

## Substantial radiation reduction in pediatric and adult congenital heart disease interventions with a novel X-ray imaging technology



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### ABSTRACT

**Background:** Pediatric catheterization exposes patients to varying radiation doses. Concerns over the effects of X-ray radiation dose on the patient population have increased in recent years. This study aims at quantifying the patient radiation dose reduction after the introduction of an X-ray imaging technology using advanced real time image noise reduction algorithms and optimized acquisition chain for fluoroscopy and exposure in a pediatric and adult population with congenital heart disease.

**Methods:** Patient and radiation dose data was retrospectively collected (July 2012–February 2013) for 338 consecutive patients treated with a system using state of the art image processing and reference acquisition chain (referred as “reference system”). The same data was collected (March–October 2013) for 329 consecutive patients treated with the new imaging technology (Philips AlluraClarity, referred as “new system”). Patients were divided into three weight groups: A) below 10 kg, B) 10–40 kg, and C) over 40 kg. Radiation dose was quantified using dose area product (DAP), while procedure complexity using fluoroscopy time, procedure duration and volume of contrast medium.

**Results:** The new system provides significant patient dose reduction compared to the reference system. Median DAP values were reduced in group A) from 140.6 cGy·cm<sup>2</sup> to 60.7 cGy·cm<sup>2</sup>, in group B) from 700.0 cGy·cm<sup>2</sup> to 202.2 cGy·cm<sup>2</sup> and in group C) from 4490.4 cGy·cm<sup>2</sup> to 1979.8 cGy·cm<sup>2</sup> with reduction of 57%, 71% and 56% respectively ( $p < 0.0001$  for all groups).

**Conclusions:** Despite no other changes in procedural approach, the novel X-ray imaging technology provided substantial radiation dose reduction of 56% or higher.

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### 1. Introduction

Patients with congenital heart defects frequently undergo numerous and repeated diagnostic and interventional catheterization procedures, in addition to other imaging studies such as chest-X-rays and CT studies. The growing number and complexity of interventional cardiology procedures have been significant in the past years as a result of advances made in transcatheter techniques and the armamentarium available (i.e. devices, stents, percutaneous valves, miniaturized balloons, coils, etc.) [1,2]. While their benefits to the patients are undisputable, all these procedures contribute to high accumulated radiation doses to the patient population [3–5]. This is particularly relevant for infants and children and even if the long term consequences of this exposure

are not well understood and extremely difficult to estimate, there is now for many decades considerable concern about the possible stochastic effects, such as the incidence of solid tumors and leukemia [6–11]. In fact, growing tissue in children is more radiosensitive than that in adults and, due to their small size, larger body parts are irradiated during cardiac catheterization including radiosensitive organs such as thyroid and eyes which are closer to the heart [12,13]. Moreover, children with complex heart defects often need to undergo increasingly complex procedures many times during their lifetime, resulting in a high cumulative dose acquired [14–16]. Minimizing radiation dose is therefore crucial for this vulnerable population, as children are likely to survive long enough through a possible latent period and develop or manifest late effects of early radiation exposure.

Successful patient radiation dose management can only be achieved by optimization of medical imaging technology together with best control of the equipment by the operator [17,18]. In this respect, best practices are applied in our lab using “ALARA” radiation reduction

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principles in terms of patient radiation safety, such as short imaging time, avoidance of field overlap in repeated acquisitions, low SID, tight collimation, use of intra-procedural echocardiography, and a frame rate for fluoroscopy acquisitions of maximum 15 frames/s [19–24]. Moreover, our cath lab has been recently upgraded to a novel X-ray imaging technology (AlluraClarity; Philips Healthcare, Best, Netherlands) developed for fluoroscopy and cine exposure for interventional cardiology for the entire patient size population, including pediatric. This technology enables significant patient entrance dose reduction achieved by a combination of advanced real-time image noise reduction algorithms with state-of-the-art hardware and an anatomy-specific optimized full acquisition chain (grid switch, beam filtering, pulse width, spot size, detector and image processing engine). Furthermore, image quality is further positively influenced by the use of smaller focal spot sizes and shorter pulses. Radiation dose reduction using this technology has already been investigated in other clinical and investigational domains outside congenital heart disease interventions by comparing state-of-the-art reference to new systems [51,52]. In complex ablation procedures, patient dose and physician dose were reduced by 40% and 50%, respectively [25]. In interventional neuroradiology, 75% patient radiation dose reduction was demonstrated during digital subtraction angiography (DSA) without affecting image quality [26], and 60% procedural patient dose reduction was achieved [27]. However, results that quantify the reduction of patient radiation dose enabled by this technology for congenital heart disease are not available in literature. The study presented here was designed to quantify the procedural patient radiation dose reduction due to the novel X-ray imaging technology in a patient cohort with congenital heart diseases in comparison with our state-of-the-art angiography system.

## 2. Methods

### 2.1. Patients

All 667 consecutive patients with congenital heart defects referred between July 2012 and October 2013 were retrospectively included in the study. Patients who received catheter investigation with echocardiography only (i.e. Rashkind procedures) or under direct vision of the area to be treated (i.e. intraoperative hybrid procedures) were excluded from the analysis. In March 2013, the biplane flat panel angiography system was upgraded from Allura Xper FD20/10 (installed in 2011) equipped with state-of-the-art image processing (“reference system”) to the new AlluraClarity with Clarity IQ technology with advanced real time image noise reduction algorithms and optimized acquisition chain for all exposure techniques (Philips Healthcare, Best, The Netherlands). Patients were therefore assigned to the “reference” or “new” groups, and categorized according to clinical requirements and technical implementation to weight: A) below 10 kg, B) 10–40 kg, and C) over 40 kg.

The study was conducted in accordance with the provisions of the Declaration of Helsinki and was approved by the local ethical committee (approval Ref. No.: 21/2014). Procedure and dose data for all patients admitted with congenital heart disease (CHD) in the period July 2012–February 2013 were collected. As per institutional protocol and enforced by the European legislation, all relevant periprocedural data were continuously monitored and documented as part of the hospital quality assurance program. The data reported here include radiation dose, fluoroscopy time, procedure time, weight, height, BMI, and contrast medium use. After upgrading to the new system, procedure and dose data information for all consecutive patients were collected during March–October 2013. During the procedures the anti-scatter grid was not removed. The same cardiologists were employed and the same procedural techniques were used. All our catheter interventions were performed under deep conscious sedation and without general anesthesia as described in detail elsewhere [28].

### 2.2. Imaging technology

ClarityIQ is a novel X-ray imaging technology that combines advanced real-time image noise reduction algorithms, with state-of-the-art hardware to reduce patient entrance dose significantly. This is realized by anatomy-specific optimization of the full acquisition chain (grid switch, beam filtering, pulse width, spot size, detector and image processing engine) for every clinical task individually. The system has been optimized for all major disease areas using over a 1000 patients. In addition to patient entrance dose reduction, the image quality is improved through the use of the smaller focal spot sizes, and shorter pulses and the introduction of automatic real-time motion compensation in subtraction imaging.

One of the features of ClarityIQ, temporal noise reduction, is implemented by averaging consecutive images. However, in interventional cardiology, cardiac and respiratory motion result in the appearance of “ghost images” of moving tissues or devices. This used to limit the number of images that could be averaged, hence requiring higher doses per frame. The implementation of a motion compensation algorithm in this technology enables alignment of moving objects before averaging, such that more consecutive images can be averaged to reduce noise more significantly.

In addition, a spatial noise reduction algorithm uses the random nature of noise to discern between noise and useful clinical information in a single image. When a pixel is identified as noise, its intensity is averaged with surrounding pixels in order to filter it out. Thanks to the powerful computational power, a larger neighborhood of pixels can be averaged, providing more noise reduction and increasing the confidence in the clinical information to maintain in the image [26, 27]. Finally, image enhancement processing reduces low frequency over- and under-exposed areas and enhances high frequency edges in order to sharpen contrast. The image enhancement enabled by these features made possible a further optimization of the X-ray acquisition chain; this was modified to achieve patient radiation dose reduction for both pediatric and adult population for fluoroscopy and cine exposure. The maximum patient entrance dose for fluoroscopy was reduced from 22 mGy/min, 44 mGy/min and 44 mGy/min in the reference system to 7 mGy/min, 12 mGy/min and 22 mGy/min in the new system for the fluoroscopy modes I, II and III respectively, with the same relative reduction over the entire patient thickness range. For the pediatric group, two cine applications are introduced based on patient weight: a) below 40 kg and b) above 40 kg. The below 40 kg group uses a small focal spot (0.4) to increase the sharpness of images. In addition, increase in copper filtration was implemented (0.4 mm Cu and 1.0 mm Al) compared to the reference pediatric cine acquisition chain (0.0 mm Cu and 0.0 mm Al). The practical aspects of adding copper filtration to reduce patient radiation dose have been already studied by other authors [13,52]. Photons with lower energy do not contribute to the image quality, as they can't penetrate the patient's body, but add needless radiation dose to the patient. Additional copper filtration enables the reduction of these photons, with consequent patient radiation dose reduction.

In conclusion, hardware imaging components such as copper filtration, power, pulse width and duration, and focal spot size enter a virtuous cycle with advanced and real-time image processing features in order to optimize the dose to image quality relationship for each clinical application.

### 2.3. Statistical analysis

Patient radiation dose was quantified as (cumulative) dose area product (DAP), measured by the internal transmission ionization chamber (KermaX plus; IBADosimetry, Schwarzenbruck, Germany) and displayed on the equipment as mGy·cm<sup>2</sup>; this was automatically converted into cGy·cm<sup>2</sup> for documentation purposes. In addition, acquisition parameters, such as fluoroscopy time, procedure time, and

volume of contrast medium were collected. The primary outcome of the study was radiation dose quantified as DAP. Secondary outcomes were the fluoroscopy time, procedure duration, and amount of contrast medium. These secondary outcomes were used as surrogates for case complexity, in order to exclude this as a potential incidental difference between the groups that could explain dose differences. The study hypotheses were that significant procedural dose reductions were achieved using the new technology in all three weight groups.

Descriptive statistics were used to describe patient and procedure characteristics, with differences between reference and new systems evaluated with a nonparametric *t*-test (assuming no Gaussian distribution) at a significance level of  $\alpha = 0.05$ .

#### 2.4. Subgroup analysis for ASD patients

Based on the absolute numbers, the timeframe of the analysis and the large variation in procedures performed, a comprehensive subgroup analysis per procedure type was not possible. However, as an illustrative case example, we performed a sub-analysis for patients with one of the most common procedures, interventional ASD closure. The protocol for ASD closure is very uniform and without relevant variations other than operator skills. This includes single plane fluoroscopy for the procedure and standard biplane cine angiography acquisitions for specific parts of the procedure such as documentation of the balloon sizing, the wiggle maneuver, the release process as well as a final documentation of the device position. All ASD closures are considered as technically simple interventions; due to the educational character of our institution, ASD closures are performed by registrars in training for pediatric cardiology or junior fellows as first operators with an experienced consultant supporting.

#### 2.5. Standardizing dose reporting

Efforts were undertaken in this ASD analysis to make the large variability in procedures performed as well as in patients treated intuitively comparable. It is of no discussion that longer procedure times will expose patients to larger radiation doses; at the same time larger patients, i.e. those with a higher body weight and body mass index (BMI) will require larger radiation doses for the same procedure. Whereas a number of other important parameters also influence dose levels (such as projection angles), and whereas fluoroscopy time does not include cine exposure, these two factors were taken into account in a sub-analysis calculating dose exposure as radiation dose per weight, fluoroscopy time, and weight  $\times$  fluoroscopy time [2,13,20].

### 3. Results

#### 3.1. Patients

In total, the complete data set of 667 consecutive patients with congenital heart disease were prospectively collected and retrospectively analyzed. There were 18 patients excluded from the dose reduction analysis because they were treated only with echocardiography or under direct vision as intraoperative hybrid procedure (13 patients from the < 10 kg group, 5 patients from the 10–40 kg group). Therefore, 649 patients (328 for the reference system and 321 for the new system) were included in the analysis.

Table 1 shows the distribution of patients among the three weight groups for both reference and new systems. The distribution between reference and new systems among the weight groups was similar, with a higher number of interventional than diagnostic procedures for all weight groups.

The patient characteristics are listed in Table 2. The mean weight for all patients included in the analysis was 32.1 kg (SD: 27.6) and the BMI was 17.8 kg/m<sup>2</sup> (SD: 5.0) for diagnostic and interventional procedures. In general there were no clinically important or statistically significant

**Table 1**

Distribution of patients among the  $\leq 10$  kg, 10–40 kg and  $>40$  kg group, for both the reference and the new system for all, diagnostic, and intervention procedures.

Procedure type	$\leq 10$ kg group		10–40 kg group		$>40$ kg group	
	(n = 189)		(n = 234)		(n = 226)	
	Reference system	New system	Reference system	New system	Reference system	New system
Diagnostic + intervention	100	89	119	115	109	117
Diagnostic	39	40	38	37	38	39
Intervention	61	49	81	78	71	78

differences in the group size and distribution of weight or BMI between the Reference and New groups in any of the three weight subgroups or the subsequent variation regarding interventional procedures or diagnostic catheters.

#### 3.2. Procedure characteristics

Table 3 shows the procedure characteristics for all patients in the three weight groups. Again, there were no statistically significant differences in fluoroscopy time between the reference and the new systems for the three weight groups, nor in procedure time and contrast medium for the < 10 kg and  $>40$  kg groups. However, for the 10–40 kg group, the procedure time was significantly lower ( $p = 0.028$ ) for the new system while the parameters affecting X-ray radiation such as volume of contrast medium as well as fluoroscopy time were similar between the two systems.

For diagnostic and intervention procedures separately, there were no differences between the new and reference systems for the below 10 kg and over 40 kg groups in terms of fluoroscopy time, procedure time and contrast. However for the 10–40 kg group, the contrast medium reaches significant difference with a higher volume of contrast used with the old system (median 80.5 ml) as compared to the new system (median 56.5 ml) in the diagnostic group ( $p = 0.018$ ).

#### 3.3. Radiation exposure

Median DAP values decreased with the new system from 140.6 cGy·cm<sup>2</sup> to 60.7 cGy·cm<sup>2</sup>, from 700.0 cGy·cm<sup>2</sup> to 202.2 cGy·cm<sup>2</sup> and from 4490.4 cGy·cm<sup>2</sup> to 1979.8 cGy·cm<sup>2</sup> with reduction quantified at 57%, 71% and 56% for the below 10 kg, 10–40 kg and over 40 kg group respectively. Patient radiation dose was significantly reduced for the three groups ( $p < 0.0001$ ) by using the new system. Fig. 1 shows the distribution of DAP values for the reference (left) and new system (right) for the below 10 kg, 10–40 kg and over 40 kg group respectively, for all procedures.

For diagnostic procedures the patient dose reduction was 46%, 79% and 46% while for the interventional procedures it was 61%, 64% and 61% for the below 10 kg, 10–40 kg and over 40 kg group respectively.

#### 3.4. Subgroup analysis for ASD patients

A total number of 19 patients were referred to our cath lab for interventional occluder closure of a secundum atrial septal defect (ASD) while we were using the reference system and 31 patients while we were using the new system. Based on the relatively small absolute patient numbers, the whole cohort was analyzed without subdivision into the different weight groups. Again there were no clinically important or statistically significant differences between the patients or procedure characteristics (see Table 5). DAP decreased from 678.0 cGy·cm<sup>2</sup> to 112.3 cGy·cm<sup>2</sup> for the new system (reduction of 83%;  $p = 0.0002$ ).

**Table 2**  
Patient characteristics for the entire population, for the  $\leq 10$  kg, 10–40 kg and  $>40$  kg group, for reference and new systems for all (diagnostic and intervention) procedures.

	All patients		$\leq 10$ kg group			10–40 kg group			$>40$ kg group		
	Ref and New system		Ref system	New system	p value	Ref system	New system	p value	Ref system	New system	p value
	(n = 649)		(n = 100)	(n = 89)		(n = 119)	(n = 115)		(n = 109)	(n = 117)	
<i>Weight [kg]</i>											
Mean (SD)	32.1 (27.6)		6.0 (1.9)	6.3 (2.2)	0.352	20.6 (8.5)	20.6 (7.4)	0.478	68.0 (19.5)	63.6 (13.9)	0.258
Median	19.0		6.0	6.1		17.0	18.0		62.0	64.0	
Min, Max	2.2, 135.0		2.3, 10.0	2.2, 10.0		10.3, 39.0	11.0, 40.0		41.0, 135.0	42.0, 116.2	
Q1, Q3	8.70, 55.00		4.4, 7.5	4.7, 8.0		14.0, 27.2	15.0, 25.3		55.5, 78.0	53.0, 72.0	
<i>BMI [kg/m<sup>2</sup>]</i>											
Mean (SD)	17.8 (5.0)		14.8 (2.6)	14.3 (2.2)	0.333	15.6 (2.3)	15.4 (2.3)	0.322	23.1 (5.2)	22.4 (4.0)	0.501
Median	16.4		14.8	14.2		15.6	15.4		22.0	21.9	
Min, Max	4.8, 40.1		9.8, 30.0	5.2, 19.9		4.8, 21.9	7.1, 21.5		14.7, 40.1	15.2, 34.7	
Q1, Q3	14.5, 20.1		13.3, 16.1	13.3, 15.5		14.4, 16.9	14.2, 16.4		19.7, 25.7	19.6, 24.6	

\* Ref system = Reference system, SD = Standard deviation, BMI = Body mass index.

**Table 3**  
Procedure characteristics for the entire population, the  $\leq 10$  kg, 10–40 kg and  $>40$  kg group, for reference and new systems for all procedures.

	All patients		$\leq 10$ kg group			10–40 kg group			$>40$ kg group		
	Ref and New system		Ref system	New system	p value	Ref system	New system	p value	Ref system	New system	p value
	(n = 649)		(n = 100)	(n = 89)		(n = 119)	(n = 115)		(n = 109)	(n = 117)	
<i>Procedure time [min]</i>											
Mean (SD)	83.0 (50.8)		78.0 (47.3)	68.6 (34.7)	0.227	92.3 (53.3)	81.0 (50.7)	0.029	89.3 (59.0)	85.1 (51.0)	0.787
Median	71.0		66.0	66.0		82.0	68.0		73.0	75.0	
Min, Max	2.0, 392.0		22.0, 356.0	17.0, 177.0		2.0, 278.0	15.0, 270.0		4.0, 392.0	4.1, 255.0	
Q1, Q3	48.0, 103.0		48.0, 96.0	44.0, 86.0		53.5, 119.5	47.0, 101.5		53.0, 110.0	47.0, 110.0	
<i>Fluoro time [min]</i>											
Mean (SD)	13.9 (15.4)		10.8 (8.1)	13.2 (26.6)	0.092	14.8 (13.1)	12.4 (10.2)	0.231	16.3 (17.4)	15.2 (12.5)	0.932
Median	9.8		9.4	7.1		10.3	9.4		10.7	11.7	
Min, Max	0.1, 239.0		0.4, 56.0	0.1, 239.0		0.3, 76.5	1.2, 59.6		0.2, 119.2	0.1, 54.9	
Q1, Q3	5.7, 17.3		5.6, 13.7	3.8, 13.5		6.4, 19.8	5.8, 16.3		7.1, 18.1	6.2, 22.5	
<i>CMV [ml]</i>											
n	578		99	88		107	96		92	96	
Mean (SD)	85.7 (66.5)		39.1 (20.7)	45.0 (46.6)	0.717	94.5 (57.7)	81.7 (42.5)	0.145	124.2 (79.4)	128.6 (75.3)	0.652
Median	70.0		35.0	36.0		81.0	75.5		107.0	112.0	
Min, Max	1.0, 495.0		6.0, 132.0	1.0, 416.0		10.0, 370.0	7.0, 210.0		5.0, 495.0	5.0, 357.0	
Q1, Q3	40.0, 110.0		24.0, 50.5	25.0, 51.8		60.0, 115.0	50.0, 109.3		70.8, 161.0	79.0, 170.5	

\* Ref = Reference system, SD = Standard deviation, CMV = contrast medium volume.

As the patient group with congenital heart defects may vary substantially regarding body composition (i.e. weight, length, BMI) as well as with regard to the procedure performed (interventional vs. diagnostic, complex vs. “simple”) and finally by the time needed to perform the procedure, a more detailed analysis is needed for comparison and to estimate and judge the influence of possible radiation reduction efforts. For this group extra efforts were undertaken to standardize the radiation dose according to patient (i.e. weight) and procedure characteristics (i.e. fluoroscopy time). There was a significant reduction of radiation dose (DAP) applied as calculated by DAP/weight (reduction 72%), DAP/fluoroscopy time (reduction 83%) and DAP/weight/fluoroscopy time (reduction 72%).

#### 4. Discussion

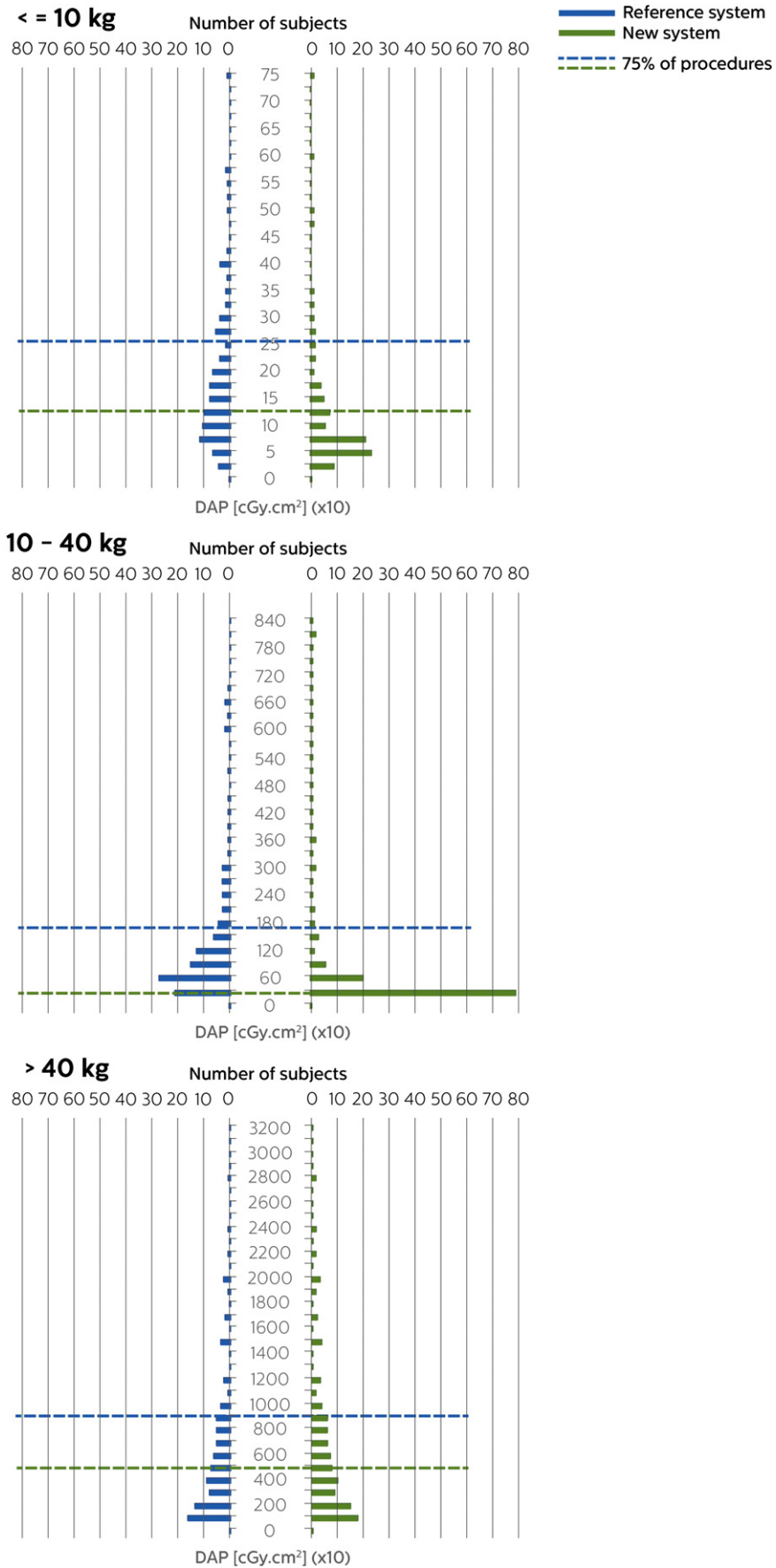
The aim of the study was to quantify the patient dose reduction achieved in a patient cohort with congenital heart disease enabled by an X-ray imaging technology combining advanced real time image noise reduction with an optimized acquisition chain for fluoroscopy and exposure in interventional cardiology for the entire population size. The results confirmed a patient dose reduction of 57%, 71% and 56% for the below 10 kg, 10–40 kg and over 40 kg group.

These results are in agreement with prior literature regarding this technology in different patient populations and clinical domains. Procedural patient and staff occupational dose reduction, enabled by

the technology investigated, has already been proven outside congenital heart disease interventions by comparing state-of-the-art reference to new systems. In complex ablation procedures, patient dose and physician dose were reduced by 40% and 50%, respectively [25]. In interventional neuroradiology, 75% patient radiation dose reduction was demonstrated during digital subtraction angiography (DSA) without affecting image quality [26], and 60% procedural patient dose reduction was achieved [27]. A preclinical study on a piglet model proved that DSA radiation dose for pediatrics can be reduced by a factor four without deterioration of image quality [51].

Patient radiation dose reduction is of extreme importance in patients with congenital heart disease as they are subjected to repeated procedures over the lifetime. As interventional procedures become more and more complex and procedural complexity is correlated with increasing fluoroscopy exposure time, adequate radiation reduction is of specific importance [29,30].

Baysson et al. reported on an epidemiological study launched in France to provide further knowledge about the potential cancer risks with pediatric catheterization procedures in 8000 patients [6]. Even though the long-term risks of fatal malignancy following a single pediatric catheter investigation seems very low, the effect of repetitive exposure is unclear [7,31]. In general, DAP values measured during pediatric catheterizations show an excellent correlation with the entrance radiation dose and skin doses measured with thermoluminescent dosimeters (TLDs) or can be transferred by calculation models to



**Fig. 1.** Distribution of DAP values for all procedures for the <10 kg (top), 10–40 kg (middle), >40 kg (bottom) group for the reference system (left) and new system (right). Dashed lines represent the third quartile (Q3). For graph layout purposes, the x-axis might be limited with percent of displayed values greater than 97%.

**Table 4**

Radiation dose for the entire population, the  $\leq 10$  kg, 10–40 kg and  $>40$  kg group, for reference and new systems for all procedures.

DAP [cGy·cm <sup>2</sup> ]	Mean (SD)	Median	Min, Max	Q1, Q3
<i>All patients</i>				
Reference and new system (n = 649)	2343.5 (5848.9)	396.3	0.1, 71271.2	126.2, 1998.1
<i><math>\leq 10</math> kg group</i>				
Reference system (n = 100)	189.0 (156.0)	140.6	10.8, 891.7	82.2, 261.9
New system (n = 89)	109.1 (125.3)	60.7	0.2, 739.0	41.0, 129.0
p value	<0.0001			
<i>10–40 kg group</i>				
Reference system (n = 119)	1649.3 (3522.7)	700.0	33.9, 35042.3	380.8, 1688.2
New system (n = 115)	420.9 (880.9)	202.2	17.4, 8011.0	110.4, 350.4
p value	<0.0001			
<i><math>&gt;40</math> kg group</i>				
Reference system (n = 109)	7303.4 (10381.6)	4490.4	45.9, 71271.2	1680.1, 8617.6
New system (n = 117)	3840.1 (6302.6)	1979.8	0.1, 45393.2	658.1, 4977.3
p value	<0.0001			

effective doses and are therefore valid to obtain a real-time measurement of the total amount of radiation used [4,13,32–35]. Similar results are obtained when calculating effective doses from DAP as published by the International Commission on Radiology Protection and measuring the effects on DNA damage [8]. Indirect cancer risk estimations and direct DNA-damage data emphasize the strict radiation dose optimization in children [36]. Using Monte Carlo simulations effective and equivalent organ doses can be derived by the use of DAP in children undergoing cardiac catheterization and estimated risk of exposure-induced death values can be calculated [9]. Therefore the substantial reduction of DAP values as presented here will be helpful to reduce the cumulative radiation risk for the pediatric patients with congenital heart defects undergoing diagnostic and interventional catheter investigations as well as for the operators performing the procedures [37].

Table 6 provides a comparison in terms of patient radiation dose with literature. Unfortunately, variability in patient size and procedure types, together with the different ways of reporting results in other studies makes comparison with literature very cumbersome. For example some authors have made an attempt of providing dose reference by classifying the population in standardized age groups [16,34,38], while others in weight groups [15,39–41] or fluoroscopy time [42,43]. Moreover, when making comparisons in terms of patient dose, procedure complexity should always be assessed. Procedure complexity should be classified based on a combination of parameters such as fluoroscopy time, procedure time and number of exposure images or amount of contrast medium used during angiography acquisitions, beside information on frame rates used for both fluoroscopy and cine acquisitions.

In accordance to other published studies reporting patient radiation doses and procedure complexity [15,16,30], this study reports consistent fluoroscopy times used for diagnostic and interventional procedures with the two systems across the weight groups, regardless of procedure complexity.

Moreover, the application of best practices in our lab to minimize fluoroscopy times and cine images to clinically acceptable levels, according guidelines [44], provide fluoroscopy times which are lower than the one reported by others [15,16], see Table 6. In light of these best practice behaviors, it is not possible to conclusively determine whether the lower radiation dose observed in our study on either system compared with literature reflects system or operator effects.

**Table 5**

Radiation dose for ASD procedures for entire population and for reference and new systems for all weight groups.

	All patients	All weight groups		p value
	Ref and new system (n = 50)	Ref system (n = 19)	New system (n = 31)	
<i>Weight [kg]</i>				
Mean (SD)	35.7 (21.7)	35.7 (22.7)	35.7 (21.4)	0.604
Median	30.0	32.0	26.0	
Min, Max	10.7, 80.0	10.7, 80.0	13.0, 80.0	
Q1, Q3	17.3, 49.8	14.5, 52.8	19.0, 48.0	
<i>BMI [kg/m<sup>2</sup>]</i>				
Mean (SD)	17.8 (3.7)	17.9 (3.7)	17.8 (3.7)	0.849
Median	16.4	16.3	16.4	
Min, Max	12.9, 27.0	13.3, 24.7	12.9, 27.0	
Q1, Q3	15.0, 20.6	15.0, 21.4	15.0, 20.0	
<i>Procedure time [min]</i>				
Mean (SD)	49.7 (22.9)	56.6 (27.3)	45.5 (18.9)	0.141
Median	43.0	47.0	42.0	
Min, Max	15.0, 120.0	19.0, 104.0	15.0, 120.0	
Q1, Q3	35.0, 56.8	36.5, 75.5	35.0, 53.5	
<i>Fluoro time [min]</i>				
Mean (SD)	7.3 (5.6)	8.4 (7.0)	6.6 (4.6)	0.263
Median	5.7	6.9	5.5	
Min, Max	1.2, 31.8	1.2, 31.8	1.2, 24.2	
Q1, Q3	3.9, 9.3	4.6, 9.0	3.8, 9.3	
<i>CMV [ml]</i>				
Mean (SD)	33.6 (26.0)	11.5 (9.2)	42.4 (25.5)	0.781
Median	22.0	11.5	50.0	
Min, Max	5.0, 70.0	5.0, 18.0	10.0, 70.0	
Q1, Q3	14.0, 55.0	8.3, 14.8	22.0, 60.0	
<i>DAP [cGy·cm<sup>2</sup>]</i>				
Mean (SD)	574.0 (991.6)	1048.1 (1445.2)	283.5 (350.9)	0.0002
Median	273.7	678.0	112.3	
Min, Max	30.2, 6368.0	33.9, 6368.0	30.2, 1475.0	
Q1, Q3	83.4, 694.5	352.0, 1014.6	68.3, 367.1	
<i>DAP/fluoro time [cGy·cm<sup>2</sup>/min]</i>				
Mean (SD)	76.9 (83.2)	132.1 (103.0)	43.0 (42.8)	p < 0.0001
Median	42.3	118.6	20.4	
Min, Max	9.9, 413.8	10.3, 413.8	9.9, 186.8	
Q1, Q3	17.2, 113.6	55.3, 176.9	14.9, 59.5	
<i>DAP/weight [cGy·cm<sup>2</sup>/kg]</i>				
Mean (SD)	24.1 (71.9)	49.6 (112.3)	8.5 (14.4)	p < 0.0001
Median	7.9	15.9	4.4	
Min, Max	1.3, 505.4	2.3, 505.4	1.3, 81.9	
Q1, Q3	3.4, 15.9	10.7, 38.5	2.9, 7.4	
<i>DAP/weight/fluoro time [cGy·cm<sup>2</sup>/kg/min]</i>				
Mean (SD)	2.6 (3.7)	4.8 (5.2)	1.2 (1.1)	p < 0.0001
Median	1.5	3.2	0.9	
Min, Max	0.2, 19.8	0.7, 19.8	0.2, 6.6	
Q1, Q3	0.8, 2.3	1.7, 5.5	0.7, 1.5	

\*Ref system = Reference system, SD = Standard deviation, BMI = Body mass index, CMV = Contrast medium volume, DAP = Dose area product.

Additional standardization of the radiation dose applied to patient and procedural factors may be helpful to differentiate these effects. We may suggest that previous studies used state-of-the-art systems, and could therefore be compared with our reference group, highlighting behavioral influence on dose. As the same conditions (i.e. operators, complexity, etc.) were present throughout our study, we infer that the dose reduction shown here between the reference and new systems in turn reflects only system capabilities.

#### 4.1. ASD patients sub-analysis

We have tried to accomplish the task of standardization by analyzing the results of dose reduction and combining them with the confounding factors exposure time, weight and BMI and the combination thereof.

**Table 6**  
Comparison of procedure characteristics and patient radiation dose with literature.

Weight [kg]	Nr of patients	Fluoro time [min]		DAP [cGy·cm <sup>2</sup> ]		Reference
		Median	[Q1, Q3]	Median	[Q1, Q3]	
<i>Diagnostic</i>						
<i>≤10 kg group</i>						
6.1	39	9.5	4.8, 12.6	103.9	82.2, 261.9	This Study – Reference system
6.0	40	6.6	3.5, 13.6	56.3	41.0, 129.4	This study – New system
4.5	242	26		743	433, 1433	[16]
<5		15	9, 23	224	116, 349	[15]
5–12.5		16	11, 26	418	272, 663	[15]
3.6	510	14	8, 22	228	122, 420	[2]
9.5	1429	14	9, 20	540	286, 957	[2]
<i>10–40 kg group</i>						
17.0	38	8.8	5.2, 14.5	706.85	385.7, 1130.2	This Study – Reference system
16.4	37	7.4	4.6, 14.9	151.60	97.7, 237.3	This study – New system
11.9	134	26		1399	852, 2222	[16]
23.2	85	20		1647	904, 2494	[16]
12.5–25		13	9, 20	945	575, 1.552	[15]
25–45		14	8, 22	2722	1.563, 4.290	[15]
27.4	498	12	7, 17	1449	674, 2674	[2]
<i>&gt;40 kg group</i>						
61.0	38	9.6	4.0, 14.00	3144.15	1123.4, 5766.0	This Study – Reference system
63.2	39	8.8	3.6, 13.6	1697.20	225.25, 3094.00	This study – New system
50.5	130	19		3415	1584, 6029	[16]
68.7	212	25		8284	3431, 18402	[16]
45–65		14	10, 25	5595	3432, 9071	[15]
>65		16	10, 21	8959	4919, 14784	[15]
58	314	11	7, 18	4006	1569, 8168	[2]
92	76	12	7, 19	10347	2811, 15874	[2]
<i>Intervention</i>						
<i>≤10 kg group</i>						
5.8	61	9.3	5.9, 14.1	167.70	86.0, 276.5	This Study – Reference system
6.9	49	6.9	4.1, 13.5	65.20	47.0, 136.7	This study – New system
<5		19	12, 32	258	171, 367	[15]
5–12.5		26	14.5, 41	656	346, 1380	[15]
3.4	680	18	11, 31	276	118, 610	[2]
<i>10–40 kg group</i>						
17.9	81	10.5	6.8, 21.2	700	384.5, 1750.8	This Study – Reference system
19.0	78	10.8	6.3, 17.1	251.60	121.3, 397.4	This study – New system
12.5–25		24	13, 44	1296	634, 3128	[15]
25–45		38	24, 59	6586	243, 9693	[15]
11.2	2231	19	11, 32	737	336, 1541	[2]
28	767	19	11, 31	1922	837, 3780	[2]
<i>&gt;40 kg group</i>						
63.0	71	12.6	8.3, 22.9	5681.40	1889.6, 9738.7	This Study – Reference system
64.0	78	12.80	7.1, 24.5	2223.95	791.6, 5826.2	This study – New system
45–65		24	16, 45	8514	3520, 14404	[15]
>65		36	19, 51	15841	8758, 38969	[15]
57	500	19	12, 31	5462	2370, 10418	[2]
88.4	90	20	12, 34	11600	6509, 20225	[2]

\*DAP = Dose area product.

Similar efforts were undertaken by Walters et al. who compared the DAP in patients during interventional electrophysiology and included the time factor to analyze the effects of collimation on radiation exposure, thus generating DAP per minute of fluoroscopy in adult patients [20]. As body size usually does not vary that substantially in adults, this additional calculation seemed adequate. Kobayashi recently published the results of a multicenter study by the Congenital Cardiovascular Interventional Study Consortium (CCISC) where the authors tried to standardize radiation dose reporting in the pediatric cardiac cath lab [2]. They analyzed the influence of weight as well as radiation exposure time and recommended that Kerma area product/body weight should be used as the standard in documenting radiation usage in pediatric laboratories and as a baseline to compare and evaluate strategies to lower radiation dosage in pediatric patients undergoing cardiac catheterizations. Chida and coworkers could demonstrate a good correlation between DAP and the weight of the patient as well as the weight-fluoroscopic time product indicating that body weight is important for determining radiation dose to children undergoing cardiac catheterization [10]. Similar assumptions were reported by Verghese

et al. and Glatz and coworkers who could show an influence of age, weight and the type of intervention on the radiation dose measured by air Kerma or DAP [15,16]. As age reflects body weight and the fluoroscopy time is influenced by the procedure type these influences must be taken into account when comparing different radiation doses of two systems.

Despite the fact that most of the procedures were performed by registrars in training, the overall procedure time (mean 49.7 min, SD 22.9 min, median 43 min) and fluoroscopy time (mean 7.3 min, SD 5.6 min, median 5.7 min) were considerably shorter than previously reported. Fischer et al. reported a single center series using the Amplatzer Septal Occluder (ASO) in 200 patients with a median fluoroscopy time of 12 min [45]. The MAGIC atrial septal defect study presented the results of an unrestricted multi-institution routine community use of the ASO for ASD closure in 458 patients; here the mean overall fluoroscopy time was 18.46 min (SD 12.10), for simple ASDs it was 17.66 (SD 11.07) and for complex cases 20.85 (SD 14.55) [46]. Similar fluoroscopy times exceeding a mean of 10 min are reported by many authors [47–50].

Papadopoulou et al. assessed patient radiation doses in 16 patients during transcatheter ASD closure. The mean body weight was 28.7 kg (median 21.0) and the mean fluoro-time 22.3 min (median 16.5 min) [4]. They reported mean DAP doses of 1.071 cGy·cm<sup>2</sup> (median 873 cGy·cm<sup>2</sup>). This is a considerably longer fluoroscopy time and higher DAP values as compared to our cohort with the new system (weight: mean 35.7 kg, median 26 kg, fluoro time: mean 6.6 min, median 5.5 min, DAP mean 283.5, median 112.3 cGy·cm<sup>2</sup>). Standardization of radiation doses allows us to reveal a dose reduction of the new system as compared to the data published by Papadopoulou of 74% [4]. When taking the different fluoroscopy times as well as the different body weight of the patients into account the dose reduction is equally evident; median dose/time: 20.4 vs 118.6 cGy·cm<sup>2</sup>/min = 83%; median dose/weight: 4.4 vs 15.9 cGy·cm<sup>2</sup>/kg = 72%; median dose/weight/fluoroscopy time 0.9 vs 3.2 cGy·cm<sup>2</sup>/kg/min = 72%.

#### 4.2. Limitations of this study

The first potential limitation was that this study was not a prospective randomized controlled trial, but a retrospective all-comer design, whereby the two groups' data were acquired sequentially. This theoretically could introduce learning curve and bias effects. However, all data was collected in a prospective manner according to the hospitals policy of data management and based on our quality assurance program, making inadequate data acquisition extremely unlikely. In addition, all cases were performed by experienced operators, making learning curve effects also unlikely. Therefore the possibility of inadequate data acquisition seems extremely low.

Second this study does not show the possibility to adequately match patients. Nevertheless, the data presented and the number of patients treated in a consecutive way adequately represents the usual patient and case load of a state of the art cath lab with a large percentage of interventions. Therefore the mix of patients, diagnoses, treatment modalities and other possible confounding factors is unlikely to have influenced the results. In order to learn about differences in radiation across types of procedures, further investigation is warranted using a paired study design to ensure equivalent patient and intervention characteristics.

Third, the clinical image quality was not taken into account. Based on the personal experience of all operators involved, there was no clinically important difference in image quality. Based on the amount of contrast medium applied, inadequate image quality should have led to a more extensive use of contrast medium or additional fluoroscopy time to obtain additional information not available by initial standard visualization; this was not the case. In addition patient outcomes did not change therefore proving that image quality was sufficient to perform the clinical task as well as before.

Finally, the mode of analyzing the radiation dose in combination with body composition (weight, BMI) as well as radiation time for standardization may be criticized. Based on the usual and large variation of patients in the field of congenital heart defects, it seems a very logical approach to analyze the influence of possible radiation reduction efforts. Only the combination of absolute radiation dose with the confounding factors provides the capability of comparing different systems without the need of extremely large patient numbers and clearly matched pairs. In addition and in congruence with other authors, this approach may contribute as a clinically relevant surrogate of radiation exposure in this very variable patient population.

Although we showed reduced exposure in our patient population, no data is available on the potential long term consequences with respect to cancer risk. Further investigation using a longitudinal study design over the decades may be warranted. However, causal relationships between exposure at a young age and later occurrence of adverse effects would be difficult to interpret. Perhaps specific blood markers measured a few months after treatment may be an acceptable surrogate indicator of future malignancy.

## 5. Conclusion

In general, an increasing number of interventional catheter procedures are performed in children and patients with congenital heart defects; the justification for these interventions are evident because they are able to avoid, postpone, replace or facilitate complex cardiac surgery. The complexity of these procedures may however often result in higher radiation doses. With the introduction of the novel X-ray imaging technology to our cath lab, we could demonstrate a significant and substantial reduction of the overall radiation dose applied to the patients, quantified at 57%, 71% and 56% for the below 10 kg, 10–40 kg and over 40 kg group respectively despite no other relevant changes in the procedural approach, the complexity of the patients or procedures involved. When analyzing specific subgroups of patients or procedures (i.e. ASD closure) this effect may become even more evident. We therefore believe that these results give confidence that this technology will add substantially to the ongoing initiatives to further limit radiation exposure and thereby reduce the risk to this potentially vulnerable patient population.

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## Conflict of interest

Maria Mauti and Cherif Sahyoun are employees of Philips Healthcare.

All other authors declare no conflict of interest.

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