JACC: CARDIOVASCULAR INTERVENTIONS VOL. 7, NO. 9, 2014

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER INC. http://dx.doi.org/10.1016/j.jcin.2014.04.013

RADIATION SAFETY

Radiation Dose Benchmarks During Cardiac Catheterization for Congenital Heart Disease in the United States

Sunil J. Ghelani, MD,* Andrew C. Glatz, MD, MSCE,† Sthuthi David, BS,* Ryan Leahy, MD, MS,‡ Russel Hirsch, MD,§ Laurie B. Armsby, MD,‖ Sara M. Trucco, MD,¶ Ralf J. Holzer, MD, MSc,# Lisa Bergersen, MD, MPH*

ABSTRACT

OBJECTIVES The aim of this study was to define age-stratified, procedure-specific benchmark radiation dose levels during interventional catheterization for congenital heart disease.

BACKGROUND There is a paucity of published literature with regard to radiation dose levels during catheterization for congenital heart disease. Obtaining benchmark radiation data is essential for assessing the impact of quality improvement initiatives for radiation safety.

METHODS Data were obtained retrospectively from 7 laboratories participating in the Congenital Cardiac Catheterization Project on Outcomes collaborative. Total air kerma, dose area product, and total fluoroscopy time were obtained for the following procedures: 1) patent ductus arteriosus closure; 2) atrial septal defect closure; 3) pulmonary valvuloplasty; 4) aortic valvuloplasty; 5) treatment of coarctation of aorta; and 6) transcatheter pulmonary valve placement.

RESULTS Between January 2009 and July 2013, 2,713 cases were identified. Radiation dose benchmarks are presented including median, 75th percentile, and 95th percentile. Radiation doses varied widely between age groups and procedure types. Radiation exposure was lowest in patent ductus arteriosus closure and highest in transcatheter pulmonary valve placement. Total fluoroscopy time was a poor marker of radiation exposure and did not correlate well with total air kerma and dose area product.

CONCLUSIONS This study presents age-stratified radiation dose values for 6 common congenital heart interventional catheterization procedures. Fluoroscopy time alone is not an adequate measure for monitoring radiation exposure. These values will be used as baseline for measuring the effectiveness of future quality improvement activities by the Congenital Cardiac Catheterization Project on Outcomes collaborative. (J Am Coll Cardiol Intv 2014;7:1060–9)
© 2014 by the American College of Cardiology Foundation.

A majority of cardiac catheterizations for congenital heart disease (CHD) are performed in children and adolescents who are at a higher risk of long-term adverse effects of radiation (1–3). Over the past 3 decades, a heightened awareness to minimize radiation during all radiological

From the *Department of Cardiology, Boston Children's Hospital, Boston, Massachusetts; †Division of Cardiology, Children's Hospital of Philadelphia, Philadelphia, Pennsylvania; ‡Division of Cardiology, University of Louisville, Louisville, Kentucky; §Cincinnati Children's Medical Center, Cincinnati, Ohio; ‖Oregon Health and Science University, Portland, Oregon; ¶Children's Hospital of Pittsburgh, Pittsburgh, Pennsylvania; and the #The Heart Center, Nationwide Children's Hospital, Columbus, Ohio.
The C3PO collaborative has received grant support from Program for Patient Safety and Quality at Boston Children's Hospital. Dr. Glatz is a consultant for Bristol-Myers Squibb. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Manuscript received January 8, 2014; revised manuscript received March 28, 2014, accepted April 10, 2014.

studies in children and substantial technical advancements in catheterization equipment have led to relatively lower radiation doses (4). However, over the same period, the complexity and relative number of interventional transcatheter procedures have increased (5-8). Although reference levels for radiation exposure have been widely used outside of pediatric cardiology, limited data are available with regard to radiation exposure in patients with CHD undergoing catheterization and interventions (9-16).

Obtaining benchmark radiation exposure data for congenital cardiac catheterization is challenging due to the wide variation in procedure complexity, which is affected by underlying pathology as well as the type and quality of previously obtained imaging. Varying age, size, equipment specifications, and performer skills add to this heterogeneity. Establishing baseline values is important for assessing the impact of quality measures being undertaken to minimize exposure as well as for intra- and interfacility comparisons. The Quality Metrics Working Group of the American College of Cardiology (ACC) has endorsed a dose metric for CHD catheterizations defined as the proportion of patients who receive radiation doses higher than 95th percentile of a pre-defined dataset (17). Application of this metric has been impeded by a paucity of published radiation data for congenital cardiac catheterization procedures.

The goal of the present study was to analyze radiation exposure for 6 common interventional procedures using the Congenital Cardiac Catheterization Project on Outcomes (C3PO) database. The C3PO collaborative multicenter group was founded in 2006 to better understand case-mix variation and to develop outcome measures for patients undergoing catheterization for CHD (18). The collaborative currently has 15 participating institutions and has initiated a quality improvement (QI) (C3POQI) project with the primary aim of reducing radiation exposure. We aimed to define initial benchmark radiation dose values for C3POQI that will be reassessed biannually (**Figure 1**). With QI initiatives, we expect these benchmark values to decrease over time. The results of the present study will allow application of the ACC-endorsed dose metric and will provide data to assess improvements in the future.

METHODS

All 15 participating centers in the C3PO collaborative were invited to contribute radiation dose data for the following 6 interventions: 1) patent ductus arteriosus (PDA) closure; 2) atrial septal defect (ASD) closure; 3) pulmonary valvuloplasty; 4) aortic valvuloplasty; 5) treatment of coarctation of the aorta; and 6) transcatheter pulmonary valve (TPV) placement. Seven of the 15 centers were able to retrospectively retrieve total fluoroscopy time and dose area product (DAP), and only 5 centers were able to retrieve total air kerma ($K_{a,r}$). Although most modern equipment is capable of reporting delivered dose at the time of the study, in most instances, the values must be recorded in a database or patient report at the time of the study. Unless recorded at the time of the study, these cannot be retrieved retrospectively. Centers that were unable to provide data were those that did not routinely record or report radiation doses during the study period. Technical data about the equipment and procedure were obtained and included the year of purchase of the equipment, equipment vendor, availability and use of the "store fluoro" feature ("store fluoro" is a feature/button on catheterization equipment. Hitting the button stores a fluoroscopic image that otherwise would have been discarded by the system. This feature is often ignored leading to more radiation exposure.), use of digital subtraction angiography, use of antiscatter grid, and use of copper filtration.

The cited procedures are typically performed as isolated cases and were selected to represent a relatively homogeneous case mix. The 5 procedures other than TPV placement are also captured in the IMPACT (Improving Pediatric and Adult Congenital Treatments) registry; however, these data have not been published (19). Procedures performed between January 2009 and July 2013 were included with 1 exception. The Medtronic Melody transcatheter pulmonary valve was approved for use in the United States in January 2010. To account for performer learning curve, data collection for this lesion was commenced in January 2011. Approval was obtained from either institutional review boards or quality improvement committees of the participating centers.

Patients were stratified by age and intervention type. Five age groups were defined based on previous publications to facilitate comparisons (younger than 1 year of age, 1 to 4 years of age, 5 to 9 years of age, 10 to 15 years of age, and older than 15 years of age) (20,21). Although different centers varied with regard to imaging equipment, radiation doses were calculated automatically according to standard existing federal laws. The following variables were analyzed. 1) Total air $K_{a,r}$ expressed in mGy and estimated as the sum of radiation doses in anteroposterior and lateral

ABBREVIATIONS AND ACRONYMS

ACC = American College of Cardiology

ASD = atrial septal defect

CHD = congenital heart disease

C3PO = Congenital Cardiac Catheterization Project on Outcomes

DAP = dose area product

$K_{a,r}$ = total air kerma

PCI = percutaneous coronary intervention

PDA = patent ductus arteriosus

QI = quality improvement

TPV = transcatheter pulmonary valve

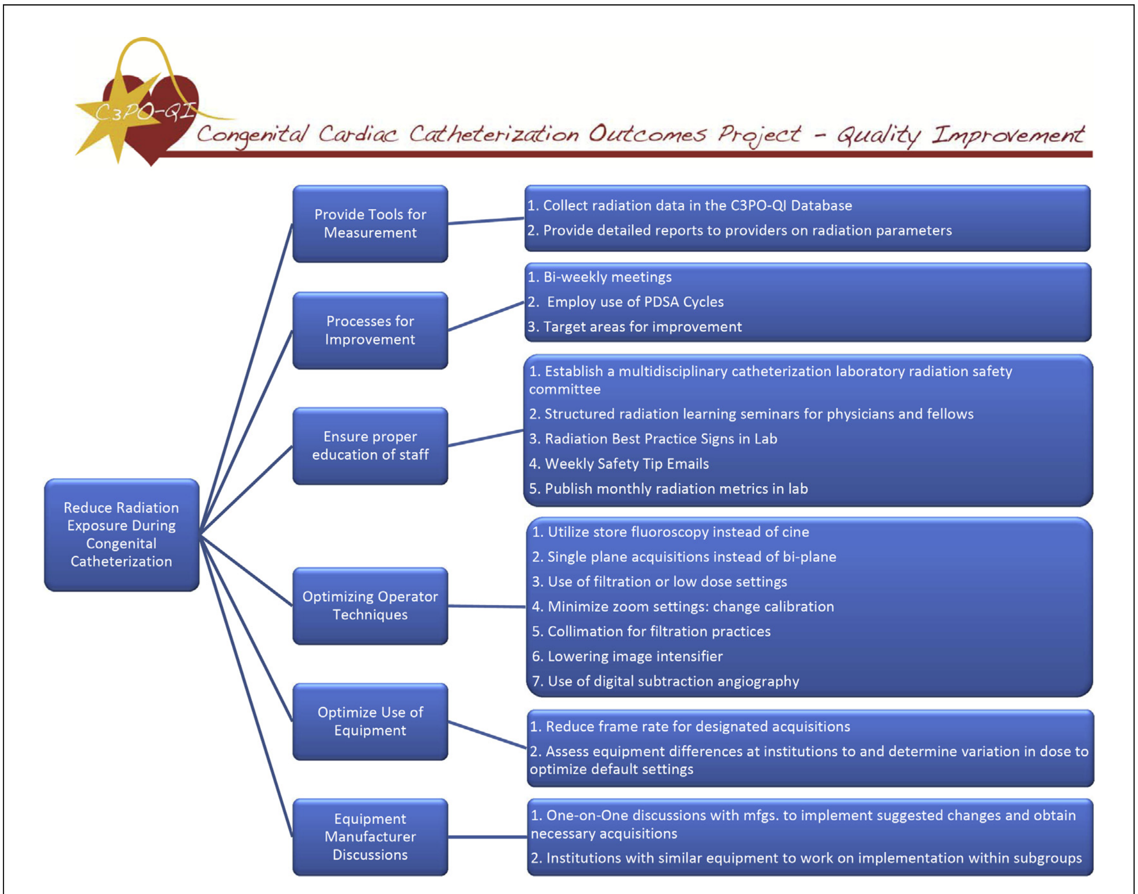

FIGURE 1 Key Elements of C3POQI Initiative

Proposed elements of Congenital Cardiac Catheterization Project on Outcomes collaborative's quality improvement project. C3POQI = Congenital Cardiac Catheterization Project on Outcomes Quality Improvement; PDSA = Plan-Do-Study-Act cycle.

imaging planes. $K_{a,r}$ is the radiation dose accumulated at a specific point in space (the patient entrance reference point) relative to the fluoroscopic gantry. It is used as a predictor of the risk of deterministic effects, such as radiation-induced skin injury (22). 2) DAP expressed in $Gy \cdot cm^2$ is the surface integral of air kerma and represents the product of radiation dose and exposed area. It is expressed as a sum of anteroposterior and lateral DAPs. It is a surrogate measure of the amount of energy delivered to the patient and thus a reasonable indicator of the risk of stochastic effects (23). 3) Total fluoroscopy time expressed in minutes as a sum of anteroposterior and lateral fluoroscopy times.

Data were summarized as medians, 75th percentile, and 95th percentile and their 95% confidence intervals (24). Stratified age groups as well as total values are presented for each of the 6 procedures. Further, smoothed percentile curves for total DAP and total air $K_{a,r}$ versus weight were estimated separately for the 4 diagnosis groups (PDA, ASD, pulmonary valvuloplasty, and aortic valvuloplasty) using quantile regression; 50th, 75th, and 95th percentiles were generated.

RESULTS

Among the 7 centers that contributed data, there were 15 catheterization laboratories. Catheterization equipment was installed between 2001 and 2009 and was supplied by 4 different vendors for 8 (Siemens AG, Medical Solutions, Malvern, Pennsylvania), 4 (Phillips Healthcare, Andover, Massachusetts), 2 (Toshiba America Medical Systems, Tustin, California), and 1 (GE Healthcare, Wauwatosa, Wisconsin) laboratories, respectively. Six of the 7 centers followed a default frame rate for fluoroscopic (10 frames per second at 1 center, 15 frames per second at 4 centers, and 30 frames per second at 1 center) and digital acquisition (15 frames per second at 4 centers, 30 frames per second at 2 centers). All the centers reported the use of the store fluoro feature; however, there was a wide range in the proportion of cases in which this was done (10% to 95%). One center used digital subtraction angiography. Six of the 7 centers used an antiscatter grid and 5 of the 5 centers that responded used copper filtration. The total number of operators in the 7 participating centers for the cases included in the study was 22. The number of operators per center ranged from 2 to 5 (median, 2 operators). Operator experience was gauged by the average number of catheterizations performed by each operator per year and ranged from 60 to 261 per year (median, 151 procedures).

A total of 2,713 cases were analyzed, and the number of cases per individual center ranged from 142 to 858 (median, 306 cases). A TPV was placed in only 2 patients between 1 and 4 years of age and in 8 patients between 5 and 9 years of age. ASD closure was performed in only 6 patients younger than 1 year of age. Data for these 3 categories of patients are not presented due to small sample size. Lesion distribution of radiation dose variables is presented in **Table 1**. Age-based stratification is presented in **Tables 2 to 4**.

Of the analyzed procedures, TPV placement had the highest median $K_{a,r}$ and DAP values at 2,286 mGy and 230 Gy·cm^2, respectively. Median and 75th and 95th percentile curves for PDA, ASD, pulmonary valvuloplasty, and aortic valvuloplasty are presented in **Figure 2**. The lowest radiation doses were noted in PDA closure and pulmonary valvuloplasty, with a median $K_{a,r}$ of 109 mGy and 114 mGy, respectively, and DAP of 7 Gy·cm^2 each.

Total fluoroscopy time was not a good measure of radiation exposure and correlated poorly with DAP and $K_{a,r}$, as seen in **Figure 3**. For example (**Table 1**), comparing TPV placement with aortic valvuloplasty, the fluoroscopy time was only double for TPV; however, the radiation exposure by $K_{a,r}$ or DAP measures was ~600% higher for TPV placement.

DISCUSSION

This is the first multicenter report of procedure-specific radiation doses during interventional catheterization for CHD. Benchmark values were generated from relatively homogeneous, age-stratified patient groups from 7 centers participating in the C3POQI collaborative. With ongoing QI efforts, as has occurred in other specialties, we anticipate radiation exposure measures to decline over time (9,10). Moreover, these benchmarks will provide a guideline to interventional cardiologists striving to achieve radiation doses as low as reasonably attainable (16). We recommend the use of DAP and $K_{a,r}$, but not fluoroscopy time, as measures of radiation exposure that are readily available and have shown good correlation with effective radiation dose (mSv) in patients (25). The present study suggests that radiation exposure varies widely among procedure type and age groups. Hence, in contrast to recommendations made by some previous studies, we recommend following procedure-specific benchmarks over a common reference value for all interventional procedures (1,26).

Limited procedure-specific reference values are available in the published literature. Verghese et al. (12) reported procedure-specific radiation doses from a single large center in the United States that also contributed data to the present study. Al-Haj et al. (14) reported their experience in Saudi Arabia. In their series, 41 patients with PDA, with a mean age of 2.4 years, had a DAP of 23.21 ± 10.1 Gy·cm^2; and 44 patients who underwent pulmonary valvuloplasty, with a mean age of 2.9 years, had a DAP of 9.96 ± 15.1 Gy·cm^2. Although it is difficult to make direct comparisons, age group-independent median values for PDA and pulmonary valvuloplasty in the present series are notably lower. In contrast, patients with coarctation of the aorta in the present study received much higher DAP than those in the Al-Haj et al. series (n = 24; mean age, 2.8 years; DAP 11.35 ± 24.3

TABLE 1 Radiation Doses for 6 Selected Interventional Catheterization Procedures

		Total Air Kerma, mGy				Dose Area Product, Gy·cm^2				Total Fluoroscopy Time, min			
Procedure	Total No.	n	Median	75th Percentile	95th Percentile	n	Median	75th Percentile	95th Percentile	n	Median	75th Percentile	95th Percentile
PDA	548	362	109	175	758	547	7	16	91	544	12	17	32
ASD	731	532	240	549	1,948	726	21	62	284	726	18	28	58
PS	462	362	114	258	1,053	461	7	18	158	461	20	32	68
AS	297	238	215	605	1,734	296	14	60	187	296	25	35	66
CoA	452	360	305	940	3,531	448	29	103	367	452	22	33	67
TPV	223	200	2,286	3,424	6,041	223	230	372	825	223	55	75	133

AS = aortic stenosis; ASD = atrial septal defect; CoA = coarctation of aorta; PDA = patent ductus arteriosus; PS = pulmonary stenosis; TPV = transcatheter pulmonary valve placement.

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 7, NO. 9, 2014
SEPTEMBER 2014:1060–9

TABLE 2 Total Air Kerma (mGy) Stratified by Procedure Type and Age Group

Procedure	Age, yrs				
	<1	1-4	5-9	10-15	>15
PDA					
No.	96	181	39	27	19
Median	76 (65-90)	96 (90-111)	160 (114-182)	300 (198-628)	949 (643-1,686)
75th percentile	118 (102-135)	140 (126-153)	195 (168-326)	715 (386-1,547)	1,686 (949-3,170)
95th percentile	230 (192-450)	253 (213-365)	392 (290-448)	1,551 (827-1,557)	3,170 (1,750-3,170)
ASD					
n	6	157	142	98	129
Median	–	120 (101-134)	188 (156-211)	444 (310-550)	630 (550-954)
75th percentile	–	220 (180-266)	300 (247-389)	768 (620-900)	1,470 (1,220-1,949)
95th percentile	–	528 (400-717)	670 (525-991)	1,738 (1,168-3,078)	3,853 (3,243-5,046)
PS					
n	244	44	18	31	25
Median	87 (79-96)	133 (119-153)	244 (100-351)	319 (272-512)	1,781 (778-2,430)
75th percentile	148 (127-174)	208 (147-282)	351 (255-698)	862 (436-1,144)	2,603 (1,789-4,976)
95th percentile	323 (289-417)	365 (282-536)	698 (382-698)	1,456 (1,053-1,710)	4,976 (3,652-9,048)
AS					
n	123	20	18	55	22
Median	122 (107-139)	258 (177-405)	170 (137-296)	780 (464-901)	882 (788-1,420)
75th percentile	204 (170-238)	421 (264-979)	296 (182-664)	1,136 (897-1,570)	1,420 (894-4,531)
95th percentile	361 (294-531)	1,377 (462-1,775)	664 (379-664)	2,111 (1,585-2,842)	4,531 (2,216-5,310)
CoA					
Median	137 (121-156)	233 (191-307)	444 (289-700)	1,043 (834-1,358)	1,716 (1,436-2,420)
75th percentile	228 (182-265)	373 (256-585)	768 (536-1,376)	1,696 (1,317-2,877)	3,024 (2,420-4,375)
95th percentile	600 (411-857)	826 (562-1,089)	1,546 (920-1,771)	3,604 (2,901-4,442)	7,128 (4,948-8,274)
TPV					
n	0	2	8	55	135
Median	–	–	–	1,461 (905-2,151)	2,502 (2,332-3,026)
75th percentile	–	–	–	2,675 (1,837-3,233)	4,050 (3,383-4,656)
95th percentile	–	–	–	4,579 (3,256-6,538)	6,820 (5,367-9,983)

Values in parentheses are 95% confidence interval.
Abbreviations as in Table 1.

Gy·cm^2). This is likely explained by a larger number of older patients undergoing coarctation stenting in the present series. In a study by Ubeda et al. (21), DAP values for aortic angioplasty, ASD closure, PDA occlusion, and pulmonary valvuloplasty were lower than in the present report. Differences in equipment, operator techniques, patient age and size, and complexity of underlying pathology are likely major contributors to these differences. Sawdy et al. (27) reported radiation dose assessment for >400 congenital heart procedures in a medium-size pediatric cardiac program and the effect of a protocol for dose reduction over time. The report includes doses for ASD and PDA closure, although radiation dose was not indexed to body surface area, and there was no grouping by age or patient size. They observed a significant reduction in the median cumulative $K_{a,r}$ for both ASD device closure (1,051 mGy vs. 634 mGy vs. 452 mGy vs. 140 mGy, $p < 0.001$) and PDA closure (328 mGy vs. 297 mGy vs. 301 mGy vs. 126 mGy, $p < 0.001$) over time. There was significant variability in the doses reported, as the cumulative $K_{a,r}$ reported for ASD closure ranged from as high as 15,795 mGy to as low as 49 mGy during the study period. Similarly for PDA closure, it ranged from as high as 4,596 mGy to as low as 66 mGy. This study demonstrates the significant variability in radiation doses in congenital procedures and enhances the importance of tracking radiation dose versus fluoroscopy times. As there was no specification of dose according to patient age and size, it would not seem possible to compare the doses reported for ASD and PDA closure with those in the present study. However, it appears that the values reported by Sawdy et al. are somewhat higher.

Values obtained in the present study can be compared with published adult data to put the numbers in perspective. Using data from 171 facilities in 30 states in the United States, Miller et al. (28) from the U.S. Food and Drug Administration have proposed

TABLE 3 Dose Area Product (Gy·cm²) Stratified by Procedure Type and Age Group

	Age, yrs				
	<1	1-4	5-9	10-15	>15
PDA					
n	130	294	60	38	25
Median	5 (4-6)	7 (6-8)	13 (10-15)	33 (17-66)	96 (70-146)
75th percentile	8 (7-10)	12 (10-14)	22 (15-31)	85 (51-146)	151 (96-253)
95th percentile	22 (16-50)	49 (39-65)	48 (33-97)	207 (142-249)	253 (179-268)
ASD					
n	6	219	180	127	194
Median	–	9 (8-10)	14 (11-16)	39 (31-50)	89 (71-113)
75th percentile	–	17 (14-22)	25 (20-32)	67 (58-90)	204 (174-262)
95th percentile	–	58 (48-84)	86 (58-129)	182 (137-568)	532 (405-716)
PS					
n	303	64	24	35	35
Median	4 (3-4)	10 (8-13)	16 (11-21)	44 (32-79)	198 (117-340)
75th percentile	9 (7-10)	18 (13-28)	23 (18-66)	98 (50-120)	448 (264-829)
95th percentile	25 (18-51)	46 (31-610)	66 (30-72)	156 (108-158)	1,336 (556-6,425)
AS					
n	155	27	22	65	27
Median	7 (5-8)	19 (12-33)	21 (13-28)	93 (70-121)	116 (82-173)
75th percentile	11 (10-14)	37 (21-67)	28 (25-57)	137 (121-161)	187 (128-576)
95th percentile	27 (22-52)	144 (53-144)	57 (41-83)	295 (211-553)	1,771 (284-2,172)
CoA					
n	202	36	38	79	93
Median	7 (6-9)	20 (14-24)	41 (30-53)	96 (72-123)	200 (162-250)
75th percentile	14 (12-18)	30 (20-53)	65 (47-98)	170 (133-210)	340 (270-571)
95th percentile	45 (36-85)	62 (43-112)	179 (76-449)	303 (231-494)	933 (659-4,981)
TPV					
n	0	2	8	59	154
Median	–	–	–	147 (96-176)	288 (251-312)
75th percentile	–	–	–	249 (176-323)	430 (388-496)
95th percentile	–	–	–	540 (331-2,362)	902 (753-1,307)

Values in parentheses are 95% confidence interval.
Abbreviations as in Table 1.

a $K_{a,r}$ reference level (75th percentile of representative data) of 1.18 Gy for diagnostic catheterization and 3.12 Gy for percutaneous coronary interventions (PCIs). In the older than 15 years age subgroup of the present study with patients closest to adult size, TPV placement exceeded the PCI reference level (4.05 Gy), whereas other interventional procedure types were between the diagnostic and PCI reference levels. These high doses are important to note given that many patients with CHD would have had previous catheterization(s) and may have more procedures in the future.

Radiation exposure during catheterization for CHD is an important issue. Children are exposed to a relatively smaller total dose of radiation due to their smaller size; hence, the incidence of deterministic effects such as skin necrosis is low (1,29). However, longer life expectancy compared with adults undergoing catheterization for coronary artery disease puts them at a higher risk of long-term stochastic effects such as malignancy (30,31). The need for multiple catheterizations and higher tissue sensitivity adds to this long-term risk in children (2,3,32). International authorities on radiation safety have estimated that the risk of stochastic effects such as malignancies is at least 2 to 3 times higher in children compared with adults (31,33). Previous single-center studies have reported success with reduction in radiation doses with standardized catheterization protocols (12,27,34,35). A number of recent technical advances have had a positive impact on radiation doses in the catheterization laboratory. Most prominent among these are the introduction of isocentric biplane imaging systems, the use of all-digital systems with ready ability to replay previous acquisitions, the use of strong copper filtration in x-ray tubes, and the use of high-efficiency flat-panel image detectors (4). Alternative imaging techniques have successfully

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 7, NO. 9, 2014
SEPTEMBER 2014:1060–9

TABLE 4 Total Fluoroscopy Time (min) Stratified by Procedure Type and Age Group

	Age, yrs				
	<1	1–4	5–9	10–15	>15
PDA					
n	129	292	60	38	25
Median	15 (13–16)	10 (10–11)	11 (9–13)	12 (10–15)	24 (18–30)
75th percentile	21 (19–24)	16 (14–17)	15 (13–23)	17 (12–20)	33 (24–49)
95th percentile	33 (28–49)	28 (22–34)	28 (23–33)	36 (19–38)	49 (43–67)
ASD					
n	6	222	180	127	191
Median	–	18 (16–20)	16 (15–18)	17 (15–19)	20 (18–24)
75th percentile	–	27 (23–31)	24 (22–28)	27 (23–36)	31 (29–34)
95th percentile	–	64 (51–81)	49 (39–64)	56 (45–83)	55 (47–88)
PS					
n	303	64	24	35	35
Median	21 (18–23)	19 (16–23)	13 (9–20)	15 (13–20)	28 (22–36)
75th percentile	35 (30–40)	30 (23–36)	20 (15–63)	22 (18–27)	42 (31–56)
95th percentile	72 (65–77)	64 (37–329)	63 (24–114)	47 (26–62)	61 (49–86)
AS					
n	155	26	22	66	27
Median	25 (22–27)	21 (16–33)	22 (18–30)	28 (25–32)	23 (19–39)
75th percentile	34 (31–42)	33 (25–58)	30 (23–52)	36 (32–40)	39 (26–55)
95th percentile	70 (58–90)	58 (48–128)	52 (35–57)	49 (40–270)	55 (49–62)
CoA					
n	205	37	38	79	93
Median	21 (19–24)	23 (20–29)	22 (18–29)	20 (18–23)	24 (22–31)
75th percentile	32 (29–39)	35 (28–60)	33 (27–48)	26 (23–35)	36 (33–46)
95th percentile	66 (56–78)	67 (46–69)	55 (38–73)	53 (39–90)	80 (59–723)
TPV					
n	0	2	8	59	154
Median	–	–	–	50 (38–61)	55 (49–57)
75th percentile	–	–	–	74 (61–107)	75 (68–89)
95th percentile	–	–	–	146 (114–173)	131 (101–222)

Values in parentheses are 95% confidence interval.
Abbreviations as in Table 1.

been used to decrease radiation exposure during catheterization for electrophysiology procedures (36). More recently, an x-ray magnetic resonance fusion technique has been investigated as a potential method to reduce radiation exposure for congenital catheterization (37). For procedures such as ASD closure, the radiation dose may depend on the relative use of transesophageal echocardiography and/or intracardiac echocardiography compared with cine or fluoroscopy. Despite these advances, cardiologists are obliged to minimize radiation exposure. This is especially important for patients undergoing prolonged procedures for complex pathology and those undergoing multiple procedures during their lifetimes.

Some studies have reported DAP values per kilogram to account for dose variability based on weight (11,26). The present study was able to estimate weight-based percentile curves for 4 of the 6 analyzed procedures and show a gradual increase in exposure with weight. However, there is a paucity of pediatric literature with regard to correlation of radiation doses with anthropometric parameters. In addition to age, the radiation dose may be affected by sex, weight, chest shape, chest thickness, angle of projection, and the presence of pulmonary pathology (26,38–41). Additionally, for reliable data on quality and outcomes, standardizing clinical practice is of utmost importance. As a part of its QI initiative, the C3PO plans to implement an educational module for participating centers with an emphasis on staff education, technique optimization, equipment standardization, and interval outcome assessments (Figure 1). Ongoing multicenter efforts, collaboration with industry, and uniform case and radiation dose definitions will be of the utmost importance to obtain nationally representative data for future QI initiatives and periodic assessments.

STUDY LIMITATIONS. This study must be viewed in light of its potential limitations. We report $K_{a,r}$, which represents the cumulative dose for the entire examination. To best estimate the risk of deterministic injury to the patient, one must estimate the maximal $K_{a,r}$ among all the skin ports on the patient's body through which the different x-ray projections passed. The second parameter that we report is the cumulative DAP. Although DAP is a reasonable estimate of stochastic risk, further assumptions must be made to estimate effective dose (mSv) (25). The reported parameters were chosen based on ease of obtaining from multiple centers, their availability from modern fluoroscopy equipment, and because they are the most commonly reported measures in published literature. However, different centers use different equipment and protocols. In the absence of standardized practice, the presented percentiles should be viewed as real-world baselines rather than guideline or reference levels that a center should aim to achieve. As C3PO evaluates radiation doses prospectively from a larger number of centers, future data are likely to be more homogeneous and representative. All 15 centers participating in the C3POQI were approached, but only 7 could retrospectively obtain required parameters. The collaborative continues to work with manufacturers to modify equipment so that radiation dose information is easily accessible. Although measurement procedures are standardized, there is a possibility of skewed data based purely on this fact. Using percentile values for data from 7 different centers may reduce the chance of such an error. As some centers in the database performed many more procedures than others, results of this study may be

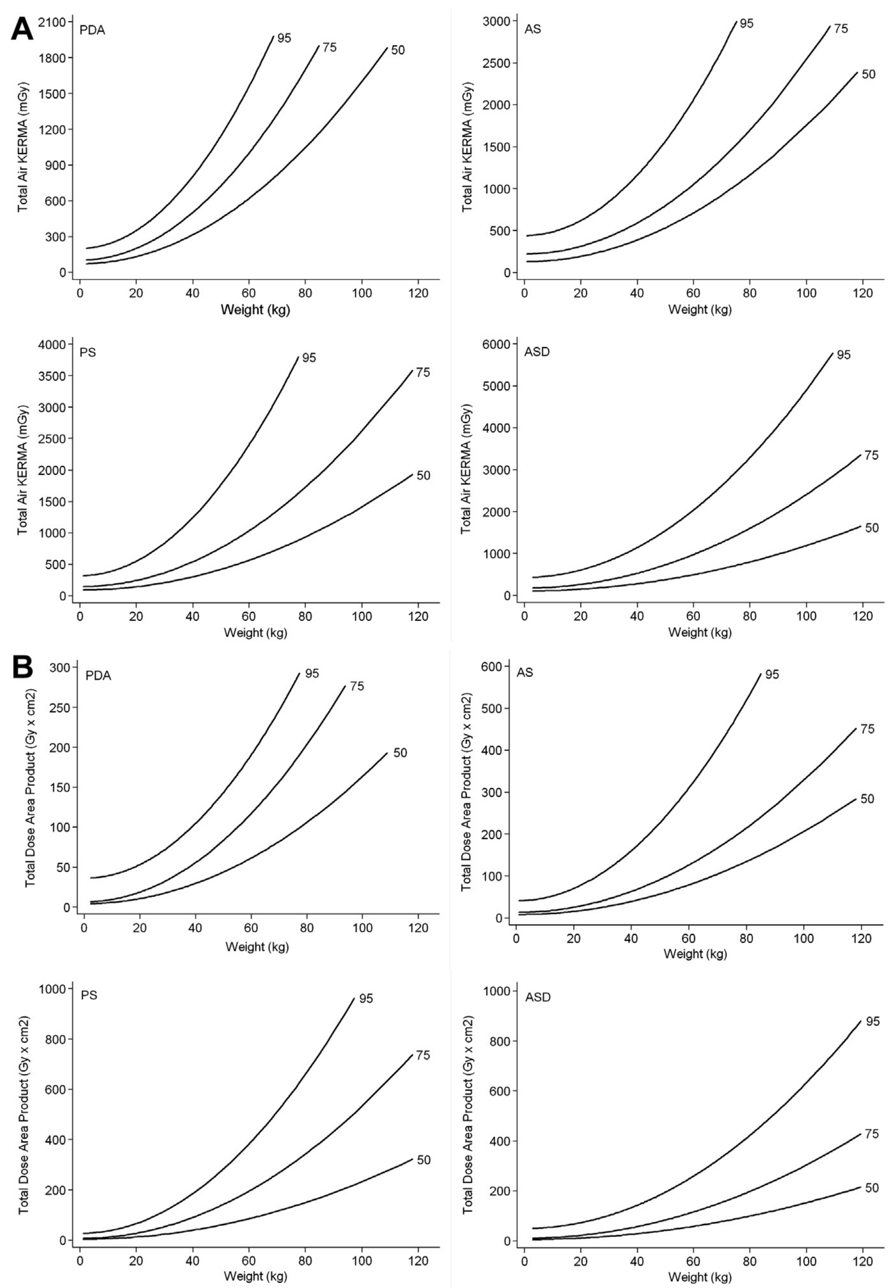

FIGURE 2 Weight-Based Percentile Curves for $K_{a,r}$ and Total Dose Area Product

Weight-based, smoothed 50th, 75th, and 95th percentile curves for total air kerma ($K_{a,r}$) **(A)** and dose area product **(B)**. AS = aortic stenosis; ASD = atrial septal defect; PDA = patent ductus arteriosus; PS = pulmonary stenosis.

unevenly affected by procedures and practices in these larger centers. However, center level analysis was precluded by a relatively small number of cases per center in individual categories. We reported data for only 6 specific procedures that represent a fraction of those that take place in the pediatric catheterization lab. Although we attempted to query lesions that typically occur in isolation and are relatively "simple," there is a possibility of significant heterogeneity within each group. For example,

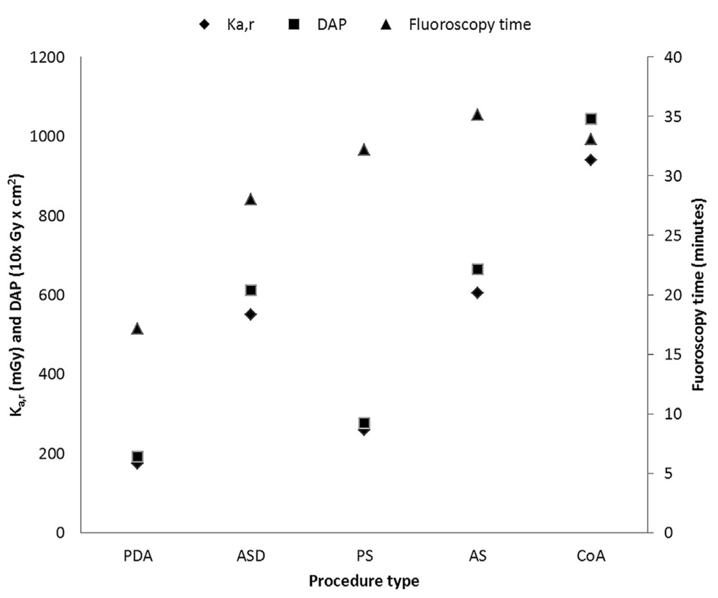

FIGURE 3 **Fluoroscopy Time, Dose Area Product, and $K_{a,r}$ for 5 Types of Procedure**

Lack of correlation of fluoroscopy time with dose area product and $K_{a,r}$. DAP = dose area product; CoA = coarctation of aorta; other abbreviations as in Table 2.

aortic coarctation interventions included balloon angioplasty, primary stenting, secondary stenting, and stent redilation, which have differing levels of risk and perhaps a need for additional angiograms and fluoroscopy time. Similarly, patients with multiple ASDs requiring multiple devices were included in addition to those with single defects. Finally, the most complex procedure included was likely TPV, which not infrequently has associated branch pulmonary artery stenosis. TPV procedures that included dilation and/or stenting of branch pulmonary arteries were not separated from those that did not, nor were TPV implantations during which stenting of the right ventricular outflow tract was performed at a previous procedure separated from those where this occurred during the same sitting. Due to extreme heterogeneity in pathology it may be impossible to obtain reference data for every individual procedure type. However, barring few exceptions, most modifiable factors in radiation safety are equipment and operator dependent. Thus, efforts aimed at reducing radiation exposure for these 6 procedures would likely also reflect similar reduction in other procedures.

CONCLUSIONS

In summary, this study represents the first multicenter effort to provide age-stratified radiation doses for 6 specific interventional catheterizations in CHD. It demonstrated that radiation exposure varies widely among types of interventional procedures and age group. It showed that fluoroscopy time alone is not an adequate measure for monitoring radiation exposure. These data will facilitate application of the ACC-endorsed pediatric radiation dose metric, namely, the proportion of cases receiving radiation in excess of the 95th percentile. The C3POQI project plans to prospectively assess collaborative-wide radiation doses biannually to determine the impact of various QI initiatives. Additionally, nonparticipating centers may consider using these values as a benchmark to compare their performance.

ACKNOWLEDGMENT The authors acknowledge the assistance of Kimberlee Gauvreau, ScD, of Boston Children's Hospital, with biostatistics and generating the percentile curves.

REPRINT REQUESTS AND CORRESPONDENCE: Dr. Lisa Bergersen, Department of Cardiology, Boston Children's Hospital, 300 Longwood Avenue, Boston, Massachusetts. E-mail: lisa.bergersen@cardio.chboston.org.

REFERENCES

1. Bacher K, Bogaert E, Lapere R, De Wolf D, Thierens H. Patient-specific dose and radiation risk estimation in pediatric cardiac catheterization. Circulation 2005;111:83–9.

2. Boothroyd A, McDonald E, Moores BM, Sluming V, Carty H. Radiation exposure to children during cardiac catheterization. Br J Radiol 1997; 70:180–5.

3. Martin EC, Olson AP, Steeg CN, Casarella WJ. Radiation exposure to the pediatric patient during cardiac catheterization and angiocardiography. Emphasis on the thyroid gland. Circulation 1981; 64:153–8.

4. Strauss KJ. Pediatric interventional radiography equipment: safety considerations. Pediatr Radiol 2006;36 Suppl 2:126–35.

5. Strauss KJ, Kaste SC. The ALARA (as low as reasonably achievable) concept in pediatric interventional and fluoroscopic imaging: striving to keep radiation doses as low as possible during fluoroscopy of pediatric patients–a white paper executive summary. Pediatr Radiol 2006;36 Suppl 2:110–2.

6. Anon. FDA White Paper: Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging. 2010. Available at: http://www.fda.gov/downloads/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/UCM200087.pdf. Accessed July 17, 2013.

7. The Joint Commission, Oakbrook Terrace, IL. Sentinel Event Policy and Procedures. Available at: http://www.jointcommission.org/sentinel_event.aspx. Accessed July 28, 2013.

8. Mercuri M, Moran GR, Gauthier L, et al. Radiation dose in interventional cardiology procedures: urgent need for monitoring dose and establishing diagnostic reference levels. Healthc Q Tor Ont 2008;11:76–83.

9. Hart D, Hillier MC, Wall BF. National reference doses for common radiographic, fluoroscopic and dental X-ray examinations in the UK. Br J Radiol 2009;82:1–12.

10. Khong P-L, Ringertz H, Donoghue V, et al. ICRP PUBLICATION 121: Radiological Protection in Paediatric Diagnostic and Interventional Radiology. Ann ICRP 2013;42:1–63.

11. Chida K, Ohno T, Kakizaki S, et al. Radiation dose to the pediatric cardiac catheterization and intervention patient. AJR Am J Roentgenol 2010;195:1175–9.

12. Verghese GR, McElhinney DB, Strauss KJ, Bergersen L. Characterization of radiation exposure and effect of a radiation monitoring policy in a large volume pediatric cardiac catheterization lab. Catheter Cardiovasc Interv 2012;79:294–301.

13. El Sayed MH, Roushdy AM, El Farghaly H, El Sherbini A. Radiation exposure in children during the current era of pediatric cardiac intervention. Pediatr Cardiol 2012;33:27–35.

14. Al-Haj AN, Lobriguito AM, Rafeh W. Variation in radiation doses in paediatric cardiac catheterisation procedures. Radiat Prot Dosimetry 2008;129:173–8.

15. McFadden S, Hughes C, D'Helft CI, et al. The establishment of local diagnostic reference levels for paediatric interventional cardiology. Radiography. Available at: http://www.sciencedirect.com/science/article/pii/S1078817413000461. Accessed July 31, 2013.

16. Justino H. The ALARA concept in pediatric cardiac catheterization: techniques and tactics for managing radiation dose. Pediatr Radiol 2006;36 Suppl 2:146–53.

17. Doyle T, Bergersen L, Armstrong A, et al. Radiation exposure metric. Paper presented at: The Annual Scientific Session of the American College of Cardiology; March 14-16, 2010; Atlanta, GA.

18. Bergersen L, Marshall A, Gauvreau K, et al. Adverse event rates in congenital cardiac catheterization-a multi-center experience. Catheter Cardiovasc Interv 2010;75:389–400.

19. Martin GR, Beekman RH, Ing FF, et al. The IMPACT registry: IMproving Pediatric and Adult Congenital Treatments. Semin Thorac Cardiovasc Surg Pediatr Card Surg Annu 2010;13:20–5.

20. Martinez LC, Vano E, Gutierrez F, Rodriguez C, Gilarranz R, Manzanas MJ. Patient doses from fluoroscopically guided cardiac procedures in pediatrics. Phys Med Biol 2007;52:4749–59.

21. Ubeda C, Vano E, Miranda P, Leyton F. Pilot program on patient dosimetry in pediatric interventional cardiology in Chile. Med Phys 2012;39:2424–30.

22. Miller DL, Balter S, Cole PE, et al. Radiation doses in interventional radiology procedures: the RAD-IR study: part I: overall measures of dose. J Vasc Interv Radiol 2003;14:711–27.

23. Hirshfeld J, Balter S, Brinker JA, et al. ACCF/AHA/HRS/SCAI clinical competence statement on physician knowledge to optimize patient safety and image quality in fluoroscopically guided invasive cardiovascular procedures. A report of the American College of Cardiology Foundation/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training. J Am Coll Cardiol 2004;44:2259–82.

24. Conover WJ. Practical Nonparametric Statistics. 2nd edition. New York, NY: John Wiley & Sons, 1980.

25. Schmidt PW, Dance DR, Skinner CL, Smith IA, McNeill JG. Conversion factors for the estimation of effective dose in paediatric cardiac angiography. Phys Med Biol 2000;45:3095–107.

26. Onnasch DGW, Schröder FK, Fischer G, Kramer H-H. Diagnostic reference levels and effective dose in paediatric cardiac catheterization. Br J Radiol 2007;80:177–85.

27. Sawdy JM, Kempton TM, Olshove V, et al. Use of a dose-dependent follow-up protocol and mechanisms to reduce patients and staff radiation exposure in congenital and structural interventions. Catheter Cardiovasc Interv 2011;78:136–42.

28. Miller DL, Hilohi CM, Spelic DC. Patient radiation doses in interventional cardiology in the U.S.: advisory data sets and possible initial values for U.S. reference levels. Med Phys 2012;39:6276–86.

29. Balter S, Hopewell JW, Miller DL, Wagner LK, Zelefsky MJ. Fluoroscopically guided interventional procedures: a review of radiation effects on patients' skin and hair. Radiology 2010;254:326–41.

30. Rassow J, Schmaltz AA, Hentrich F, Streffer C. Effective doses to patients from paediatric cardiac catheterization. Br J Radiol 2000;73:172–83.

31. ICRP. 1990 Recommendations of the International Commission on Radiological Protection. ICRP Publication 60. Ann. ICRP 1991;21:1–3.

32. Allen HD, Driscoll DJ, Fricker FJ, et al. Guidelines for pediatric therapeutic cardiac catheterization. A statement for health professionals from the Committee on Congenital Cardiac Defects of the Council on Cardiovascular Disease in the Young, the American Heart Association. Circulation 1991;84:2248–58.

33. United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR). UNSCEAR 2000 Report Vol. II. Sources and Effects of Ionizing Radiation. 2000:2–17.

34. Sutton NJ, Lamour J, Gellis LA, Pass RH. Pediatric patient radiation dosage during endomyocardial biopsies and right heart catheterization using a standard "ALARA" radiation reduction protocol in the modern fluoroscopic era. Catheter Cardiovasc Interv 2014;83:80–3.

35. Gellis LA, Ceresnak SR, Gates GJ, Nappo L, Pass RH. Reducing patient radiation dosage during pediatric SVT ablations using an "ALARA" radiation reduction protocol in the modern fluoroscopic era. Pacing Clin. Electrophysiol. PACE 2013;36:688–94.

36. Mah DY, Miyake CY, Sherwin ED, et al. The use of an integrated electroanatomic mapping system and intracardiac echocardiography to reduce radiation exposure in children and young adults undergoing ablation of supraventricular tachycardia. Europace 2014;16:277–83.

37. Dori Y, Sarmiento M, Glatz AC, et al. X-ray magnetic resonance fusion to internal markers and utility in congenital heart disease catheterization. Circ Cardiovasc Imaging 2011;4:415–24.

38. Fetterly KA, Lennon RJ, Bell MR, Holmes DR Jr., Rihal CS. Clinical determinants of radiation dose in percutaneous coronary interventional procedures: influence of patient size, procedure complexity, and performing physician. J Am Coll Cardiol. Intv 2011;4:336–43.

39. Van de Putte S, Verhaegen F, Taeymans Y, Thierens H. Correlation of patient skin doses in cardiac interventional radiology with dose-area product. Br J Radiol 2000;73:504–13.

40. Kuon E, Günther M, Gefeller O, Dahm JB. Standardization of occupational dose to patient DAP enables reliable assessment of radiation-protection devices in invasive cardiology. Rofo 2003;175:1545–50.

41. Hart D, Wall BF, Shrimpton PC, Bungay DR, Dance DR. NRPB- R318-Reference Doses and Patient Size in Paediatric Radiology. Available at: http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1195733786824. Accessed July 30, 2013.

KEY WORDS congenital heart disease, quality improvement, radiation dose