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Radiation Dose Reduction in Congenital Heart Disease Patients During Cardiac Catheterization by a Novel Protocol

Selman Gokalp, Ibrahim Cansaran Tanidir, Erkut Ozturk, Yakup Ergul, Alper Guzeltas

Department of Pediatric Cardiology, Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Training and Research Hospital, Istanbul Saglik Bilimleri University, Istanbul, Turkey

What is already known on this topic?

- *Cardiac catheterization is still one of the most important sources of radiation exposure in patients with congenital heart disease. In order to minimize this risk, safe and effective new radiation exposure reducing methods are required .*

What this study adds on this topic?

- *Implementing lower fluoroscopy rates could minimize radiation's possible side effects, concomitantly increasing the safety of the patient and the health care provider without increasing the total fluoroscopy time and the amount of contrast.*

ABSTRACT

Objective: Cardiac catheterization remains a major source of radiation exposure for patients with congenital heart disease. This study reports the magnitude of radiation with a 3.75 frame per second (fps) pulse fluoroscopy rate and compares the reduction with the previous 15 fps protocol during cardiac catheterization for pediatric and adult congenital heart disease.

Material and Methods: All diagnostic and interventional cardiac catheterization procedures from a single tertiary center were analyzed from January 1, 2014 to December 31, 2015, one year before and after implementing lower starting pulse fluoroscopy rates. The radiation dose was quantified as air kerma dose (mGy) and dose-area product (DAP; μGy/m^2). Radiation exposure was analyzed for diagnostic and interventional procedures; the diagnostic group was subdivided into cyanotic and acyanotic patients, whereas the interventional group was subdivided according to the most common indications.

Results: A total of 786 procedures were analyzed. The median fluoroscopy times and contrast amounts did not show a statistically significant difference between both periods (487 vs. 456 seconds and 42.5 vs. 45.3 cm^3). The median air kerma for all procedures showed an 88% reduction after implementing lower pulse fluoroscopy rates (340-41 mGy). The doses were reduced significantly for diagnostic and interventional angiograms from 470 mGy and 162 mGy to 40 mGy and154 mGy. Among all patient groups, the most striking decrease was observed in the diagnostic procedures we use, of which fluoroscopy is more prominent than cine angiography.

Conclusion: We claim that novel radiation dose reduction protocols could be easily applied without increasing fluoroscopy time or losing image quality.

Keywords: cardiac catheterization, congenital heart disease, radiation dose

INTRODUCTION

Cardiac catheterization is still one of the most important sources of radiation exposure in patients with congenital heart disease (CHD).[1] Catheter interventions expose these groups of patients to high radiation doses due to the technically challenging procedures (patent ductus arteriosus stenting, percutaneous pulmonary valve implantation, etc.), complex anatomic features, manipulation difficulties, prolonged procedure time, heart rate, and frequent use of magnification result. In addition, the radiation dose may be further increased depending on the operative-dependent (distance between the patient and device) and the operative-independent (angiography device, image intensifier factors, the nature of procedure) factors.[2,3]

CHD patients are more prone to deterministic (direct dose–response relationship) and stochastic radiation effects due to the growing organism's biological properties. A stochastic

Corresponding author:
Selman Gokalp
✉sgokalp@hotmail.com
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effect is one in which the probability of the effect, rather than its severity, increases with dose. Radiation-induced cancer and genetic injuries are stochastic.[1-3]

Considering the long life expectancy of children and the cumulative radiation doses that patients and laboratory workers are exposed to during catheter angiography, both groups are at risk of radiation's deleterious effects such as immune dysfunction, cataract, and congenital anomalies and malignancy.[4,5] In order to minimize this risk, safe and effective new methods are required that reduce fluoroscopy time and radiation dose.[1]

These new methods aim to provide the most accurate diagnostic and therapeutic benefit with the lowest possible radiation dose by applying as low as reasonably achievable (ALARA) concept to cardiac catheterization, as radiation has no known safe-dose range for the patient and health personnel. The second aim is to reduce the radiation dose without compromising the image quality. The use of low pulse rate fluoroscopy to achieve these 2 objectives was reported in a limited number of studies.[6]

In this study, we determined radiation doses using a 3.75 frame rate per second (fps) pulse rate (lowest possible pulse rate) fluoroscopy during cardiac catheterization of patients with CHD, both children and adults. The results were compared with the 15 fps standard pulse rate fluoroscopy findings that we previously used.

MATERIALS AND METHODS

We evaluated all the data of CHD patients who underwent cardiac catheterization between January 1, 2014 and December 31, 2015. All data were retrospectively obtained from the pediatric cardiology department's angiographic database. Fluoroscopic procedures for pericardiocentesis, central catheter insertion, electrophysiology studies, and hybrid cases were excluded from the study. A total of 4 primary interventional pediatric cardiology staff were involved in the study.

A descriptive table including age, weight, sex, echocardiographic diagnosis, procedure and intervention type (if performed), fluoroscopy time, procedure time, and radiation doses was obtained.

The catheter angiographies performed between January 1, 2015 and December 31, 2015 at 3.75 fps were defined as group I. Catheter angiographies. The standard 15 fps method was used between January 1, 2014 and December 31, 2014 formed group II.

Measurements of radiation dose are reported for each case by the catheterization system of Philips Allura Xper FD20/10® (Philips Medical Systems, Eindhoven, Netherlands), and categorized as those that are obtained through fluoroscopy alone versus those obtained through digital acquisition. To monitor radiation exposure, the patient dose was indirectly recorded using standard techniques, including total fluoroscopy time (minutes), air kerma (mGy), and dose-area product (DAP; μGy m^2).

Air kerma dose is the dose measured in air at a fixed distance from the X-ray tube and is the best surrogate of the radiation absorbed at the skin surface at the site of beam entrance. It is correlated with the risk of skin injury; doses > 2000 mGy at a single skin site are known to increase the risk of acute skin injury.

DAP; μGy m^2) is the instantaneous air kerma dose times the X-ray field area, reflecting the total dose given to the patient.

Radiation exposure was analyzed for diagnostic and interventional procedures. The diagnostic group was subdivided into cyanotic and acyanotic patients (>30 procedures). The interventional group was subdivided according to the most common indications (>15 procedures). To minimize the effect of body weight and age, patient groups were subdivided according to weight and age. There were 6 groups, according to the body weight of the patients, as 0-5, 5-15, 15-40, 40-55, 55-70, and >70 kg; the patients were also divided into 6 age groups, as newborn (0-30 days), infants (1-12 months), 1-5 years, 5-10 years, 10-15 years, and >15 years.

Statistical Analysis

The Statistical Package for the Social Sciences for Windows (SPSS) Version 15 (SPSS, Chicago, IL, USA) was used for the statistical analyses. The distribution of each continuous variable was tested for normality using the Kolmogorov–Smirnov test. Non-parametric tests were used in cases where normality was not provided. Continuous variables are expressed as the median and interquartile range (IQR, first, and third quartiles); categorical variables are expressed as percentages. The Mann–Whitney *U*-test was used to compare the 2 groups' median values, while the chi-square and Fisher's exact tests were used to compare the findings between groups. *P* values < .05 were considered statistically significant.

Ethical Standards

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national guidelines on human experimentation and the Helsinki Declaration of 1975, as revised in 2008, and approved by the institutional committees (Reference Number 2020-46). Written informed consent was obtained from all children and/or their parents.

RESULTS

A total of 786 cases were included in the study. Among them, 415 patients were studied with 15 fps and 371 patients with 3.75 fps. In the first year of study, the median air kerma for all procedures was 340 mGy; it was decreased to 41 mGy (≈88%). The most striking decrease was observed in diagnostic procedures (470 mGy vs. 40 mGy), of which we use fluoroscopy more prominently than cine angiography. Although the median procedure (30 min vs. 30 min) and fluoroscopy times did not show a statistically significant difference for both periods (487 seconds vs. 456 seconds), DAP had changed dramatically (4731 μGy m^2 vs. 3149 μGy m^2). Again, the most important decrease was seen in the diagnostic group (9512 μGy m^2 vs. 3490 μGy m^2). Moreover, the mean contrast amount was almost identical without increasing the contrast for better visualization of the anatomic structure (42.5 cm^3 vs. 45.3 cm^3). Basic demographic and procedural data for the study cohort are summarized in Table 1.

Table 1. Comparison of Patient Groups According to Pulse Fluoroscopy Rates

Characteristics	**15 fps(*n* = 371)**	**3.75 fps(*n* = 415)**	***P***
Age at procedure (month) (median, IQR)	16.6 (7.2-69.8)	22.3 (7.6-73)	NS
Weight (kg) (median, IQR)	9.8 (6.7-19.4)	10 (6.2-20)	NS
Body surface area (m²) (median, IQR)	0.46 (0.36-0.76)	0.48 (0.34-0.78)	NS
Sex (Male/Female)	193/178	224/191	NS
Procedure type, *n* (%)*			NS
Diagnostic		250(60)	
Interventional		165(40)	
Procedure time minutes (median, IQR)	30 (20-50)	30 (20-45)	NS
Fluoroscopy time seconds (median, IQR)	487 (283-766)	456 (283-679)	NS
Air kerma (mGy) total (median, IQR)	340 (190-460)	41 (25.6-79.1)	**.001**
DAP (μGy m²) total (median, IQR)	4731 (2627-9388)	3149 (1936-6102)	**.04**
Air kerma (mGy) diagnostic (median, IQR)	470 (310-550)	40 (27-71)	**.02**
DAP (μGy m²) diagnostic (median, IQR)	9512 (3509-14 125)	3490 (2250-6340)	**.001**
Air kerma (mGy) interventional (median, IQR)	162 (81-235)	154 (92-220)	NS
DAP (μGy.m²) interventional (median, IQR)	11 325 (3420-18 952)	8623 (2786-6874)	**.01**

DAP, dose-area product; IQR, interquartile range.

Table 2 summarizes the radiation doses of the patients according to age distribution. According to age groups, there was a statistically significant decrease in radiation dose for newborns and infants.

Table 3 summarizes the radiation doses of the patients according to weight distribution. Air kerma and DAP values were significantly decreased, especially in 15-40 kg group ($P = .023$ and $P = .04$, respectively).

Table 4 summarizes the radiation doses according to the subgroup of diagnostic procedures, which includes at least 30 cases. There was a striking reduction in dosage in radiation performed for evaluation before Glenn and Fontan operation ($P < .05$), especially in angiographies.

Table 5 summarizes the radiation doses according to the subgroup of interventional procedures, which includes at least 15 cases. It was determined that all radiation dose parameters decreased significantly, especially in atrial septal defect (ASD) and patent ductus arteriosus (PDA) closure procedures ($P < .05$).

DISCUSSION

In this study, radiation dose during fluoroscopy was significantly decreased with a simple and easily applicable protocol—changing 15 fps to 3.75 fps—during diagnostic or interventional catheterization in patients with CHD. It was proved that radiation exposure could be significantly reduced without compromising image quality and increasing the amount of radiopaque used. Besides, both patients and healthcare personnel could be significantly protected from radiation exposure.

Table 2. Radiation Exposure According to Procedure Type and Age Groups

	Newborn		Infant		1-5 years		5-10 years		10-15 years		>15 years	
	15 fps	3.75 fps	15 fps	3.75 fps	15 fps	3.75 fps	15 fps	3.75 fps	15 fps	3.75 fps	15 fps	3.75 fps
All procedures (*N*)	27	26	118	130	124	139	40	48	31	38	30	34
Diagnostic (*N*)	6	7	80	84	90	104	17	20	9	16	21	19
Interventional (*N*)	21	19	38	46	34	35	24	28	22	22	9	15
Air kerma (mGy), All procedures	87	59	168	109	103	44	82	71	389	120	2624	354
Air kerma (mGy), Diagnostic	50	54	173	45	68	43	83	66	864	131	3645	273
Air kerma (mGy), Interventional	100	63	163	227	205	61	81	74	195	110	245	455
DAP (μGy m²) All procedures	4604	2745*	4540*	3320*	8187	4260	8928	8996	23 890	11 985	35 923*	32 169
DAP (μGy m²) Diagnostic	2200	2862	4771	3136	6256	3938	9965	11 525	20 877	12 965	38 158	26 754
DAP (μGy m²) Interventional	5428	2744	3731	3430	12 961	4704	8051	6958	24 949	11 064	27 782	40 758
Fluoroscopy time	972	882	571	588	503	480	574	559	855	584	652	837

*Values are given as median. Interquartile ranges are not given, for simplicity. *P* values are given only for statistically significant results ($P < .05$). Newborns DAP $P = .045$, infants DAP $P = .004$, 10-15 age group DAP $P = .027$.

Table 3. Radiation Exposure According to Body Weight

	0–5 kg		5–15 kg		15–40 kg		40–55 kg		55–70 kg		>70 kg	
	15 fps	3.75 fps	15 fps	3.75 fps	15 fps	3.75 fps	15 fps	3.75 fps	15 fps	3.75 fps	15 fps	3.75 fps
All procedures (*N*)	52	66	202	214	76	87	19	26	13	17	9	5
Diagnostic (*N*)	22	23	145	162	33	42	11	13	8	7	4	3
Interventional (*N*)	30	43	57	52	43	45	8	13	5	10	5	2
Air kerma (mGy) All procedures	140	56	66	85	118	**71***	4126	209	241	338	1906	551
Air kerma (mGy) Diagnostic	47	47	65	45	118	65	732	178	293	382	2708	351
Air kerma (mGy) Interventional	206	61	69	210	118	76	124	240	158	307	1261	851
DAP (μGy m²) All procedures	3872	2850	6510	4442	13 750*	7195*	21 272	20 195	27 606	31 969	53 505	49 916
DAP (μGy m²) Diagnosti	2861	2716	5550	4355	13 808	6771	26 819	17 576	32 171	37 927	59 170	34 425
DAP (μGy m²) Interventional	4591	2910	9011	4656	13 221	7227	13 580	22 795	20 273	27 791	48 937	73 138
Fluoroscopy time	755	725	534	527	691	517	572	675	701	928	405	585

**P* values are given only for statistically significant results ($P < .05$). 15-40 kg air kerma $P = 0.023$. DAP $P = .04$.

Many patients with CHD undergo multiple cardiac catheterization procedures; they are exposed to ionizing radiation, which can have both immediate and long-term effects. The negative consequences of ionizing radiation can also be categorized as either deterministic or stochastic effects. While deterministic effects, like cataract formation or skin injury have a somewhat predictable dose–response relationship with the degree of injury directly correlating with absorbed radiation dose, stochastic effects, like cancer and genetic mutations, are unpredictable without a threshold effect. Strides have been made, particularly in the past decade, in improving radiation safety profiles as well as public awareness. Initiatives such as the ALARA conference, conducted by the Society for Pediatric Radiology in 2006, concluded that fluoroscopy dose optimization and reduction were critical areas of concern. Campaigns such as "Image Gently, Step Lightly," first launched in August of 2009, incorporated a standard safety checklist to encourage proper preparation, technique, and lower radiation exposure. In particular, this checklist encouraged utilizing pulse fluoroscopy rather than continuous fluoroscopy when possible, as well as using the lowest pulse rate possible.[1-3]

In their study, Covi et al.[3] classified patients into 3 different groups, according to pulse fluoroscopy rates of 15, 7.5, and 5 frames. All 3 groups were equivalent in terms of difficulty, duration, and complication rate of procedures. They showed that reducing the frame rate from 15 to 7.5 fps significantly reduced radiation dose without compromising on image quality. There were no significant differences in physician-perceived ability to complete the procedure or impact of frame rate on the procedural length.

Lamers et al.[7] compared radiation doses during the standard imaging method and the new generation pediatric imaging method (10 fps) in their study, including 21 patients of less than 20 kg body weight undergoing PDA closure. Patient demographics, procedural technique, PDA dimensions, closure devices, and fluoroscopy time were similar for the 2 groups. Air kerma and DAP decreased by 65-70% by the new method (*P* values < .001).

Recently, Amdani et al.[8] showed that it is possible to reduce radiation exposure by lowering the frame rate in children undergoing cardiac catheterization without compromising the efficacy and safety of catheterization. They reported that fluoroscopy time, contrast volume, and complication rates did not increase, while diagnostic image quality was maintained. Boudjemline[9] applied a similar principle by reducing the frame rate from 7.5 to 4 fps during transcatheter atrial septal defect closure, while maintaining excellent clinical results. He argued that there was no increase in the median procedure and fluoroscopic times or complications.

Similarly, in our study, a significant decrease in air kerma and DAP levels was shown for diagnostic and interventional procedures.

Although the link between high levels of radiation exposure and cancer risk is unequivocal,[10-12] translating the relatively low level of radiation exposure from pediatric cardiac catheterization into a demonstrably increased cancer risk is more challenging. There was no demonstrable increase in cancer risk or cancer-related mortality either in an initial study of 4891 children exposed to pediatric cardiac catheterization[13] or a later study of the same cohort with up to 35 years of follow-up.[8] A separate study of 674 patients who underwent cardiac catheterization as children between 1950 and 1970 did find a significantly increased risk of lymphoma.[11]

Despite the difficulties in definitively proving an increased cancer risk after childhood radiation exposure, the theoretical possibility remains clear, as evidence for chromosomal damage has been seen immediately following cardiac catheterization.[14-17]

Limitations

This single-institution, a retrospective study has several limitations. First, the air kerma and DAP doses reported here are directly reported from the X-ray system. It is important to understand that these measures reflect what is generated at

Table 4. Radiation Exposure According to Subgroups (Diagnostic Catheterizations)

	Tetralogy of Fallot			Pre-Fontan			Pre-Glenn		
DiagnosticProcedures	15 fps	3.75 fps	*P*	15 fps	3.75 fps	*P*	15 fps	3.75 fps	*P*
Patient (*n*)	43	37	.97	14	30	.63	47	38	.83
Age (months), (median, IQR)	12(4-17)	11(5-17)	.92	39(30-45)	38(29-42)	.93	6(4-8)	5(4-7)	.32
Weight (median, IQR)	7(2.9-0.8)	8(3-9.6)	.43	25(18-32)	21(10-29)	.47	7.6(5.6-9.5)	8.1(5.9-10.6)	.48
BMI (median, IQR)	0.4(0.2-0.5)	0.4(0.2-0.5)	.30	0.9(0.4-1.2)	0.8(0.4-1.1)	.45	0.4(0.3-0.6)	0.4(0.3-0.5)	.53
Procedure time (minutes) (median, IQR)	26(15-36)	21(12-30)	.08	45(22-58)	32(25-39)	.006	35(21-47)	34(22-45)	.59
Fluoroscopy time (seconds) (median, IQR)	359(80-430)	348(110-400)	.81	750(240-960)	570(310-830)	.08	640(215-852)	611(201-811)	.75
Air kerma (mGy) (median, IQR)	59(10-92)	35(14-84)	.07	154(30-220)	81(20-180)	.05	65(28-96)	38(16-51)	.001
DAP (μGy m^2) (median, IQR)	3755(1211-5320)	3018(950-4839)	.12	17 159(2300-21 236)	8650(1954-14 589)	.02	5400(2700-7600)	3200(2100-6100)	.001
Air kerma (mGy/kg) (median, IQR)	7.2(1.5-18.3)	5.2(2.1-12.6)	.10	5.9(2.1-8)	3.7(2-4.8)	.008	9.3(3.5-12.7)	5.4(2.3-8.1)	.004
DAP (μGy m^2/kg) (median, IQR)	51(20-80)	39(16-60)	.18	120(25-150)	70(30-142)	.008	77(25-96)	42(15-80)	.001
Air kerma (mGy/BMI) (median, IQR)	155(18-210)	102(25-195)	.10	150(60-205)	90(50-160)	.01	185(59-269)	98(40-203)	.001
DAP (μGy m^2/BMI) (median, IQR)	9326(3952-13 598)	7522(3125-12 369)	.20	19 102(6325-23 587)	10 256(7589-17 589)	.002	13 500(4300-18 900)	8100(5200-12 450)	.001

Values are given as median and interquartile ranges.

Table 5. Radiation Exposure According to the Subgroups (Interventional Catheterizations)

Interventional Procedures	AS Balloon		PS Balloon		CoA Stent		CoA Balloon		PDA Stenting		ASD Closure		PDA Closure	
	15 fps	3.75 fps	15 fps	3.75 fps	15 fps	3.75 fps	15 fps	3.75 fps	15 fps	3.75 fps	15 fps	3.75 fps	15 fps	3.75 fps
Patient	15	7	15	30	9	6	9	16	13	11	19	29	31	36
Age (months)	18.0	30.1	30	43.8	156	135	35	43.7	2	1.2	133	115	48	63
Weight	8.9	11.2	13	13.8	50	40	12.4	14.4	4	3.4	40	33	18	19
BMI	0.42	0.45	0.5	0.53	1.4	1.3	0.57	0.6	0.23	0.2	1.2	1	0.7	0.7
Procedure time	36	33.5	29	36.1	41.8	42.5	33.8	38.4	58	66	26	25	32	26.2
Fluoroscopy time (seconds)	474	490	473	562	650	615	347	504	1200	1120	372	300	5.6	5.9
Air kerma (mGy)	50	45	108	82	240	129	61	72	336	69	56*	18*	187*	30*
DAP (µGy m²)	3706	3533	12 240	6864	25 920	13 248	4800	5232	5472	3456	6240	2014*	3552*	2400*
Air kerma (mGy/kg)	42 287	42 170	8	42 229	42 227	42 080	42 112	42 318	131	21	2*	1*	5*	2*
DAP (µGy m²/kg)	410	332	529	493	461	307	442	461	1440	1056	216*	72*	240*	142*
Air kerma (mGy/BMI)	132	109	168	148	154	96	129	152	1920	336	53*	22*	154*	45*
DAP (µGy m²/BMI)	8448	6413	13 200	10 560	16 128	9696	9024	9360	24 960	16 320	6000*	2400*	5520*	3264*

Values are given as median. Interquartile ranges are not given for simplicity. *$P < .05$.

the energy source and not necessarily what is actually absorbed by the patient. Effective dose and equivalent dose were not reported, but as simple logic, the reduction in generated radiation should be reflected as a reduction in both parameters.

CONCLUSION

In this study, we have demonstrated that by using the lowest possible fluoroscopy rate of 3.75 fps, the radiation dose can be significantly reduced during cardiac catheterization. This method effectively reduces the radiation dose, especially in diagnostic procedures where fluoroscopy is used extensively instead of cine angiography. Implementing this simple and effective radiation dose reduction protocol could minimize radiation's possible side effects, concomitantly increasing the safety of the patient and the health care provider without increasing the total fluoroscopy time and the amount of contrast.

Ethical Committee Approval: Ethical committee approval was received from the Ethics Committee of University of Health Sciences Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Center Department of Pediatric Cardiology (Approval No:2020/46).

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