat, and monitor the progress of congenital heart disease (CHD). As patients grow older, they undergo repeated fluoroscopy, often over the course of their entire life. This fluoroscopic approach for diagnosis and treatment is called interventional radiology (IVR), and there are two types of IVR: diagnostic IVR, which is aimed at diagnosing conditions, and therapeutic IVR, which is aimed at providing treatment. It has been reported that in general, therapeutic catheterization involves higher radiation doses than diagnostic catheterization.[1–3] In CHD patients, both types of cardiac catheterization are performed repeatedly; thus, each session poses a risk of excessive radiation exposure, and there is concern about the cumulative dose received by an individual patient over the course of one's life becoming exceedingly large. Both problems are serious. For these reasons, management of the cumulative dose received by patients is extremely important. Because children are particularly sensitive to the effects of radiation, reducing the amount of radiation children receive is of the utmost importance. The American Food and Drug Administration (FDA) published a report in 1994 regarding the issue of radiation overexposure via fluoroscopy.[4] This report proposed that we, as professionals in the field of radiology, must redouble our efforts to develop evidence-based methods for the reduction of radiation exposure to patients, their families, radiation technicians, and physicians. In order to do so, we must also implement reliable ways of ascertaining accurate measurements of radiation doses. Unfortunately, dose quantification is a difficult problem, and the scale and frequency of adverse effects of exposure vary considerably.

Much research has been undertaken on the doses involved during the catheterization of patients with CHD. Research by George et al. categorized patients by age and explored the relationship between testing procedures and doses absorbed by pediatric patients.[5] However, few large-scale research studies have been conducted, and most studies are plagued by issues caused by small sample sizes.[6] The few large-scale studies that do exist involve investigation of the effects of radiation dose on comparatively older children,[1,2,7–11] and there are no reports of these effects on younger children. International, multicenter trials using database data have been performed.[3] In these studies, methods of monitoring radiation dose using dose-area (KAP: kerma-area product) divided by body weight (BW) have been examined. However, in Japan, monitoring methods that take KAP into consideration are not widely used. In addition to previous research conducted by the authors on dose management in CHD,[12] research on dose management using registries has used data from a Japanese registry of child catheterization—Japanese Society of Congenital Interventional Cardiology Registry (the JCIC-R). This previous research reported that measurements readily available from fluoroscopy devices—entrance skin dose (mGy), fluoroscopy time (min), as well as height (cm) and BW (kg)—can be used to assess radiation doses (17th Conference on RS Research Society, Tokyo, Japan, Feb 2018). Diagnostic reference levels for use in IVR procedures in Japan (Japan DRLs 2015 and 2020) are provided as fluoroscopic dose rates (FDRs).[13,14] FDRs can be calculated from registry data, including entrance skin dose and fluoroscopy time. In this study, we aimed to analyze previous reports on the radiation dose received by CHD patients during diagnostic and therapeutic procedures, propose a standard method for the monitoring of radiation dose in Japan, and ensure that this method will be applicable to database-type data repositories.

2. Methods

2.1 Target cases and categorization

This was a retrospective study, and all procedures in this study involving human participants were performed in accordance with the Research Ethics Committee of Niigata University of Health and Welfare (Approval number: 18397-200311) and the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

The data of this study were originally presented by us at the Society for Japanese Pediatric Radiological Technology symposium in 2014.[12] Data on all 484 cases who underwent IVR procedures at the Saitama Children's Medical Center seen between March 18, 2011 and February 28, 2013 were used. After referencing the age groupings used in studies by Verghese et al. and Martinez et al.,[5,15] we sorted our data into five age-based categories. These categories were as follows: patients aged younger than 1 year, 1–4 years, 5–9 years, 10–15 years, and older than 15 years. These age categories are consistent with those prescribed in the European pediatric guidelines for quality standards for diagnostic radiological imaging and were selected to facilitate comparisons between our data and that of other reports and studies. Furthermore, patients aged 20 years and older were deemed adults, and their data were therefore excluded from this analysis.[5] Our data contained the following information for each patient: age at the time of testing (age in years, age in months, and age in days), BW, height, type of procedure (diagnostic or therapeutic), fluoroscopy time, KAP, and FDR (calculated from KAP and fluoroscopy time). The radiation dose-related data values most commonly used in our statistical analyses were KAP values. We elected to use these values because KAP is the standard measurement used to monitor radiation dose in the West. We elected to use it to facilitate both comparisons with past literature and as a reference for future work. Simply put, KAP is the average air kerma (in Gy) multiplied by the corresponding cross-sectional area (in cm^2) of the X-Ray beam.[16] We have reanalyzed the data here, and it has been monitored using the units $mGy{\cdot}cm^2$. In this study, several referenced international research reporting these values used units of the $\mu Gy{\cdot}m^2$; thus, we have converted these units. In addition to the dose amount, information on procedural type was also monitored. The therapeutic category was further divided into five subcategories: major aortopulmonary collateral artery (MAPCA), atrial septal defect (ASD), balloon atrial septostomy (BAS), patent ductus arteriosus (PDA), and others (OT).

2.2 Equipment

All the dose data used in this study were acquired using the Allura Xper FD 10/10 IVR device (Koninklijke Philips Electronics N.V., Amsterdam, Netherlands), a biplane imaging system. Radiation exposure conditions were controlled by the intensity of the radiation incident on the flat panel of the device, and reflect the dose absorbed by the patient being imaged. As a biplane system, this device irradiates patients along two axes (front-back and left-right); thus, KAP, fluoroscopy time, and FDR values were the totals of the two values obtained for each axis.

2.3 Data analysis

We collected the following information using a preliminary survey: age, height, BW, fluoroscopy time, product of BW and fluoroscopy dose, KAP, KAP/BW, and FDR. We determined that these values did not conform to normal distributions using the Shapiro-Wilk test. Therefore, in this study, these values are reported using medians, quartiles, and 90th percentile figures. Applying a logarithmic transformation to these data brought them closer to being normally distributed, except for age, for which no such effect was observed.

First, after referencing past survey data, we divided participant data based on age and BW groups. In each group, distributions in height, BW, fluoroscopy time, KAP, and FDR were examined. Next, in order to determine whether or not the monitoring format of KAP/BW proposed in foreign research could be used for Japanese individuals, we investigated correlations between KAP and the following data points: age (in days), height, BW, fluoroscopy time, index of BW and fluoroscopy dose, and FDR. We then examined the variability in KAP/BW values among children age groups for different procedures. Finally, in an effort to evaluate a method that did not use KAP values, we explored whether FDR could be used as a monitoring index and investigated correlations between KAP/BW and FDR, FDR/BW, FDR/Height, and the index of FDR and BW.

Spearman's rank correlation coefficients and Pearson's correlation coefficients were calculated and used to compare data. The Mann-Whitney U test and the Kruskal-Wallis test were used to compare groups. The threshold for statistical significance was defined as $p < 0.05$. The JMP 14.3 software for Macintosh (SAS Institute Inc., Cary, NC) was used to carry out all statistical analyses.

3. Results

3.1 Variables for diagnostic and therapeutic procedures according to age and BW groups

Eight of the 484 cases initially collected were excluded due to the lack of information on dose amounts. Of the remaining 476 cases, 469 were determined to be within the acceptable age range of this study, while 7 were adult patients and were not incorporated into our analysis. Thus, a total of 469 cases were analyzed, comprising 365 diagnostic procedures and 104 therapeutic procedures. Medians and quartiles (25th and 75th percentiles) for height, BW, fluoroscopy time, KAP, and FDR values for age and BW groups stratified by procedure type are shown in Table 1. Fluoroscopy time

Table 1 **Height, weight, fluoroscopic time, KAP, and fluoroscopic dose rate (FDR) of two procedure types**

(A) Age group

Proceduer type	Age group	Patinet (n)	Height (cm)	Weight (kg)	Fluoro time (min)	KAP (μGy•m²)	FDR (mGy/min)
Diagnostic	<1 yr	96	64.1 (56.7, 69.0)	6.3 (4.6, 7.8)	14:45 (11:08, 19:18)	189.5 (117.4, 303.7)	1.27 (0.73, 2.09)
	1–4 yr	138	82.4 (75.0, 93.9)	10.6 (8.5, 13.7)	14:31 (10:52, 20:13)	388.0 (239.0, 599.8)	2.87 (2.01, 4.44)
	5–9 yr	73	111.6 (105.9, 121.5)	18.5 (16.2, 22.8)	15:51 (10:19, 22:32)	685.1 (504.9, 1100.8)	6.83 (4.66, 9.20)
	10–15 yr	42	145.0 (137.0, 162.9)	36.7 (29.2, 45.1)	15:48 (11:49, 19:27)	2015.0 (1006.6, 4033.8)	19.55 (7.56, 44.49)
	>16	16	159.9 (149.6, 167.9)	52.6 (40.2, 63.3)	16:58 (14:31, 19:00)	3412.6 (2009.9, 4694.1)	30.37 (20.38, 61.07)
Therapeutic	<1 yr	28	57.3 (50.0, 67.5)	5.0 (3.2, 7.0)	23:21 (15:31, 34:25)	314.0 (126.0, 497.1)	0.86 (0.40, 1.75)
	1–4 yr	36	87.6 (81.2, 96.2)	11.8 (9.8, 14.2)	33:25 (16:21, 55:14)	816.9 (464.1, 1040.0)	2.01 (1.34, 3.31)
	5–9 yr	19	117.0 (104.0, 125.0)	20.9 (16.0, 26.0)	34:18 (17:32, 37:24)	1173.0 (991.2, 1761.9)	5.36 (2.59, 6.61)
	10–15 yr	12	146.3 (138.5, 158.3)	38.7 (35.0, 46.1)	16:45 (14:44, 20:08)	1900.0 (1084.8, 2730.4)	14.71 (6.84, 21.61)
	>16	9	155.5 (151.9, 167.5)	55.0 (46.7, 61.2)	20:06 (16:46, 29:01)	3453.0 (2928.5, 7184.7)	29.89 (18.44, 60.11)

(B) Weight group

Proceduer type	Weight gropu	Patinet (n)	Height (cm)	Weight (kg)	Fluoro time (min)	KAP (μGy•m²)	FDR (mGy/min)
Diagnostic	<5 kg	27	52.0 (49.0, 55.7)	3.5 (3.1, 4.3)	13:43 (10:52, 19:20)	97.3 (69.4, 151.1)	0.57 (0.48, 0.88)
	5–20 kg	248	79.9 (69.5, 96.7)	10.0 (7.5, 14.1)	14:59 (11:04, 19:52)	343.0 (224.9, 577.1)	2.81 (1.63, 4.84)
	20–45 kg	67	132.3 (122.0, 144.0)	27.6 (23.1, 35.0)	15:41 (11:09, 24:00)	1161.1 (808.0, 2342.8)	11.30 (7.00, 21.97)
	45–80 kg	23	164.0 (155.8, 167.0)	52.6 (48.0, 56.3)	16:05 (11:39, 18:02)	3646.4 (1987.8, 5381.8)	37.92 (13.74, 62.79)
Therapeutic	<5 kg	14	50.0 (48.0, 52.3)	3.2 (2.8, 3.6)	16:55 (14:10, 34:20)	132.1 (67.7, 358.0)	0.41 (0.38, 0.86)
	5–20 kg	59	86.7 (71.5, 97.8)	11.5 (8.4, 14.4)	26.57 (18:46, 46:00)	593.7 (404.7, 991.2)	1.88 (1.23, 3.25)
	20–45 kg	19	127.0 (121.7, 140.0)	26.8 (23.4, 38.3)	20:30 (15:45, 36:54)	1728.6 (1016.3, 2040.1)	6.49 (4.37, 15.27)
	45–80 kg	12	157.0 (152.5, 166.8)	51.1 (47.6, 59.1)	19:01 (15:55, 24:02)	3663.4 (2873.3, 7447.8)	31.59 (19.24, 43.57)

Stratified by (A) age group and (B) weight group.
Median and interquartile range (25th, 75th percentile) are provide in columns 4–8.
KAP, kerma-area product; FDR, fluoroscopic dose rate

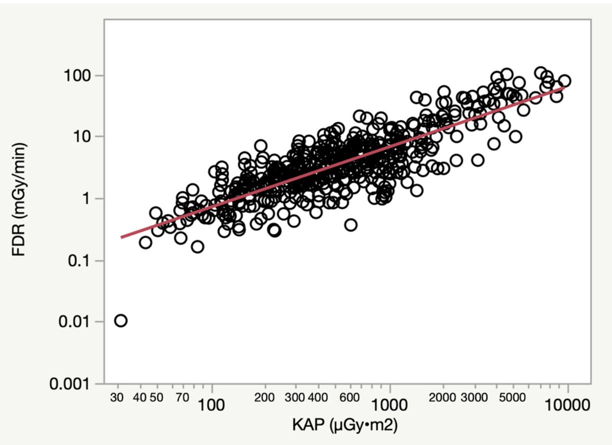

Fig. 1 **KAP and FDR scatterplots**
The Pearson's correlation coefficient (*r*) was 0.833.
KAP, kerma-area product; FDR, fluoroscopic dose rate

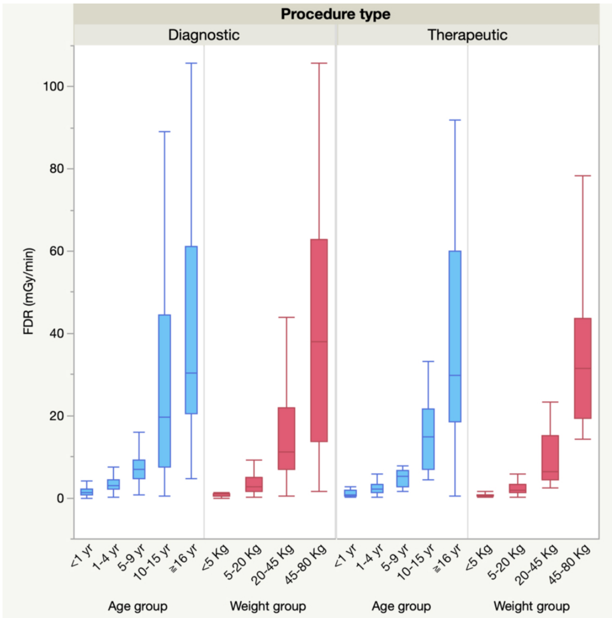

Fig. 2 **Box plot of FDR by age group and weight group in the two types of procedure**
FDR, fluoroscopic dose rate

and KAP were larger for diagnostic procedures. For both diagnostic and therapeutic procedures, KAP and FDR tended to increase as age and BW increased. The correlation between KAP and FDR is shown in Fig. 1 (Pearson correlation coefficients (*r*) of KAP and FDR was 0.833) and the trend of FDR are depicted in Fig. 2. Further, in the therapeutic subgroup, BW, fluoroscopy time, and KAP exhibited considerable variance within each age group and BW group. For example, fluoroscopy time ranged from 16 to 55 minutes for patients aged 1–4 years, and between 18–46 minutes for patients weighing between 5–20 kg.

Table 2 **Pearson correlation coefficients (*r*) of KAP with six different parameters in diagnostic and therapeutic catheterizations**

	Diagnostic	Therapeutic	Total
Age (days)	0.734	0.761	0.715
Height (cm)	0.790	0.798	0.781
Weight (kg)	0.791	0.834	0.791
Fluoroscopic time (min)	0.247	0.264	0.301
Weight-fluoroscopic product	0.815	0.848	0.829
FDR (mGy/min)	0.870	0.850	0.833

Logarithmic transformed data of KAP, age, weight, fluoroscopic time, weight-fluoroscopic product, and fluoroscopic dose rate were used in the above analysis. All correlation coefficients are $p < 0.05$.
KAP, kerma-area product; FDR, fluoroscopic dose rate

3.2 Correlations between variables according to procedure type

Pearson's correlation coefficients for KAP and other monitored data points (after logarithmic transformation) are shown in Table 2. No significant difference was found between analyses using the original monitored data and correlation coefficient calculations performed with logarithmically transformed data. Overall, KAP was strongly correlated with the index of BW and fluoroscopy time or FDR. It was moderately correlated with age (in days), height, and BW. Because the therapeutic subgroup was comprised of a large variety of procedures, we examined each procedure type separately. The results of these separate examinations are shown in Table 3. Across the five studied procedure types, BW and FDR correlated best with KAP. The correlation coefficients for BW ranged from 0.4 to 0.8, and those for FDR ranged from 0.5 to 0.9. No robust correlation was observed between KAP and fluoroscopy time.

3.3 Variation in KAP normalized according to BW using the KAP/BW parameter

KAP and BW were used as indices, and Table 4 shows the KAP/BW (μGy·m^2/kg) and fluoroscopy time for each procedure type in the diagnostic and therapeutic subgroups. This table contains medians (50%), upper quartiles (75%), and 90th percentiles. Therapeutic procedures had higher values than diagnostic procedures for all items. MAPCA showed the highest KAP/BW values of all the procedures. Correlation coefficients for KAP/BW and age (in days) in the diagnostic and therapeutic subgroups are shown in Fig. 3. The correlation coefficients for KAP/BW and age (in days) ranged from 0.006 to 0.327 ($p < 0.05$) across the diagnostic, therapeutic, and total categories. This suggests that regardless of the age of the child in question, KAP/BW maintains a stable value.

3.4 Variability in radiation dose monitoring indices using FDR

To evaluate the use of FDR as a means of monitoring radiation doses, we calculated correlation coefficients for KAP/BW with FDR, FDR/BW, FDR/Height, and the index of FDR and BW (Wt-FDR product) in the diagnostic, therapeutic, and total categories (Table 5). FDR/BW correlated best with KAP/BW and the coefficients ranged between 0.4 and 0.6. In addition, the correlation coefficients according to age (in days) for FDR and FDR/BW are shown in Fig. 4. In terms of the correlation coefficient for FDR/BW and age (in days), FDR/BW was 0.47, which was found to be significantly lower than for other indices ($p < 0.05$). Further, similar results

Table 3 **Pearson correlation coefficients (*r*) between KAP and six different parameters in 5 specific therapeutic procedures**

	Age (days)	Height (cm)	Weight (kg)	Fluoroscopic time (min)	Wt-fluoroscopic product	FDR (mGy/min)
ASD	0.726	0.702	0.849	0.202	0.723	0.876
BAS	0.494	0.395	0.445	0.178	0.350	0.767
MAPCA	0.491	0.486	0.505	0.584	0.675	0.492
PDA	0.602	0.691	0.773	0.398	0.860	0.740
OT	0.238	0.338	0.364	0.279	0.462	0.732

Logarithmic transformed data of KAP, age, weight, fluoroscopic time, weight-fluoroscopic product, and fluoroscopic dose rate were used in the above analysis. All correlation coefficients are $p < 0.05$.
KAP, kerma-area product; FDR, fluoroscopic dose rate

Table 4 **Fluoroscopic time and normalized KAP by body weight (KAP/BW) of median, 75th and 90th percentile**

Procedure type	Patient (n)	Fluoroscopic time (min)			KAP/BW		
		50th percentile	75th percentile	90th percentile	50th percentile	75th percentile	90th percentile
Total	469	16	23	35	39.4	64.7	91.7
Diagnostic	365	15	20	27	37.4	56.6	85.0
Therapeutic	104	24	37	60	58.5	84.1	132.8
ASD	20	18	20	36	59.2	77.1	123.3
BAS	9	15	17	22	28.3	38.6	92.1
MAPCA	20	50	64	70	85.2	109.9	183.7
PDA	30	21	32	49	58.0	73.1	129.9
OT	25	35	43	56	57.0	88.1	155.6

KAP, kerma-area product; BW, body weight

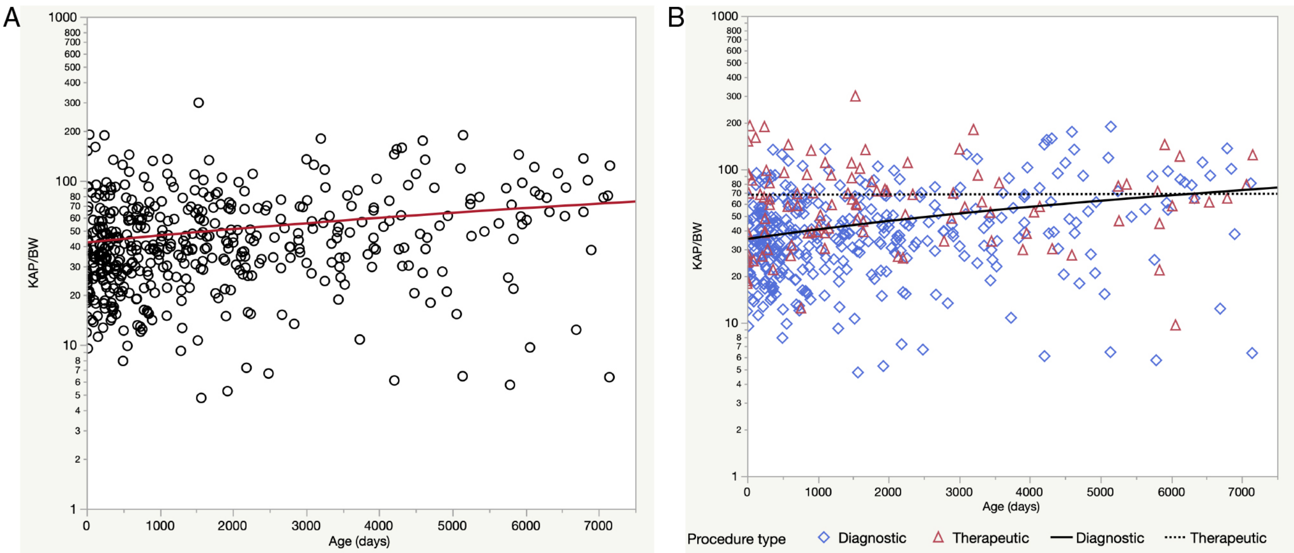

Fig. 3 **Scatterplot of KAP/BW and age (days)**

A Pearson's correlation coefficient (*r*) is shown for each graph.
(A) Total ($r = 0.230$), (B) Diagnostic ($r = 0.327$) and Therapeutic ($r = 0.006$)
KAP, kerma-area product

Table 5 **Pearson correlation coefficients (*r*) between KAP/BW and four different parameters in diagnostic and therapeutic procedures**

	Diagnostic	Therapeutic	Total
FDR (mGy/min)	0.516	0.253	0.406
FDR/BW	0.622	0.378	0.477
FDR/H	0.547	0.293	0.431
Wt-FDR product	0.419	0.237	0.347

KAP, kerma-area product; BW, body weight; H, height

were found after separate analyses of the diagnostic and therapeutic procedures. These results suggest that even without the use of KAP, FDR/BW correlates with the area of the irradiated field and can be used as an age-independent monitoring index for radiation dose.

4. Discussion

Cardiac catheterization is a critical part of the diagnosis and treatment of pediatric CHD patients, and this technique has saved the lives of many children. However, as explained above, many patients have to undergo the procedure repeatedly throughout their lives. Thus, it is vital that we work to reduce radiation doses associated with cardiac catheterization both by changing the ages at which patients are exposed and minimizing the cumulative dose that patients receive throughout their lives.

The biological effects of radiation can be broadly divided into two categories: deterministic and sto-

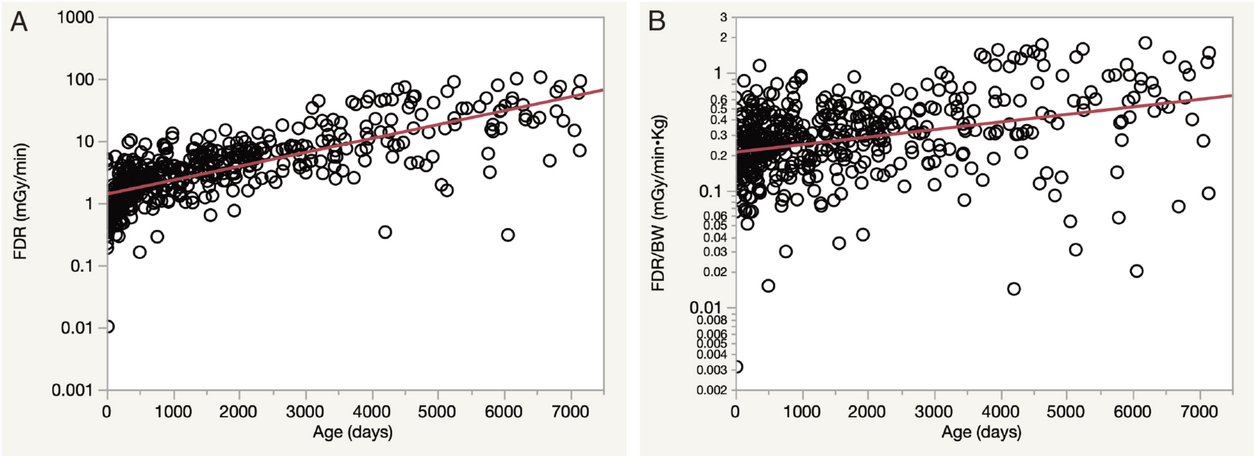

Fig. 4 **Scatterplot of (A) Fluoroscopic dose rate and (B) FDR/BW and age (days)**
Pearson's correlation coefficient (r) is shown for each graph.
(A) Fluoroscopic dose rate (r = 0.68), (B) FDR/BW (r = 0.48)
KAP, kerma-area product; BW, body weight; FDR, fluoroscopic dose rate

chastic.[17] Emblematic examples of deterministic effects include dermatitis, hair loss, and cataracts. Indeed, the aforementioned FDA report[4] was published in an effort to forestall such effects. However, stochastic effects have no definite threshold beyond which their occurrence is guaranteed. Thus, their occurrence is considered to be proportional to the radiation dose received and are of particular concern among younger patients.[18]

Two values are used widely in the reports of the radiation doses received by patients undergoing cardiac catheterization—cumulative-air kerma and KAP.[18] Cumulative air kerma is an index of entrance skin dose, is associated with deterministic effects, and is used as a benchmark for the basic performance of IVR devices in Japan. In contrast, KAP is the cumulative sum of the products of kerma and irradiated area. Studies by Bacher et al. report that KAP, as a measure of absorbed dose, is highly correlated with effective dose, which represents the occurrence risk of stochastic effects.[2] However, because effective dose can be difficult to calculate, KAP, which is easily obtained from device readouts, is of great use as a reporting index in the field of pediatric radiology. Physicians who practice IVR follow a rule of thumb known as "ALARA," or "as low as reasonably achievable." In other words, procedures performed to obtain images that may enable a diagnosis must be undertaken in such a way as to minimize radiation dose wherever possible.[19,20] Furthermore, repeated evaluation of radiation dose measurement and monitoring methods by practitioners will raise their awareness of the doses that patients are exposed to, and ultimately lead to reducing patient exposure. However, data from a single center are prone to biases stemming from the types of patients studied or equipment failures and are therefore insufficient. Thus, the use of data from a multicenter registry, such as the JCIC-R, enables the comparison of data from many different centers, IVR-practicing physicians, and measurement equipment, furthering efforts to develop dose indices.

Two issues stand in the way of standardization of radiation dose indices for pediatric patients in Japan. The first is rather unique to our country. In Japan, national registry records do not list data for the area of the irradiated field. However, in this study, our analysis has shown that, of the items that are present in the registry, BW correlates best with the irradiated field area. In other words, it is possible to use data contained in Japanese national registries (dose, fluoroscopy time, and BW) to standardize the monitoring of the doses received by pediatric patients.

The second issue is one that is a problem worldwide; the fact that the bodies of children, especially in comparison to those of adults, vary considerably in size. Children range in size and body composition from low birth weight neonates to teenagers with adult-level physiques. This makes IVR procedures in children a more complicated affair than in adults, and significantly hampers the development of standard values for radiation doses. On this matter, foreign researchers have published a report with a narrowed scope, to just one type of procedure in one age bracket.[5] On the other hand, database research incorporating data obtained during a variety of procedures and across many age brackets, indicates that KAP/BW can be used as a useful scale of radiation dose in pediatric catheterization.[21,22] KAP has also been reported to correlate strongly with BW,[21] and age-related variance in KAP can be eliminated by normalizing it to BW. Our data involves the best of both worlds. Similar to Onnasch et al.,[7] our data are sourced from a single center, but similar to the study by Kobayashi et al.,[3] the data suggest that KAP/BW is useful as a standard reporting scale for radiation doses in pediatric catheterization. Finally, in light of the data items available in large-scale Japanese registries, the fact that FDR/BW correlates well with KAP/BW suggests that much of the data already recorded in Japan can be used to perform standardized comparisons of stochastic effects.

Our study only enrolled children tested and treated in Japan and evaluated the radiation doses to which these children had been exposed. Variance in BW, height, and the age of children can cause great variability in KAP and FDR values. However, excellent correlations were observed between KAP and BW, as well as between KAP/BW and FDR/BW. In particular, FDR/BW produced stable values across all of the ages surveyed in this study, suggesting the possibility of its use as an index. FDR/BW is therefore a useful, reliable value that can be used to monitor the radiation doses received by all pediatric patients in Japan.

Limitations

This study is limited in a number of aspects. First, the data used in this study were obtained from a single facility. We cannot deny that this may bring some degree of selection bias in terms of the types of cases examined here. Nor can we definitively state that variances caused by the specific equipment available to us are not present in our results. In the future, we hope to use data from several different facilities or from a national registry to conduct an analysis that takes into account a variety of different conditions.

Further, because the most widely used pediatric registry in Japan, the JCIC-R, has not, as of April 2020, included a database item that lists information on the size of the irradiated field (such as KAP, which is in use throughout the world), care must be taken when performing data comparisons. Note that reports from various different vendors use different unit systems. Standardization of units, such as mGy·m^2 vs. Gy·cm^2, across different industry fields is therefore another important issue.

5. Conclusion

The results of our research indicate that FDR/BW is the most reliable index for the comparison of Japanese and international data. We therefore propose the calculation of FDR/BW as a standardized method for monitoring stochastic effects related to radiation dose. Calculation of this statistic is easy, and future database research should enable inter-center comparisons as well. The use of a simple evaluation method to compare radiation doses should lead to further initiatives to reduce radiation doses received by patients of all ages.

Compliance with Ethical Standards

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Conflict of interest

The authors declare that they have no conflicts of interest.

Ethical approval

All procedures performed in studies involving human participants were in accordance with the Research Ethics Committee of Niigata University of Health and Welfare (Approval number: 18397-200311) and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

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原著

小児先天性心疾患における心臓カテーテル検査の透視線量率を用いた放射線線量記録の簡易評価方法

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要旨

先天性心疾患の診断，治療及び経過観察には心臓カテーテル検査が用いられる．国外のデータベースを用いた多施設共同研究では面積線量（kerma-area product; KAP）を体重（body weight; BW）で割った値を用いた放射線量の記録の検討がされている．しかし，本邦においては，KAP を考慮した記録方法はあまり普及していない．本研究は，本邦で過去に行われた心臓カテーテル検査時の放射線量を解析し，本邦における放射線量の標準的な記録方法を提案し，既存のデータベースにて活用可能とすることを目的とした．放射線量の記録として透視線量率（fluoroscopic dose rate; FDR）の使用を評価した．FDR/BW は KAP/BW と相関が高く，解析された年齢で安定した値を得ることが可能と示唆された．FDR/BW は，本邦と国外のデータを比較する上で信頼できる指標であり，本邦における放射線量の標準的な記録の方法として用いることを提案する．これは，非常に簡便な方法であり，データベースを用いた研究での施設間比較が可能となる．

キーワード：透視線量率, 先天性心疾患, IVR, 放射線線量記録, 放射線線量管理