Catheterization and Cardiovascular Interventions 00:00–00 (2017)

Original Studies

Radiation Dose Benchmarks in Pediatric Cardiac Catheterization: A Prospective Multi-Center C3PO-QI Study

Priscila C. Cevallos,[1] BS, **Aimee K. Armstrong,**[2] MD, **Andrew C. Glatz,**[3] MD MSCE, **Bryan H. Goldstein,**[4] MD, **Todd M. Gudausky,**[5] MD, **Ryan A. Leahy,**[6] MD MS, **Christopher J. Petit,**[7] MD, **Shabana Shahanavaz,**[8] MD, **Sara M. Trucco,**[9] MD, and **Lisa J. Bergersen,**[1*] MD MPH

Objectives: This study sought to update benchmark values to use a quality measure prospectively. Background: Congenital Cardiac Catheterization Outcomes Project – Quality Improvement (C3PO-QI), a multi-center registry, defined initial radiation dose benchmarks retrospectively across common interventional procedures. These data facilitated a dose metric endorsed by the American College of Cardiology in 2014. Methods: Data was collected prospectively by 9 C3PO-QI institutions with complete case capture between 1/1/2014 and 6/30/2015. Radiation was measured in total air kerma (mGy), dose area product (DAP) (μGy*M^2), DAP per body weight, and fluoroscopy time (min), and reported by age group as median, 75th and 95th%ile for the following six interventional procedures: (1) atrial septal defect closure; (2) aortic valvuloplasty; (3) treatment of coarctation of the aorta; (4) patent ductus arteriosus closure; (5) pulmonary valvuloplasty; and (6) transcatheter pulmonary valve implantation. Results: The study was comprised of 1,680 unique cases meeting inclusion criteria. Radiation doses were lowest for pulmonary valvuloplasty (age <1 yrs, median mGy: 59, DAP: 249) and highest in transcatheter pulmonary valve implantation (age >15 yrs, median mGy: 1835, DAP: 17990). DAP/kg standardized outcome measures across weights within an age group and procedure type significantly more than DAP alone. Radiation doses decreased for all procedures compared to those reported previously by both median and median weight-based percentile curves. These differences in radiation exposure were observed without changes in median fluoroscopy time. Conclusions: This study updates previously established benchmarks to reflect QI efforts over time.

[1]Department of Cardiology, Boston Children's Hospital, Boston, Massachusetts
[2]Department of Cardiology, Nationwide Children's Hospital, Columbus, Ohio
[3]Cardiac Center, The Children's Hospital of Philadelphia, Philadelphia, Pennsylvania
[4]Department of Cardiology, Cincinnati Children's Hospital, Cincinnati, Ohio
[5]Division of Cardiology, Children's Hospital of Wisconsin, Milwaukee, Wisconsin
[6]Department of Cardiology, Kosair Children's Hospital, Louisville, Kentucky
[7]Department of Cardiology, Children's Healthcare of Atlanta Sibley Heart Center, Atlanta
[8]Division of Pediatric Cardiology, St. Louis Children's Hospital, St. Louis, Missouri
[9]Division of Pediatric Cardiology, Children's Hospital of Pittsburgh, Pittsburgh, Pennsylvania

Conflict of Interest: The authors declare that they have no conflicts of interest.

Funding: None.

*Correspondence to: Lisa Bergersen, MD MPH, Department of Cardiology, Boston Children's Hospital-Bader 607, 300 Longwood Avenue, Boston, MA 02115. E-mail: lisa.bergersen@cardio.chboston.org

Received 1 September 2016; Revision accepted 12 December 2016

DOI: 10.1002/ccd.26911
Published online 00 Month 2017 in Wiley Online Library (wileyonlinelibrary.com)

These thresholds can be applied for quality measurement and comparison.

Key words: congenital heart disease; pediatrics; comparative effectiveness/patient centered outcomes research; health care outcomes; imaging; angiographic/fluoroscopic; pediatric intervention

INTRODUCTION

Catheterization procedures are increasingly utilized to treat pediatric congenital heart disease, necessarily exposing children to radiation [1–5]. The risk of radiation exposure in children is of particular concern compared to the adult population, as children are more vulnerable to direct tissue damage and induced biochemical damage [3,6–8]. Further, as life expectancy in children with congenital heart disease increases, often from the interventional procedures themselves, these children may be subject to repeated catheterizations, resulting in higher cumulative radiation exposure over their lifetimes [9,10]. As a result of increased awareness and publication on radiation exposure in children with congenital heart disease, many pediatric catheterization labs have begun to participate in radiation reduction initiatives, such as implementing local radiation safety protocols, as well as collaborating in national and international radiation reduction quality improvement (QI) efforts [9,11–17]. However, there is a paucity of published radiation dose metrics for reference and comparison among pediatric cardiac catheterization procedures.

The American College of Cardiology (ACC) Quality Metrics Working Group endorsed a QI radiation dose metric defined as the proportion of cases receiving radiation doses not exceeding the 95th percentile of a predefined dataset [18]. Ghelani et al. established initial radiation dose benchmarks with data from the Congenital Cardiac Catheterization Project on Outcomes – Quality Improvement (C3PO-QI), a multi-institutional registry which aims to reduce radiation doses at participating sites [13]. These benchmarks were established retrospectively with data obtained from 2009 to 2013 to allow application of the quality metric and to assess the impact of C3PO-QI's radiation reduction initiative. This initiative included 2,713 cases among 7 participating centers. However, benchmarks should be adjusted periodically to account for broad reductions in radiation dose and to revise improvement expectations. This study sought to prospectively update the previously retrospectively established benchmarks with contemporary data to reflect the collaborative's outcomes since 2014. Importantly, the current study not only includes a larger number of participating centers, but also comes after institution of radiation reduction efforts in all participating centers, thus reflecting improving, lower radiation exposures.

METHODS

Prospective data collection began among C3PO-QI participating institutions on January 1, 2014 for all cases including interventional catheterization procedures classified into six procedural types: (1) atrial septal defect (ASD) closure; (2) aortic valvuloplasty (AV); (3) treatment of coarctation of the aorta (COA); (4) patent ductus arteriosus (PDA); (5) pulmonary valvuloplasty (PV); and (6) transcatheter pulmonary valve (TPV) implantation. These procedures were selected for this analysis to best represent a homogeneous case mix and to facilitate comparison based on previously reported measures [13]. Out of the 15 participating institutions, 9 centers contributed complete institutional case entry in the C3PO-QI database during this study period required for inclusion in this dataset analysis. All data from the remaining centers were excluded due to incomplete case capture during the study period. IRB approval was obtained for this study at each participating site in accordance with institutional requirements. All cases performed between January 1, 2014 and June 30, 2015 were screened for eligibility. Interventional procedures involving more than one procedure were excluded to maintain case type homogeneity and generalizable interpretation of the radiation outcome among these isolated procedure types.

Radiation doses were analyzed as the sum of biplane imaging for the following variables: (1) total air kerma (mGy), a predictor of deterministic effects, estimates the radiation exposure at the interventional reference point, (2) dose area product (DAP, uGy*M^2), an indicator of the risk of stochastic effects, represents the products of radiation dose and exposed area (also known as kerma area product, P_{KA}), (3) DAP per body weight (μGy*M^2/kg) a surrogate for energy delivered indexed by body weight, and (4) total fluoroscopy time (min).

Statistical Summary

Radiation dose outcomes were reported as median, 75th percentile, and 95th percentile with corresponding 95% confidence interval, stratified by case type and age group (<1 yr of age, 1–4 yrs of age, 5–9 yrs of age, 10–15 yrs of age and >15 yrs of age). To determine the relationship between radiation exposure and body weight, as previously reported in other studies,

TABLE I. Radiation Doses for 6 Selected Interventional Catheterization Procedures

		Total air kerma, mGy				Dose area product, μGy·M^2				Dose area product per body weight, μGy·M^2/kg				Total fluoroscopy time, min			
Procedure	Total No.	*N*	Median	75th	95th	N	Median	75th	95th	*N*	Median	75th	95th	*N*	Median	75th	95th
ASD	307	294	106	228	1111	296	771	1769	8841	295	34	64	199	276	17	27	67
AV	140	139	173	433	1973	137	959	3372	15532	136	99	165	383	127	27	41	83
COA	299	292	207	592	1910	289	1307	4467	16580	288	90	165	384	268	23	34	68
PDA	463	444	73	135	481	445	407	818	3139	443	37	72	217	384	13	20	41
PV	267	261	69	153	657	259	326	785	7713	258	53	104	335	233	18	32	68
TPV	204	200	1450	2590	5691	199	13551	24498	60012	199	257	400	671	195	43	61	119

ASD = atrial septal defect; AV = aortic valvuloplasty; COA = coarctation of the aorta; PDA = patent ductus arteriosus; PV = pulmonary valvuloplasty; TPV = transcatheter pulmonary valve.

TABLE II. Total Air kerma (mGy) Stratified by Procedure Type and Age Group

	Age, yrs				
Procedure	<1	1–4	5–9	10–15	>15
ASD					
n	7	108	83	50	46
Median	–	66 (52, 88)	91 (61, 118)	137 (79, 235)	548 (288, 852)
75th percentile	–	130 (107, 160)	159 (131, 218)	337 (170, 735)	1019 (631, 1407)
95th percentile	–	403 (221, 1685)	598 (265, 1070)	1823 (735, 2650)	2635 (1371, 4070)
AV					
n	72	12	14	24	17
Median	112 (88, 139)	142 (73, 389)	202 (118, 1103)	427 (220, 596)	901 (433, 1307)
75th percentile	202 (144, 273)	385 (120, 2031)	571 (156, 2166)	812 (455, 1463)	1316 (901, 3794)
95th percentile	502 (351, 1022)	2031 (389, 2031)	2166 (394, 2166)	1927 (949, 2081)	3794 (1325, 3794)
COA					
n	139	26	35	44	48
Median	102 (82, 118)	170 (138, 392)	333 (220, 510)	479 (338, 656)	918 (665, 1461)
75th percentile	185 (153, 231)	609 (176, 1353)	561 (376, 805)	859 (648, 1417)	1875 (1309, 2491)
95th percentile	586 (334, 881)	2046 (782, 2419)	1937 (743, 3769)	3703 (1417, 5382)	3181 (2397, 7551)
PDA					
n	149	202	51	25	17
Median	71 (58, 78)	58 (51, 68)	90 (67, 124)	230 (165, 344)	481 (304, 1107)
75th percentile	106 (87, 127)	112 (91, 129)	162 (105, 251)	438 (248, 2519)	1288 (481, 2931)
95th percentile	369 (245, 510)	255 (190, 370)	520 (251, 576)	3080 (1047, 3321)	2931 (1469, 2931)
PV					
n	187	34	15	16	9
Median	59 (53, 67)	85 (52, 147)	125 (99, 400)	360 (255, 702)	–
75th percentile	100 (84, 123)	184 (103, 331)	400 (125, 1397)	686 (328, 2304)	–
95th percentile	271 (235, 311)	722 (287, 959)	1397 (400, 1397)	2304 (702, 2304)	–
TPV					
n	0	4	14	57	125
Median	–	–	881 (213, 1254)	1224 (766, 1646)	1835 (1545, 2305)
75th percentile	–	–	1218 (876, 1377)	1819 (1539, 2612)	3289 (2604, 4323)
95th percentile	–	–	1377 (1206, 1377)	3665 (2861, 4684)	7102 (5312, 10519)

Values in parenthesis are 95% confidence intervals for the reported value. ASD = atrial septal defect; AV = aortic valvuloplasty; COA = coarctation of the aorta; PDA = patent ductus arteriosus; PV = pulmonary valvuloplasty; TPV = transcatheter pulmonary valve.

DAP per body weight was further stratified by body weight group according to the following categories: <10 kg, 10–20 kg, 20–30 kg, 30–50 kg, and >50 kg [10,13,16]. Case types, age groups, and body weight categories with insufficient data, arbitrarily chosen to be less than 10 representative cases, were excluded in the summary tables. To determine the relationship between age, weight, and DAP and DAP/kg, a scatter plot was created for TPV placement in patients > 15 yrs to compare trend lines between median DAP and DAP/kg. Linear regression lines were fitted for DAP and DAP/kg by weight, and the slopes of these lines were compared using standardized regression coefficients. Additionally, smoothened weight-based percentile curves for total air kerma and DAP were generated by procedure type (ASD, AV, PDA, PV) using quantile

TABLE III. Dose Area Product (μGy·M^2) Stratified by Procedure Type and Age Group

Procedure	Age, yrs <1	1–4	5–9	10–15	>15
ASD					
n	7	110	83	50	46
Median	–	466 (324, 612)	646 (468, 867)	1155 (844, 1952)	4240 (2581, 5810)
75th percentile	–	841 (699, 1115)	1117 (988, 1427)	3219 (1772, 8229)	7572 (5567, 12399)
95th percentile	–	2676 (1779, 7607)	3200 (1622, 6780)	13245 (8229, 21955)	22486 (11456, 37222)
AV					
n	72	12	13	24	16
Median	467 (354, 580)	608 (499, 1585)	1915 (1141, 9126)	4000 (2649, 6393)	10003 (7767, 14039)
75th percentile	887 (613, 1120)	1492 (594, 3454)	6304 (1915, 20424)	6756 (5072, 15457)	14018 (9580, 36242)
95th percentile	1988 (1491, 2769)	3454 (1585, 3454)	20424 (9126, 20424)	16017 (8589, 16203)	36242 (14039, 36242)
COA					
n	136	26	35	44	48
Median	401 (349, 514)	1068 (787, 2497)	2398 (1453, 3308)	5052 (3228, 6751)	8751 (6985, 11763)
75th percentile	872 (674, 1247)	2733 (1612, 5905)	3724 (2550, 6628)	8451 (6299, 12129)	14942 (10585, 19985)
95th percentile	2488 (1528, 4237)	11654 (3282, 14750)	11919 (4577, 19657)	28490 (12129, 41468)	28352 (19393, 99180)
PDA					
n	150	201	52	25	17
Median	323 (268, 370)	355 (290, 433)	615 (452, 751)	1743 (1281, 2504)	3881 (2716, 8881)
75th percentile	493 (435, 719)	712 (564, 781)	1023 (691, 1754)	3877 (1935, 12703)	9219 (3881, 42511)
95th percentile	1720 (1226, 1996)	1665 (1184, 2610)	3154 (1754, 3387)	20987 (5253, 24537)	42511 (9557, 42511)
PV					
n	186	33	15	16	9
Median	249 (203, 280)	497 (325, 808)	989 (677, 2116)	3247 (2343, 7911)	–
75th percentile	410 (355, 560)	1082 (583, 1830)	2116 (989, 10696)	7871 (2657, 20915)	–
95th percentile	1062 (811, 1178)	4972 (1554, 7442)	10696 (2116, 10696)	20915 (7911, 20915)	–
TPV					
n	0	4	14	57	124
Median	–	–	7825 (2649, 10102)	9920 (7267, 13420)	17990 (15141, 21967)
75th percentile	–	–	9903 (7676, 11391)	17483 (11586, 23152)	30687 (26065, 42362)
95th percentile	–	–	11391 (9837, 11391)	29263 (24498, 39107)	72845 (55848, 114853)

Values in parenthesis are 95% confidence intervals for the reported value. ASD = atrial septal defect; AV = aortic valvuloplasty; COA = coarctation of the aorta; PDA = patent ductus arteriosus; PV = pulmonary valvuloplasty; TPV = transcatheter pulmonary valve.

regression to estimate the 50th, 75th and 95th percentiles. Curves for COA and TPV procedures were not included as these procedures are most commonly performed within a certain age group (48% of COA treatments occur in patients < 1 yrs, 62% of TPV placements occur in patients >15 yrs).

This current study's data was further compared to the procedure-specific radiation benchmarks reported by Ghelani et al. in 2014. DAP radiation doses obtained from Ghelani et al. were converted to μGy*M^2 from Gy*cm^2 to facilitate comparisons. To identify changes since the establishment of the initial radiation dose benchmarks, comparison weight-based percentile curves for median total air kerma and DAP for the two cohorts were performed by including interaction terms of weight by study cohort in the quantile regression models. The C3PO-QI quality metric was applied to the contemporary cohort using the benchmark values established by Ghelani et al. The quality metric equals the number of observed cases not exceeding the benchmark percentile value divided by the total cases in the procedure and age group. The metric was applied to all procedure type age groups with the largest volume by percentile (%) of cases not exceeding the Ghelani et al. benchmarks. Statistical significance was defined as $P < 0.05$.

RESULTS

A total of 1680 unique cases, among 8707 cases entered for the nine sites in the registry between January 1, 2014 and June 30, 2015 were included and ranged from 75 to 301 cases per site (median, 214 cases). The distribution of interventional cases is shown in Table I. While all three radiation dose variables, total air kerma, DAP and fluoroscopy time, were collected for nearly all cases, data for one of the three variables were not available in a small number of cases (missing: total air kerma, $n = 50$; DAP, $n = 55$; fluoroscopy time, $n = 197$). Among the analyzed procedures, the lowest radiation doses were noted in PDA closure and PV, with a median total air kerma of 73

TABLE IV. Dose Area Product indexed to Body Weight (μGy·M^2/kg) Stratified by Procedure Type and Age Group

	Age, yrs				
Procedure	<1	1–4	5–9	10–15	>15
ASD					
n	7	110	82	50	46
Median	–	33 (22, 43)	29 (20, 39)	27 (19, 38)	66 (42, 94)
75th percentile	–	61 (49, 78)	54 (39, 63)	63 (33, 103)	126 (89, 177)
95th percentile	–	171 (115, 343)	156 (83, 339)	288 (103, 725)	370 (164, 471)
AV					
n	71	12	13	24	16
Median	104 (81, 135)	49 (34, 130)	92 (45, 317)	81 (42, 118)	139 (80, 236)
75th percentile	175 (143, 256)	116 (43, 256)	230 (92, 706)	121 (94, 232)	219 (135, 502)
95th percentile	375 (283, 462)	256 (130, 256)	706 (317, 706)	317 (129, 345)	502 (236, 502)
COA					
n	136	26	35	43	48
Median	79 (65, 96)	95 (66, 197)	93 (61, 121)	98 (77, 130)	140 (88, 157)
75th percentile	165 (114, 227)	223 (118, 422)	128 (101, 237)	146 (107, 263)	170 (152, 240)
95th percentile	393 (312, 766)	947 (262, 1229)	440 (221, 455)	1016 (254, 3582)	373 (235, 707)
PDA					
n	150	199	52	25	17
Median	59 (52, 71)	30 (26, 34)	27 (21, 35)	41 (30, 55)	70 (33, 140)
75th percentile	121 (93, 145)	50 (42, 61)	44 (35, 67)	76 (42, 302)	150 (70, 318)
95th percentile	338 (229, 465)	132 (118, 180)	79 (67, 113)	303 (115, 303)	318 (160, 318)
PV					
n	185	33	15	16	9
Median	53 (44, 62)	33 (24, 56)	48 (26, 106)	82 (38, 124)	–
75th percentile	104 (88, 137)	78 (50, 189)	106 (48, 335)	118 (82, 283)	–
95th percentile	347 (255, 396)	432 (134, 610)	335 (106, 335)	283 (124, 283)	–
TPV					
n	0	4	14	57	124
Median	–	–	226 (144, 549)	235 (179, 274)	271 (233, 310)
75th percentile	–	–	453 (213, 673)	330 (271, 408)	436 (353, 506)
95th percentile	–	–	673 (422, 673)	559 (422, 954)	812 (583, 1418)

Values in parenthesis are 95% confidence intervals for the reported value. ASD = atrial septal defect; AV = aortic valvuloplasty; COA = coarctation of the aorta; PDA = patent ductus arteriosus; PV = pulmonary valvuloplasty; TPV = transcatheter pulmonary valve.

and 69 mGy, DAP of 407 and 326 μGy*M^2, and DAP/kg of 37 and 53 μGy*M^2/kg, respectively. As seen in Table I, fluoroscopy time did not correlate with radiation exposures. For example, while radiation exposures varied widely between ASD and PV procedures for total air kerma, DAP, and DAP/kg, similar total fluoroscopy times were recorded for both procedure types.

Age-based stratification is presented in Tables (II–V) for age groups including more than 10 cases. As ASD and TPV cases among younger patients and PV procedures among older patients are not commonly performed, data for these procedure types were not included due to small case volume. Age-stratified radiation doses for PDA closure were lowest in children less than 4 yrs of age for total air kerma (median 58 mGy) and lowest in <1 yrs and 1–4 yrs for DAP (median 323 μGy*M^2 and 355 μGy*M^2 respectively). However, when using a weight based correction factor, the lowest exposure outcome was in the larger 5–9 yr olds for DAP/kg (median 27 μGy*M^2/kg). The lowest exposure for PV procedures was seen in the highest volume age group <1 yr old for total air kerma and DAP (median 59 mGy, 249 μGy*M^2). However, again, when a weight based corrected outcome was applied, 1–4 yrs had lowest exposure for DAP/kg (median 33 μGy*M^2/kg). Among the procedures reported, TPV placement had the highest exposures for any age group but was predominantly performed in patients >15 yrs of age. TPV placement had the highest median total air kerma, DAP and DAP/kg values at 1450 mGy, 13551 μGy*M^2 and 257 μGy*M^2/kg, respectively. Age-stratified TPV placement radiation doses were highest in >15 yrs for total air kerma, DAP and DAP/kg (median 1835 mGy, 17990 μGy*M^2 and 271 μGy*M^2/kg).

DAP/kg by body weight category is presented in Table VI. Median radiation doses are comparable to those seen across DAP/kg by age group presented in Table IV. Among COA cases, for example, radiation doses varied similarly across body weight categories (median 79, 99, 97, 83, 129 DAP/kg across increasing weight groups) and age group (median 79, 95, 93, 98, 140 DAP/kg across increasing age groups). The scatterplot depicting linear trend lines by median DAP and DAP/kg for TPV placements in patients >15 yrs is

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

	Age, yrs				
Procedure	<1	1–4	5–9	10–15	>15
ASD					
n	7	100	77	48	44
Median	–	17 (15, 20)	15 (13, 18)	14 (10, 18)	24 (18, 29)
75th percentile	–	28 (21, 39)	22 (19, 34)	20 (16, 29)	32 (26, 44)
95th percentile	–	77 (49, 157)	58 (40, 85)	72 (27, 91)	77 (44, 175)
AV					
n	66	11	12	21	17
Median	29 (23, 35)	25 (17, 74)	29 (22, 54)	26 (17, 32)	28 (21, 42)
75th percentile	42 (35, 51)	67 (24, 104)	51 (28, 105)	34 (26, 44)	44 (28, 125)
95th percentile	76 (55, 100)	104 (67, 104)	105 (54, 105)	45 (38, 45)	125 (46, 125)
COA					
n	134	25	32	39	38
Median	23 (21, 26)	29 (23, 48)	20 (15, 26)	20 (17, 29)	21 (18, 27)
75th percentile	35 (29, 40)	51 (36, 85)	27 (23, 51)	33 (26, 40)	31 (23, 50)
95th percentile	74 (58, 93)	113 (52, 125)	56 (38, 57)	59 (40, 97)	63 (44, 85)
PDA					
n	139	160	45	25	15
Median	16 (15, 18)	12 (11, 13)	9 (8, 13)	16 (8, 23)	18 (10, 27)
75th percentile	22 (20, 26)	17 (16, 19)	14 (13, 24)	24 (19, 27)	27 (18, 40)
95th percentile	57 (41, 99)	32 (28, 53)	32 (24, 109)	31 (24, 33)	40 (27, 40)
PV					
n	170	28	13	13	9
Median	19 (16, 23)	14 (12, 20)	19 (11, 47)	21 (12, 41)	–
75th percentile	33 (29, 42)	22 (15, 37)	35 (19, 60)	34 (21, 55)	–
95th percentile	71 (58, 95)	80 (29, 109)	60 (47, 60)	55 (41, 55)	–
TPV					
n	0	4	14	56	121
Median	–	–	40 (30, 72)	46 (39, 56)	43 (38, 46)
75th percentile	–	–	61 (40, 119)	60 (56, 83)	62 (51, 73)
95th percentile	–	–	119 (57, 119)	110 (85, 119)	121 (97, 145)

Values in parenthesis are 95% confidence intervals for the reported value. ASD = atrial septal defect; AV = aortic valvuloplasty; COA = coarctation of the aorta; PDA = patent ductus arteriosus; PV = pulmonary valvuloplasty; TPV = transcatheter pulmonary valve.

seen in Fig. 1. DAP/kg (standardized coefficient, 0.47) shows a significant decrease in slope when graphed across weight compared to that of DAP (standardized coefficient, 0.21). In this age group, the slope of the curve for DAP/kg is less than that of DAP alone as an outcome measure when the outcomes are assessed across weights. This suggests that DAP indexed to weight may provide better standardization of the outcome measure which might allow more equitable comparison of dose in populations with different weight cohorts.

Radiation dose outcomes and previously established benchmarks as published by Ghelani et al. for this collaborative are shown in Table VII. For all procedure types, the median total air kerma and DAP radiation dose were lower ($P < 0.001$) (Table VII). TPV placement showed the greatest difference (median decreased by 836 mGy and 9449 μGy*M^2). The lowest exposure procedures, AV, PDA closure, and PV, exhibited the smallest change in median radiation doses. The decreases in total air kerma and DAP seen across all procedure types were observed without changes in median fluoroscopy time across all procedure types, except for TPV where the time decreased significantly ($P = 0.002$) in the contemporary cohort.

The weight-based percentile curves showing radiation doses for total air kerma and DAP are shown in Fig. 2 and 3. As seen in Fig. 2, the current study indicates a parabolic relationship between the radiation dose variables, total air kerma and DAP, and weight. This relationship is similarly seen in the previously published Ghelani et al. data, however, there is a significant decrease in radiation doses for total air kerma and DAP across all procedure types ($P < 0.001$) in the contemporary cohort (Fig. 3).

Application of the C3PO-QI quality metric to the contemporary cohort shows age specific, procedure type radiation doses for both total air kerma and DAP meeting quality metric goals (Tables IX and VIII). The highest percentage not exceeding the 75th percentile quality metric was seen in ASD closures in patients 1–4 yrs for total air kerma (90%), and PDA closures in

TABLE VI. Dose Area Product by Body Weight (μGy·M^2/kg) Stratified by Procedure Type and Body Weight (kg)

		Body Weight, kg			
Procedure	<10 kg	10–20 kg	20–30 kg	30–50 kg	>50 kg
ASD					
n	12	126	57	31	69
Median	100 (13, 155)	30 (22, 42)	30 (21, 41)	24 (14, 41)	46 (32, 68)
75th percentile	149 (93, 256)	54 (48, 76)	56 (40, 77)	54 (29, 237)	95 (68, 129)
95th percentile	256 (155, 256)	156 (115, 343)	264 (83, 725)	344 (177, 471)	246 (143, 402)
AV					
n	70	13	11	12	30
Median	104 (81, 135)	59 (38, 130)	95 (31, 435)	67 (35, 118)	112 (77, 143)
75th percentile	192 (143, 256)	117 (59, 256)	143 (92, 706)	116 (65, 345)	164 (134, 317)
95th percentile	375 (288, 462)	256 (130, 256)	706 (143, 706)	345 (118, 345)	479 (236, 502)
COA					
n	139	31	21	33	64
Median	79 (65, 96)	99 (75, 221)	97 (45, 124)	83 (59, 123)	129 (92, 148)
75th percentile	155 (114, 223)	225 (118, 422)	126 (105, 222)	139 (93, 312)	169 (148, 235)
95th percentile	418 (340, 881)	765 (298, 1229)	235 (213, 237)	661 (263, 1185)	359 (240, 707)
PDA					
n	206	162	22	26	27
Median	53 (43, 60)	29 (25, 35)	26 (18, 45)	43 (29, 78)	47 (30, 118)
75th percentile	105 (87, 127)	45 (38, 54)	45 (27, 67)	82 (47, 281)	139 (62, 217)
95th percentile	298 (185, 426)	130 (90, 223)	75 (50, 77)	295 (96, 302)	312 (160, 318)
PV					
n	189	32	10	6	21
Median	53 (44, 62)	37 (22, 56)	63 (26, 137)	–	98 (51, 148)
75th percentile	107 (89, 137)	65 (48, 189)	114 (50, 335)	–	149 (102, 181)
95th percentile	347 (247, 396)	445 (104, 610)	335 (106, 335)	–	272 (156, 283)
TPV					
n	0	6	17	44	132
Median	–	–	335 (196, 398)	189 (129, 238)	274 (240, 309)
75th percentile	–	–	410 (335, 954)	265 (234, 392)	428 (349, 501)
95th percentile	–	–	954 (422, 954)	547 (392, 634)	789 (553, 1418)

Values in parenthesis are 95% confidence intervals for the reported value. ASD = atrial septal defect; AV = aortic valvuloplasty; COA = coarctation of the aorta; PDA = patent ductus arteriosus; PV = pulmonary valvuloplasty; TPV = transcatheter pulmonary valve.

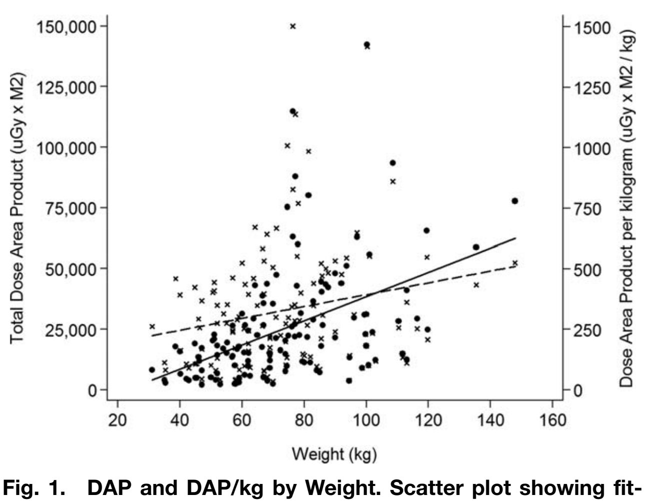

Fig. 1. DAP and DAP/kg by Weight. Scatter plot showing fitted linear regression lines for DAP (solid line) and DAP/kg (dashed line) by weight for TPV placement in patients > 15 yrs. DAP: Dose area product, μGy*M^2.

1–4 yrs and PV in < 1 yr for DAP (92%). The highest percentage not exceeding the 95th percentile quality metric was seen in PV in patients < 1 yrs for total air kerma (98%), and treatment of COA and PV in patients < 1 yr for DAP (100%). The procedure type with the lowest percentage not exceeding the 75th and 95th percentile quality metric for total air kerma was seen in AV in patients <1 yrs (78% and 89%, respectively). For DAP, the lowest percentage not exceeding the 75th percentile was seen in AV in patients < 1 yrs (85%), and the lowest percentage not exceeding the 95th percentile was seen in ASD closures in patients 1–4 yrs (98%).

DISCUSSION

This is the first multi-center report to update previously established benchmark values to allow for calculation of a novel radiation dose exposure metric proposed by the ACC Quality Metric Working Group using prospectively collected contemporary data by the C3PO-QI collaborative. In our recent experience, radiation doses for total air kerma and DAP decreased across all procedure types. These decreases were seen with little observed changes in median fluoroscopy

TABLE VII. Radiation Doses for 6 Selected Interventional Catheterization Procedures Compared to Ghelani et al. Median, 75th Percentile and 95th Percentiles were Calculated as (Final - Initial). The [-, -] Next to the Count (n) Represent the Reported Count in the Ghelani et al. Study and in this Contemporary Cohort, Respectively

		Total Air kerma, mGy				Dose Area Product, μGy·M^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
ASD	[731, 307]	[532, 294]	−134	−321	−837	[726,296]	−1358	−4469	−19546	[726, 276]	−1	−1	+9
AV	[297, 140]	[238, 139]	−42	−172	+239	[296, 137]	−475	−2623	−3177	[296, 127]	+2	+6	+17
COA	[452, 299]	[360, 292]	−98	−344	−1586	[448, 289]	−1563	−5860	−19732	[452, 268]	+1	+1	+2
PDA	[548, 463]	[362, 444]	−36	−40	−258	[547, 445]	−338	−792	−5955	[544, 384]	+1	+3	+9
PV	[462, 267]	[362, 261]	−45	−103	−355	[461, 259]	−356	−1012	−8132	[461, 233]	−2	0	0
TPV	[223, 204]	[200, 200]	−836	−827	−184	[223, 199]	−9492	−12684	−22451	[223, 195]	−12	−14	−14

ASD = atrial septal defect; AV = aortic valvuloplasty; COA = coarctation of the aorta; PDA = patent ductus arteriosus; PV = pulmonary valvuloplasty; TPV = transcatheter pulmonary valve.

time, except for a significant decrease fluoroscopy time for TPV placements. Since this reduction in fluoroscopy time in TPV procedures occurred without a change in median weight over time (59.6 kg, Ghelani, et al.; 59.0 kg, Contemporary Cohort; $P = 0.75$), it is likely attributed to increased operator experience and shorter procedure times in the contemporary cohort. This lack of decrease in median fluoroscopy time indicates that clinicians still use fluoroscopy as needed for catheter manipulations and likely reduced radiation dose by reducing frame rates, using "store fluoro" instead of cine, and good collimation. Hence, we continue to recommend the use of DAP and total air kerma, but not fluoroscopy time, as measures of radiation exposure. Additionally, our findings support the use of procedure-specific benchmarks for radiation dose variables across both age groups and body weight as a necessary standardizing adjustment in metric reporting. These contemporary benchmarks, including the application of the quality metric, are being used to quantify improvements in C3PO-QI's ongoing quality improvement efforts.

The decreases in radiation dose seen in these new benchmarks occurred as participating centers formalized QI in their radiation dose reduction efforts. Examples of such initiatives include increased radiation safety awareness in the catheterization lab, inter-institutional sharing of practices and operator techniques among participating sites in C3PO-QI, online reporting tools allowing for tracking of radiation doses longitudinally, and identification of procedural specific areas requiring improvement using new reporting programs such as Tableau™ (Tableau Software, Seattle, Washington). Importantly, some participants have noted that the radiation dose data immediately available for review via the C3PO-QI website enables and empowers physicians to further reduce radiation dose [16]. Additionally, installation of new catheterization laboratory equipment and utilization of radiation reporting software have made it easier for operators to make modifications to radiation settings (e.g. frame rate, pulse rate) and receive notifications of patient radiation exposures throughout the case. Installation of next generation catheterization laboratory equipment may further result in substantial radiation dose reduction without necessitating changes in exposure settings or resulting in loss of image quality [19]. Efforts to minimize radiation exposure as low as reasonably achievable (the ALARA principle) while maintaining "optimization" of imaging protocols have driven advances and refinement of operator techniques to ensure ongoing decreases in radiation exposure [19–24]. The impact of these ongoing improvements on radiation dose reduction, as demonstrated in this study, suggests that benchmarks should be periodically revised to reflect broad reductions in radiation doses [11,19,21]. Importantly, while efforts to reduce radiation should be maximized, the ability to perform interventional procedures safely and effectively should not be compromised.

The present study included a DAP/kg analysis by age group and body weight category to allow comparisons with recent literature [11,14,21,25]. Our study found median DAP/kg values for ASD closure and PV lower than those reported by Kobayashi et al. (34 and 53 DAP/kg, 40.9 and 55.5 DAP/kg, respectively). However, the DAP/kg doses presented in this study for AV and TPV placement were higher than those published by Kobayashi et al. The Kobayashi et al. analysis was not stratified by body weight categories or age groups and thus do not allow for direct comparison or necessary adjustment based on the age and weight distribution in the two populations. Differences among participating sites in age of equipment, equipment manufacturer, operator techniques, patient population, case mix distribution and complexity of procedure type are major contributors to the differences in radiation doses reported by other studies. While these new radiation dose benchmarks may be higher in comparison to

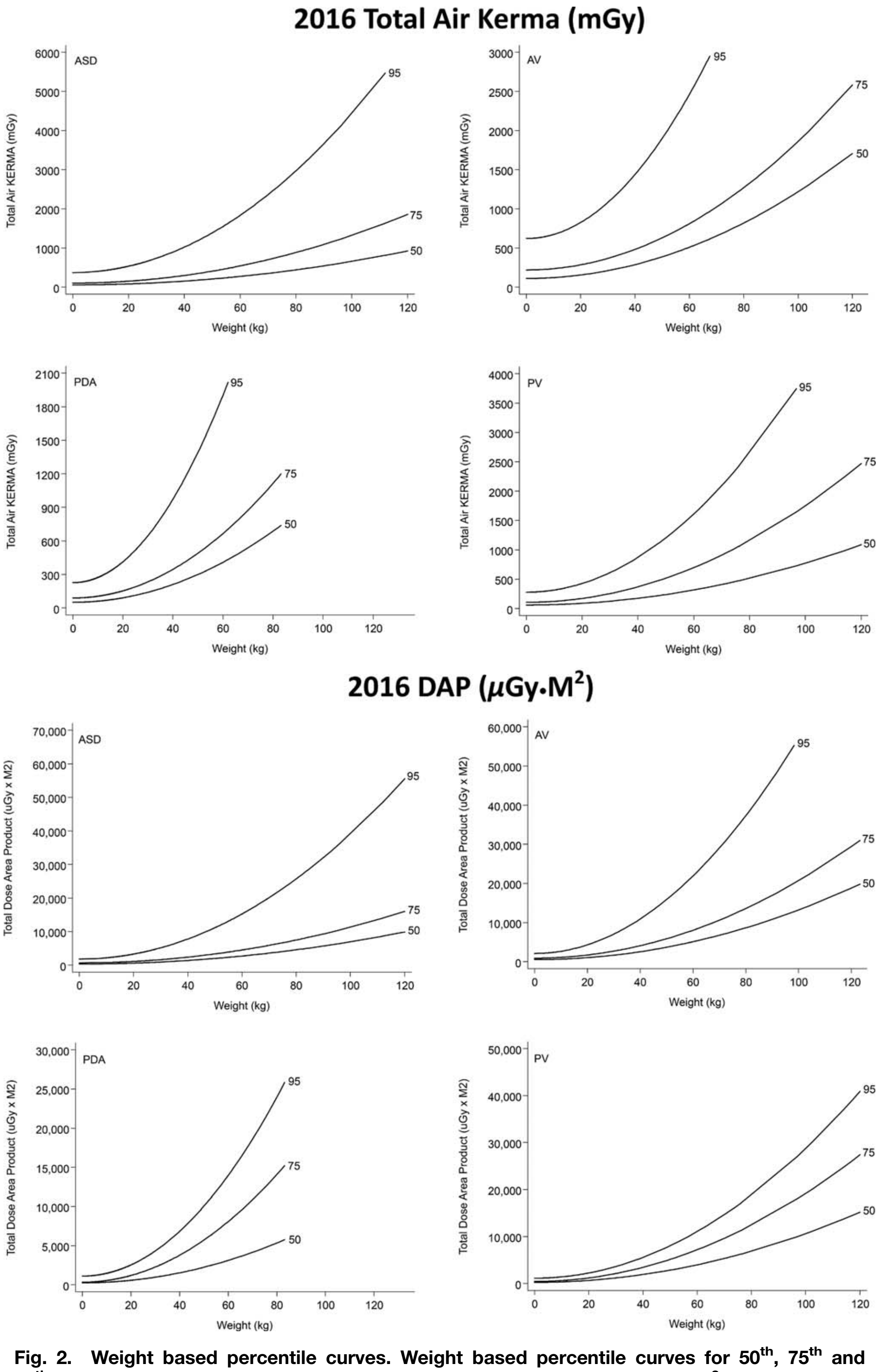

Fig. 2. Weight based percentile curves. Weight based percentile curves for 50th, 75th and 95th percentiles for total air kerma and DAP. DAP: Dose area product, μGy*M^2.

the broader community at this time, they are derived from participating centers that have had an initiative in place to reduce radiation doses for at least a year. The DAP and DAP/kg by weight analysis in this study for TPV placements in patients > 15 yrs showed a normalization of the outcome metric across a certain patient

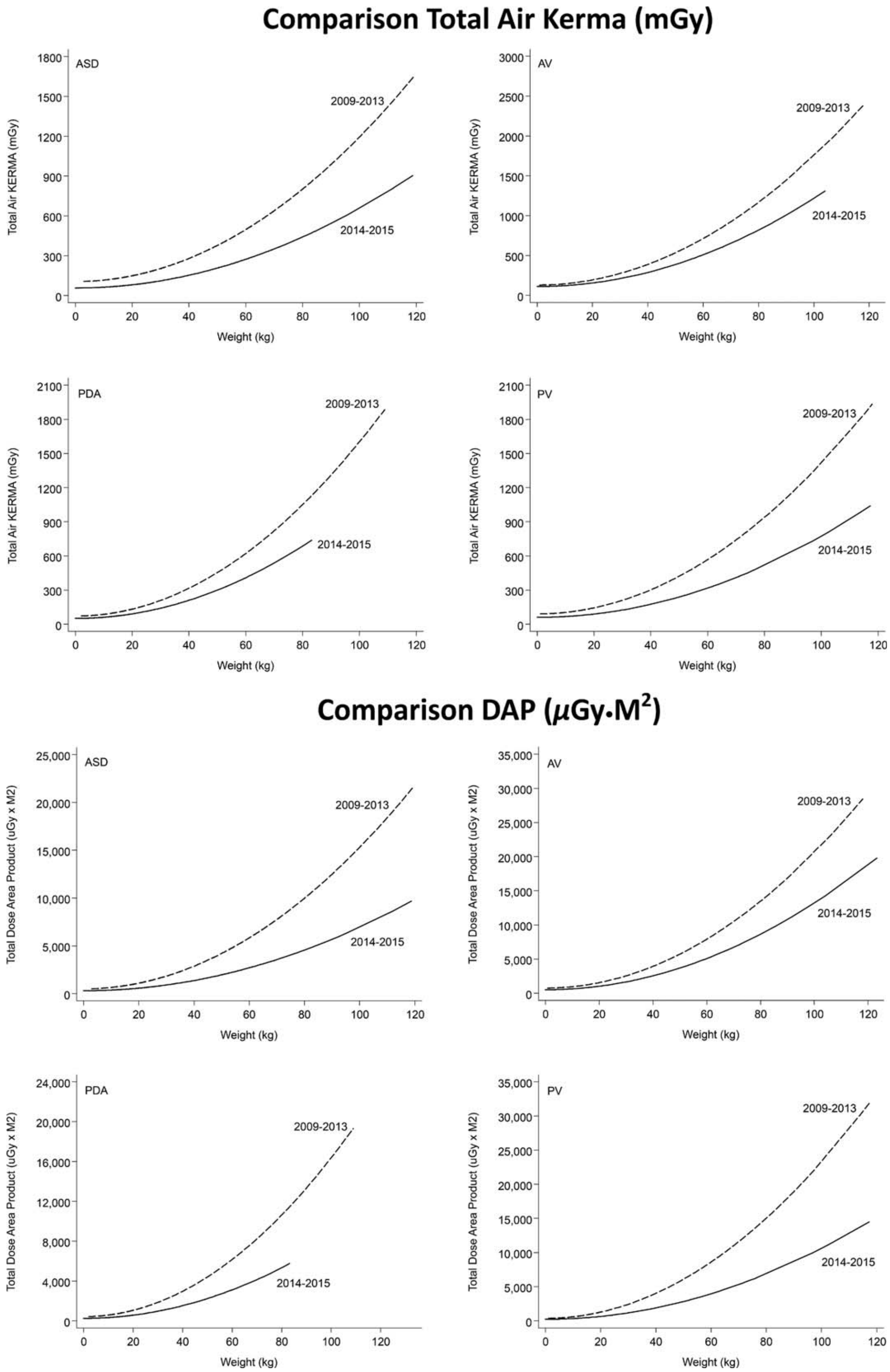

Fig. 3. Comparison median weight-based percentile curves. Median weight-based percentile curves comparing Ghelani et al. data to the present study's data for total air kerma and DAP (*P* < 0.001 for all procedure types and radiation doses). DAP: Dose area product, μGy*M^2.

TABLE VIII. Application of the ACC Quality Metric for all Procedure Types with the Largest Volume Age Group for Total Air kerma (mGy)

	Observed		Benchmark, Ghelani et al.		Quality Metric	
	n	Median	75th %ile	95th %ile	75th %ile	95th %ile
ASD (1–4 yrs)	108	66 (52, 88)	220	528	97/108 (90%)	105/108 (97%)
AV (<1 yr)	72	112 (88, 139)	204	361	56/72 (78%)	64/72 (89%)
COA (<1 yr)	139	102 (82, 118)	228	600	114/139 (82%)	133/139 (96%)
PDA (1–4 yrs)	202	58 (51, 68)	140	253	170/202 (84%)	192/202 (95%)
PV (<1 yr)	187	59 (53, 67)	148	323	157/187 (84%)	184/187 (98%)
TPV (> 15 yrs)	125	1835 (1545, 2305)	4050	6820	102/125 (82%)	119/125 (95%)

Values in parenthesis are 95% confidence intervals for the reported value. ASD = atrial septal defect; AV = aortic valvuloplasty; COA = coarctation of the aorta; PDA = patent ductus arteriosus; PV = pulmonary valvuloplasty; TPV = transcatheter pulmonary valve.

TABLE IX. Application of the ACC Quality Metric for all Procedure Types with the Largest Volume Age Group for DAP (μGy·M²)

	Observed		Benchmark, Ghelani et al.		Quality Metric	
	n	Median	75th %ile	95th %ile	75th %ile	95th %ile
ASD (1–4 yrs)	110	466 (324, 612)	1700	5800	99/110 (90%)	108/110 (98%)
AV (<1 yr)	72	467 (354, 580)	1100	2700	61/72 (85%)	71/72 (99%)
COA (<1 yr)	136	401 (349, 514)	1400	4500	121/136 (89%)	136/136 (100%)
PDA (1–4 yrs)	201	355 (290, 433)	1200	4900	185/201 (92%)	200/201 (99%)
PV (<1 yr)	186	249 (203, 280)	900	2500	171/186 (92%)	186/186 (100%)
TPV (> 15 yrs)	124	17990 (15141, 21967)	43000	90200	104/124 (84%)	121/124 (98%)

Values in parenthesis are 95% confidence intervals for the reported value. ASD = atrial septal defect; AV = aortic valvuloplasty; COA = coarctation of the aorta; PDA = patent ductus arteriosus; PV = pulmonary valvuloplasty; TPV = transcatheter pulmonary valve..

population by weight distribution. The significant decrease in slope for DAP/kg indicates that it is a better outcome metric for population comparisons than DAP alone within an age group to account for differences in distribution of weights in similar age and case type populations being compared for radiation exposure. Thus, DAP/kg may have value as a metric for longitudinal assessment of radiation exposure for QI reduction efforts, not as a direct measure for evaluating or comparing stochastic risk.

The present study is not without limitations. While this study attempts to update radiation dose benchmarks since the study by Ghelani et al., the present study includes two additional sites overall, and, therefore, exact comparisons do not account for baseline radiation dose measures from the newer cohort of hospitals. This report, limited by individual site numbers, does not explore variation of equipment age and type, individual site outcomes or identification of best practices, as the data are summarized by the median for the group. Additionally, as the benchmarks provided reflect longitudinal averages obtained from a large cohort, radiation exposure comparisons are more suitable when conducted with aggregate data as opposed to an individual procedure. Lastly, as the cohort of hospitals present in this study differs greatly in size of hospital, number of procedures performed and case type distribution, the results of this study may be skewed by the procedures and practices of the larger centers.

CONCLUSION

This prospective multi-center study updates previously established procedure-specific radiation dose values to reflect QI efforts over time. Across all interventional procedure types explored, we observed a decrease in radiation exposure across all ages. This difference in radiation exposure was seen at C3PO-QI participating institutions incentivized to reduce radiation and as QI initiatives were formalized at participating centers. These contemporary thresholds can be applied in quality measurement and comparative assessment at institutions performing cardiac catheterization procedures for congenital heart disease.

ACKNOWLEDGMENTS

The authors would like to recognize the study coordinators and personnel that have made this project possible: Cynthia Cardwell, Joanne Chisolm, Rashi Gupta, Andrea Kennedy, Diane Kickbush, and Karen Minsterman.

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;111:83–89.
2. Allen HD, Beekman RH, Garson A, Hijazi ZM, Mullins C, O'Laughlin MP, Taubert KA. Pediatric therapeutic cardiac catheterization: A statement for healthcare professionals from the

council on cardiovascular disease in the young, American Heart Association. Circulation 1998;97:2375.
3. Schueler BA, Julsrud PR, Gray JE, Stears JG, Wu KY. Radiation exposure and efficacy of exposure-reduction techniques during cardiac catheterization in children. AJR Am J Roentgenol 1994;162:173–177.
4. National Council on Radiation Protection and Measurements. Ionizing Radiation Exposure of the Population of the United States. NCRP Report No. 160. 2009. Available at: http://ncrponline.org/publications/reports/ncrp-report-160/. Accessed June 17, 2016.
5. Cousins C, Miller DL, Bernardi G, Rehani MM, Schofield P, Vano E, Einstein AJ, Geiger B, Heintz P, Padovani R, Sim KH. International Commission on radiological protection. ICRP publication 120: Radiological protection in cardiology. Ann ICRP 2013;42:1–125.
6. Andreassi MG, Ait-Ali L, Botto N, Manfredi S, Mottola G, Picano E. Cardiac catheterization and long-term chromosomal damage in children with congenital heart disease. Eur Heart J 2006;27:2703–2708.
7. Boothroyd A, McDonald E, Moores BM, Sluming V, Carty H. Radiation exposure to children during cardiac catheterization. Br J Radiol 1997;70:180–185.
8. Johnson JN, Hornik CP, Li JS, Benjamin DK, Yoshizumi TT, Reiman RE, Frush DP, Hill KD. Cumulative radiation exposure and cancer risk estimation in children with heart disease. Circulation 2014;130:161–167.
9. Glatz AC, Patel A, Zhu X, Dori Y, Hanna BD, Gillespie MJ, Rome JJ. Patient radiation exposure in a modern, large-volume, pediatric cardiac catheterization laboratory. Pediatr Cardiol 2014;35:870–878.
10. Glatz AC, Purrington KS, Klinger A, King AR, Hellinger J, Zhu X, Gruber SB, Gruber PJ. Cumulative exposure to medical radiation for children requiring surgery for congenital heart disease. J Pediatr 2014;164:789–794.
11. Borik S, Devadas S, Mroczek D, Lee KJ, Chaturvedi R, Benson LN. Achievable radiation reduction during pediatric cardiac catheterization: How low can we go? Catheter Cardiovasc Interv 2015;86:841–848.
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. Ghelani SJ, Glatz AC, David S, Leahy R, Hirsch R, Armsby LB, Trucco SM, Holzer RJ, Bergersen L. Radiation dose benchmarks during cardiac catheterization for congenital heart disease in the United States. JACC Cardiovasc Interv 2014;7:1060–1069.
14. Kobayashi D, Meadows J, Forbes TJ, Moore P, Javois AJ, Pedra CA, Du W, Gruenstein DH, Wax DF, Hill JA, Graziano JN, Fagan TE, Alvarez WM, Nykanen DG, Divekar AA. Standardizing radiation dose reporting in the pediatric cardiac catheterization laboratory-A multicenter study by the CCISC (Congenital Cardiovascular Interventional Study Consortium). Catheter Cardiovasc Interv 2014;84:785–793.
15. Moore JW, Vincent RN, Beekman RH, Benson L, Bergersen L, Holzer R, Jayaram N, Jenkins K, Li Y, Ringel R, Rome J, Martin GR. NCDR IMPACT Steering Committee. Procedural results and safety of common interventional procedures in congenital heart disease: Initial report from the national cardiovascular data registry. J Am Coll Cardiol 2014;64:2439–2451.
16. Nicholson GT, Gao K, Kim SI, Kim DW, Vincent RN, Balfour V, Petit CJ. Direct physician reporting is associated with reductions in radiation exposure in pediatric cardiac catheterizations. Catheter Cardiovasc Interv 2015;86:832–840.
17. 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;83:80–83.
18. Doyle T, Bergersen L, Armstrong A, et al. Radiation dose metric. American College of Cardiology Adult Congenital & Pediatric Cardiology Section Meeting. March 2010. Atlanta, GA.
19. Onnasch DGW, Schröder FK, Fischer G, Kramer HH. Diagnostic reference levels and effective dose in paediatric cardiac catheterization. Br J Radiol 2007;80:177–185.
20. Fazel R, Gerber TC, Balter S, Brenner DJ, Carr JJ, Cerqueira MD, Chen J, Einstein AJ, Krumholz HM, Mahesh M, McCollough CH, Min JK, Morin RL, Nallamothu BK, Nasir K, Redberg RF, Shaw LJ. American Heart Association Council on Quality of Care and Outcomes Research, Council on Clinical Cardiology, and Council on Cardiovascular Radiology and Intervention. Approaches to enhancing radiation safety in cardiovascular imaging: a scientific statement from the American Heart Association. Circulation 2014;130:1730–1748.
21. Lamers LJ, Moran M, Torgeson JN, Hokanson JS. Radiation reduction capabilities of a next-generation pediatric imaging platform. Pediatr Cardiol 2016;37:24–29.
22. Harbron RW, Pearce MS, Salotti JA, McHugh K, McLaren C, Abernethy L, Reed S, O'Sullivan J, Chapple CL. Radiation doses from fluoroscopically guided cardiac catheterization procedures in children and young adults in the United Kingdom: a multicentre study. Br J Radiol 2015;88:20140852.
23. Hill KD, Einstein AJ. New approaches to reduce radiation exposure. Trends Cardiovasc Med 2016;26:55–65.
24. Lin P-JP. Technical advances of interventional fluoroscopy and flat panel image receptor. Health Phys 2008;95:650–657.
25. Strauss KJ. Pediatric interventional radiography equipment: safety considerations. Pediatr Radiol 2006;36: 126–135.