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Estimation of radiation exposure in the pediatric cath lab in Ain Shams University: Cross-sectional observational study

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Abstract
Background: Radiation exposure in pediatric cardiac catheterization is a critical concern, especially considering the long-term risks of radiation-induced malignancies. This study aimed to assess the average radiation doses in the pediatric catheterization laboratory at Ain Shams University and compare them to international benchmarks.
Methods: This observational cross-sectional study was conducted from January to September 2020, with a significant reduction in case numbers during the COVID-19 pandemic. A total of 198 patients underwent various procedures, including ASD, VSD, PDA closures, and coarctation stenting. Radiation exposure parameters, including fluoroscopy time (FT), cumulative dose (CD), and dose area product (DAP), were automatically recorded using the Philips Allura Xper FD10/10® system. Data were compared to international studies and previous findings from our institute.
Results: The median DAP for VSD closure was 6,297 µGy·m², and for coarctation stenting, 17,736.25 µGy·m², both significantly higher than international benchmarks ($p<0.001$). However, ASD device closure and BAV showed lower median total air kerma (79.23 mGy and 134.78 mGy, respectively) compared to Cevallos *et al*. Comparison with earlier data from our institution revealed a significant reduction in DAP for PDA interventions (P = 0.045) and coarctation stenting (P = 0.014), indicating improved radiation safety.
Conclusion: While radiation exposure in certain procedures exceeded international averages, significant improvements have been made in reducing radiation doses in our institute over the last decade.

Keywords: Pediatric cardiac catheterization, radiation exposure, dose area product, fluoroscopy time, Ain Shams University

Introduction

Congenital heart diseases (CHD) account for almost one third of all major birth defects with incidence around 8-10 cases per 1000 births. Cardiac catheterization is still a mainstay in congenital heart diseases, in means of diagnosis, assessing operability and prognosis, and most importantly intervention [1].

One worrisome problem in the management of patients with CHD is certainly the long-term effects of ionizing radiation received during childhood, especially for interventional catheterization procedures. Ionizing radiation exposure is a definite risk factor for cancer development. Catheterization procedures are longer in children due to technical causes including more difficult cannulation, repeated catheterization, and more fluoroscopy time for more views and more detailed study. Thus, an infant or child patient has a longer lifetime risk for developing radiation-induced hazards than adult patients [1].

In our institute, Ain Shams University Hospitals, one of the centers in Egypt that does congenital catheterization with average 60 cases per week, we sought we sought to have a local study to record the current practice regarding radiation exposure and where we stand in comparison to international centers.

The aim of the study is to assess the average radiation doses recorded per procedure and to the patient in our Institute and to compare it to the international average doses.

Patients and Methods

This study was designed as an observational, comparative cross-sectional study conducted in the congenital catheterization laboratory of the cardiology department at Ain Shams University hospitals. The study period extended from January 1, 2020, to September 30, 2020. Due to the global COVID-19 pandemic, the number of procedures performed significantly decreased from mid-February to July, when the case load returned to normal.

Study Population

The study included all patients presenting to the Ain Shams University pediatric catheterization laboratory for elective cardiac catheterization, without age or sex restrictions. The procedures included in the study were atrial septal defect (ASD) device closure, ventricular septal defect (VSD) device closure, patent ductus arteriosus (PDA) closure (using either device or coil), coarctation treatment (via stenting or ballooning), balloon pulmonary valvuloplasty (BPV), balloon aortic valvuloplasty (BAV), diagnostic cases, and hemodynamic studies.

Ethical Considerations

Ethical approval for the study was obtained from the Ethical Committee at Ain Shams University before the commencement of the research.

Equipment and Radiation Measurement

The procedures were performed using the Philips Allura Xper FD10/10® system, which is equipped with biplane and rotational angiography capabilities. Radiation exposure data were recorded automatically by the catheterization laboratory equipment, without influencing the operator's preferences regarding fluoroscopy time, cine time, number of acquisitions, or choice between fluoroscopy or cine acquisition.

The following radiation exposure parameters were automatically calculated by the catheterization machine and included in the study

- **Fluoroscopy Time (FT):** Measured in minutes, this parameter represents the total X-ray exposure time during the procedure, as automatically recorded by the machine [2].
- **Cumulative Dose (CD in mGy) (Air Kerma):** Air kerma refers to the kinetic energy released per unit mass when an X-ray beam passes through air. It is used to quantify the intensity of the X-ray beam [3].
- **Dose Area Product (DAP in μGy·m² and μGy·m²/kg):** DAP is calculated as the absorbed dose multiplied by the area irradiated. It reflects not only the radiation dose within the field but also the total area of tissue irradiated, making it a better indicator of the overall risk of radiation-induced cancer than the dose alone [4].

Statistical Analysis

All collected data were tabulated and statistically analyzed using IBM SPSS software, version 22. Numerical data were expressed as mean ± standard deviation (SD) or as median and interquartile range (IQR), while categorical data were presented as frequencies and percentages. Independent t-tests and Mann-Whitney tests were used to compare numerical data, and categorical data were compared using the chi-square test. A p-value of less than 0.05 was considered statistically significant.

Results

Demographic data

The study included 198 patients ranging in age from 0.02 to 48 years, with the majority being under 10 years of age (69.2%). There was a male predominance, with 62.1% of the patients being male and 37.9% female. The weight distribution ranged from 2.8 kg to 90 kg, with the largest proportion of patients (33.3%) weighing less than 10 kg. Similarly, the height ranged from 42 cm to 182 cm, with the most common height range being between 72 and 100 cm (26.8%). Table 1.

Table 1: Demographic data of patients included in the study

Variable	Category	No. (%)
Age (years)	Range	0.02 – 48
	<1 year	50 (25.3%)
	1-4 years	43 (21.7%)
	5-9 years	44 (22.2%)
	10-15 years	27 (13.6%)
	>15 years	34 (17.2%)
Sex	Females	75 (37.9%)
	Males	123 (62.1%)
Weight (kg)	Range	2.8 – 90
	<10 kg	66 (33.3%)
	10-20 kg	57 (28.8%)
	20-30 kg	17 (8.6%)
	30-50 kg	20 (10.1%)
	>50 kg	38 (19.2%)
Height (cm)	Range	42 – 182
	<72 cm	46 (23.2%)
	72 – <100 cm	53 (26.8%)
	100 – <144 cm	47 (23.7%)
	>144 cm	52 (26.3%)

kg = kilograms, cm = centimeters

Radiation exposure per procedure

There was a significant variation in radiation exposure across different procedures. The highest total air kerma was recorded for VSD device closure (1463.54 mGy), while the lowest was observed for COAO angioplasty (86.84 mGy). Similarly, the total DAP was highest for COAO stenting (17,736.25 μGy·m²) and lowest for PDA coil (668.95 μGy·m²). Fluoroscopy time ranged widely, with VSD device closure requiring the longest time (51.26 minutes) and PDA coil the shortest (9.17 minutes). Table 2.

Table 2: Radiation exposure per procedure in total air kerma, total DAP, and fluoroscopy time

Procedure	Count	Total Air Kerma (mGy)		Total DAP (µGy·m²)		Fluoroscopy Time (minutes)	
		Median	Min.	Max.	Median	Min.	Max.
Diagnostic & HD	57	136.43	41.1	1836.32	1226.5	241.4	21312.75
BPV	46	148.26	48.14	1108.37	1113.1	228.31	4771.65
ASD	38	79.23	13.07	2562.04	693.65	126.60	25835.70
PDA device	16	196.41	58.24	1856.36	1208.9	257.80	15735.90
COAO stenting	14	1269.96	123.70	3682.82	17736.25	1101.60	27893.55
BAV	12	134.78	64.85	676.17	714.45	334.80	7042.80
PDA coil	6	106.1	57.40	189.15	668.95	319.80	1287.30
VSD device	5	1463.54	975.69	4697.07	6297	4198.00	26452.20
COAO angioplasty	4	86.84	57.89	86.84	652.2	434.80	652.20

mGy = milligray, DAP = dose area product, µGy·m² = microgray square meters, HD = hemodynamic study, BPV = balloon pulmonary valvuloplasty, ASD = atrial septal defect, PDA = patent ductus arteriosus, COAO = coarctation of the aorta, BAV = balloon aortic valvuloplasty, VSD = ventricular septal defect

VSD device closure showed the highest total air kerma followed by aortic coarctation, whereas ASD device closure showed the least. Figure 1.

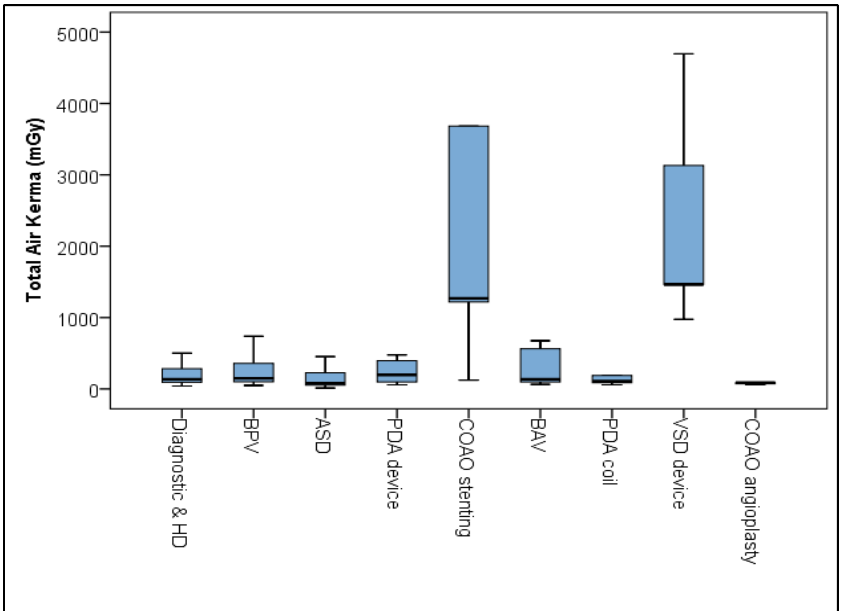

Fig 1: Total air kerma compared per procedure

Coarctation stenting showed the highest total DAP followed by VSD device closure. The lowest total DAP was measured in balloon dilatation of aortic coarctation followed by PDA coil closure. Figure 2.

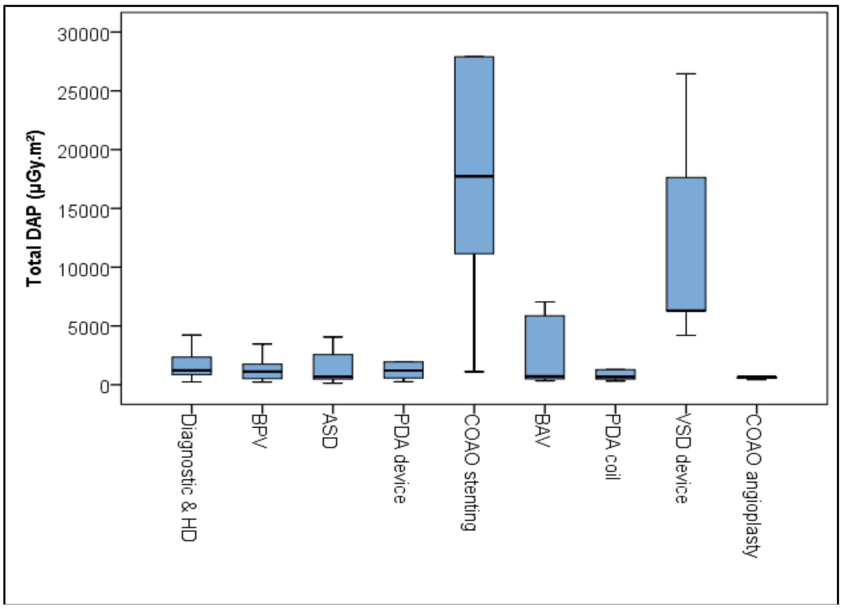

Fig 2: Total DAP compared per procedure

VSD device closure showed the longest fluoroscopy time followed by coarctation stenting. The shortest fluoroscopy time was measured in PDA coil followed by diagnostic and hemodynamic studies. Figure 3.

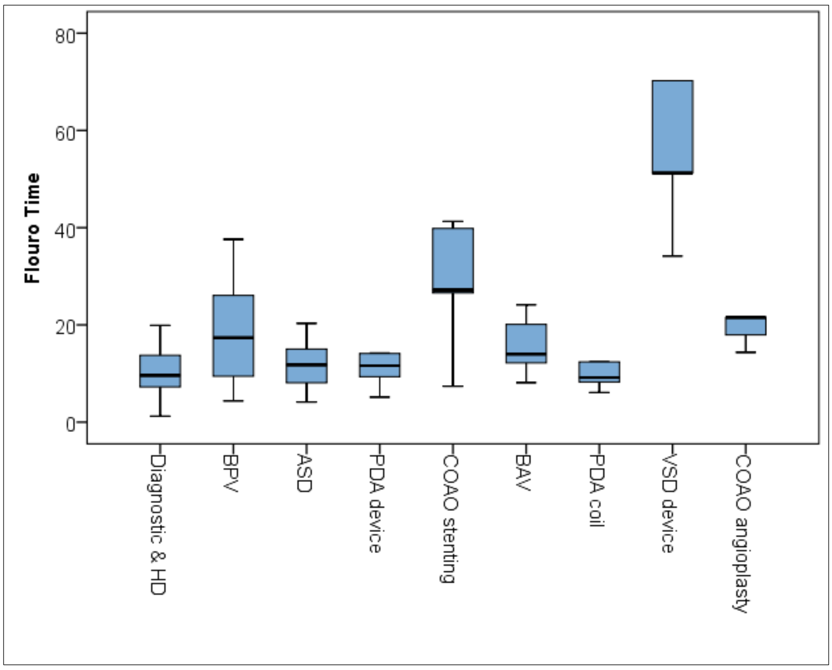

Fig 3: Fluoro time compared per procedure.

We compared our results to three international studies.

1. The multi-center study by Cevallos *et al.* was conducted in the United States between 2014 and 2015 on 1,680 cases that underwent interventional procedures, including ASD device closure, BAV, BPV, coarctation treatment, PDA closure, and transcatheter pulmonary valve implantation (TPV) [5].
2. The study by Harbron *et al.*, a multicenter study from the United Kingdom, analyzed data from 1994 to 2013, collecting around 7,726 cases [6].
3. The study by Glatz *et al.* was conducted in the United States in 2014 on 2,265 cases that underwent interventional and diagnostic congenital cardiac catheterization procedures [7].

We also compared our results with previous research conducted at our institute nine years ago. In 2011, El Sayed *et al.* conducted a study on 107 patients, comparing radiation exposure between interventional and diagnostic procedures performed at our institute [8].

I. Comparison Between Our Institute's Radiation Dosages and International Radiation Dosages

Five interventional catheterizations (BPV, ASD, PDA device, coarctation stent, and BAV) were compared to international benchmarks in terms of total air kerma and total DAP.

A. Comparison in Total DAP (μGy·m²)

There was a significant difference between the dosages recorded in our study and those in the study by Cevallos *et al.*, particularly for BPV, PDA device closure, and coarctation stenting, where our study reported much higher dosages. However, for ASD device closure and BAV, there was no significant difference. When comparing our results to those of Harbron *et al.*, all five procedures showed a significant difference in radiation doses, with our study recording higher dosages. Table 3.

Table 3: Comparison of Median Total DAP (μGy·m²) Between Our Study and Two International Studies

Procedure	Median Total DAP (μGy·m²)			P1 Value	P2 Value
	Our Study (n = 198)	**Cevallos *et al.* (n = 1680)**	**Harbron *et al.* (n = 7726)**		
BPV	1113.1	326	69	< 0.001	< 0.001
ASD	693.65	771	338	0.063	0.009
PDA Device	1208.9	407	112	< 0.001	< 0.001
Coarctation Stent	17736.25	1307	824	< 0.001	< 0.001
BAV	714.45	959	203	0.056	< 0.001

DAP: Dose Area Product, μGy·m²: Microgray square meter, BPV: Balloon Pulmonary Valvuloplasty, ASD: Atrial Septal Defect, PDA: Patent Ductus Arteriosus, BAV: Balloon Aortic Valvuloplasty, P1: First p-value comparison, P2: Second p-value comparison, n: Sample size

B. Comparison in Total Air Kerma (mGy): When comparing total air kerma with the Cevallos *et al.* study, our results for BPV, PDA device, and coarctation stenting showed significantly higher doses. However, for ASD device closure and BAV, our study reported significantly lower dosages. Table 4.

Table 4: Comparison of Median Total Air Kerma (mGy) Between Our Study and the Cevallos *et al.* Study

	Median Total Air Kerma (mGy)		P-value
	Our study	Cevallos *et al.*	
	n = 198	n = 1680	
BPV	148.26	69	<0.001
ASD	79.23	106	<0.001
PDA device	196.41	73	<0.001
COAO stenting	1269.96	207	<0.001
BAV	134.78	173	<0.001

mGy: Milligray, BPV: Balloon Pulmonary Valvuloplasty, ASD: Atrial Septal Defect, PDA: Patent Ductus Arteriosus, COAO: Coarctation of Aorta, BAV: Balloon Aortic Valvuloplasty, n: Sample size, P-value: Probability value indicating statistical significance.

C. Comparison of Median Fluoroscopy Time, Total Air Kerma, and Total DAP

The median fluoroscopy time and total DAP were significantly higher in our study compared to the Glatz *et al.* study. However, the total air kerma between the two studies did not show a statistically significant difference. Table 5.

Table 5: Median flouro time, total air kerma, and total DAP of all procedures were compared to Glatz *et al.*

	Our study	Glatz *et al.* study	P-value
Flouro Time (minutes)	13.18	15	<0.001
Total Air Kerma (mGy)	136.4	135	0.576
Total DAP (µGy.m²)	1173.8	760	<0.001

P-value: Probability value indicating statistical significance, Fluoro Time: Fluoroscopy Time (measured in minutes), mGy: Milligray, DAP: Dose Area Product, µGy·m²: Microgray square meter.

II. Comparison Between Our Study and the El Sayed *et al.* Study

When comparing our study with the El Sayed *et al.* study, we observed a significant decrease in total DAP for all three interventional procedures (ASD device closure, PDA intervention, and coarctation intervention). The most noticeable improvement was in coarctation treatment, which indicates a significant reduction in radiation exposure in Ain Shams cath lab from 2011 to 2020. Table 6 and Figure 4 A-C.

Table 6: Comparison of Median, 75th Percentile, and 95thPercentile Total DAP (µGy·m²) Between Our Study and the El Sayed *et al.* Study

		Total DAP (µGy.m²)			P-value
		Median	75th	95th	
ASD	Our study	693.65	2570.6	7877	0.044
	El sayed study	1900.00	4550.00	7860.00	
PDA intervention	Our study	668.95	1287.3	1287.3	0.045
	El sayed study	1583.5	2260	3720	
Coarctation intervention	Our study	802.20	1202.20	1352.20	0.014
	El sayed study	4200	5000	5350.00	

DAP: Dose Area Product, µGy·m²: Microgray square meter, ASD: Atrial Septal Defect, PDA: Patent Ductus Arteriosus, n: Sample size, P-value: Probability value indicating statistical significance

Figure 4: A) Our study total DAP in ASD device closure compared to EL Sayed *et ald et al.*, B) Our study total DAP in PDA intervention compared to EL Sayed *et al.*, and C) Our study total DAP in coarctation treatment compared to EL Sayed *et al.*

Discussion

In the study by Glatz *et al.* on 2,265 cases, the median fluoroscopy time was 15 minutes, the median air kerma dose was 135 mGy, and the median DAP was 760 µGy·m². In our study, the median fluoroscopy time was 13 minutes, the median air kerma was 136.4 mGy, and the median DAP was 1,173 µGy·m² [7].

Similarly, Sullivan *et al.* conducted a study on 332 pediatric cardiac catheterization cases, using the Allura Xper system, which reported a median total DAP of 866 µGy·m². In our study, the median total DAP for all procedures was 1,173 µGy·m² [9].

Harbron *et al.* raised the question of why radiation doses at some centers are much higher than at others. One possible reason is confusion between units, such as between µGy·m² and mGy·cm², which can lead to a ten-fold difference in doses. In our study, we ensured that all units were correctly converted for consistency. This confusion is a well-known issue faced by researchers and is commonly mentioned in radiation dosage studies. Approximately half of the previous publications make no mention of dose calibration. Additionally, recorded radiation dosages are typically subject to an uncertainty of ±15% [6].

When we compared our results to those of El Sayed *et al.*, a study conducted in our institute nine years ago on radiation exposure in interventional and diagnostic congenital cardiac catheterization, our results showed significantly lower doses. This improvement can be attributed to the adoption of new radiation protocols, the training of staff, and the installation of a new catheterization lab machine [8].

Compared to Cevallos *et al.*, our results showed higher radiation dosages. This may be related to the increased difficulty of the procedures performed at our institute. For example, when we excluded two outliers in the coarctation stenting group (Table 8), the total DAP and total air kerma in the 75th and 95th percentiles significantly decreased. Procedure difficulty can greatly affect radiation dosages. Our institute, as a tertiary center, often handles complicated cases referred from other centers, leading to longer procedures and higher radiation doses [5].

The two outlier patients were particularly complex cases: one patient had a near-interrupted coarctation with a procedure time of two and a half hours, and the other had a large post-stenotic dilation that required careful stent size adjustment, with a procedure length of two hours. These challenging, lengthy procedures inevitably resulted in higher radiation exposure.

Another critical factor is the heterogeneity of groups in comparative studies, which is a well-known challenge in radiation research. For instance, we compared coarctation stenting in our study with coarctation treatment in the

Cevallos *et al*. study, which included both balloon angioplasty and stenting.

Glatz *et al*. noted that even when fluoroscopy times were comparable between studies, total air kerma and DAP levels varied significantly. This underscores the fact that fluoroscopy time alone is not sufficient to compare results, and that comparing actual radiation energy exposure is more appropriate. For this reason, we focused our comparisons on total DAP and total air kerma. This highlights the need for efforts to reduce radiation exposure that go beyond merely decreasing fluoroscopy time. These efforts should include using the lowest possible fluoroscopy pulse rate, reducing dose per pulse, and minimizing cine frame rates while maintaining good image quality. When possible, cine acquisition should be replaced by stored fluoroscopy images [7].

Chamberlain *et al*. explained that procedural habits and settings can account for differences in radiation dosages, even within the same procedure and patient group. For instance, keeping pulse width ≤5 ms in small children and ≤10 ms in adolescents or adult patients is recommended. Shorter pulse widths freeze cardiac motion, improving image sharpness of rapidly moving objects, while longer pulse widths for adults improve penetration through thicker body parts [10].

Although we have significantly improved our radiation doses over the past decade, we still fall short of international standards. This necessitates the implementation of stricter protocols in the catheterization lab and raising awareness among operators and technicians about the importance of utilizing all available methods to reduce radiation exposure.

Conclusion

Our study established radiation exposure benchmarks per procedure in our institute without interference with operators' preferences. When compared to previous research conducted at our institute, we observed significantly lower total DAP in ASD and PDA transcatheter closures, as well as in coarctation interventions. However, compared to international radiation exposure standards, our results were still higher. In light of our findings, we plan to employ all available methods to decrease radiation exposure and extend the study with new, stricter protocols.

Conflict of Interest

Not available.

Financial Support

Not available.

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