Radiation dosage during pediatric diagnostic or interventional cardiac catheterizations using the "air gap technique" and an aggressive "as low as reasonably achievable" radiation reduction protocol in patients weighing <20 kg

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ABSTRACT

Background : **Cardiac catheterizations expose both the patient and staff to the risks of ionizing radiation. Studies using the "air gap" technique (AGT) in various radiological procedures indicate that its use leads to reduction in radiation exposure but there are no data on its use for pediatric cardiac catheterization. The aim of this study was to retrospectively review the radiation exposure data for children weighing <20 kg during cardiac catheterizations using AGT and an "as low as reasonably achievable (ALARA)" radiation reduction protocol.**

Patients and Methods: : **All patients weighing <20 kg who underwent cardiac catheterization at the Children's Hospital at Montefiore (CHAM), New York, the United States from 05/2011 to 10/2013 were included. Transplant patients who underwent routine endomyocardial biopsy and those who had surgical procedures at the time of the catheterizations were excluded. The ALARA protocol was used in concert with AGT with the flat panel detector positioned 110 cm from the patient. Demographics, procedural data, and patient radiation exposure levels were collected and analyzed.**

Results : **One-hundred and twenty-seven patients underwent 151 procedures within the study period. The median age was 1.2 years (range: 1 day to 7.9 years) and median weight was 8.8 kg (range: 1.9-19.7). Eighty-nine (59%) of the procedures were interventional. The median total fluoro time was 13 min [interquartile range (IQR) 7.3-21.8]. The median total air Kerma (K) product was 55.6 mGy (IQR 17.6-94.2) and dose area product (DAP) was 189 Gym2 (IQR 62.6-425.5).**

Conclusion : **Use of a novel ALARA and AGT protocol for cardiac catheterizations in children markedly reduced radiation exposure to levels far below recently reported values.**

Keywords : Air gap technique (AGT), cardiac catheterization, diagnostic cardiac catheterization, fluoroscopy, interventional cardiac catheterizations, radiation exposure

Abbreviations : AGT: Air gap technique, ALARA: As low as reasonably achievable.

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INTRODUCTION

Fluoroscopy, which is dependent on the use of ionizing radiation, is extensively utilized during the performance of cardiac catheterizations in infants and children. While the benefits of the use of radiation in these procedures are unquestionable, its intendant risks, including both deterministic and stochastic effects, are of concern.[1-3] It has been postulated that the risks associated with radiation exposure may potentially be greater in the pediatric age group.[4-8]

Operator radiation exposure is also of concern due to its close proximity to the patient and the scatter effect of the machine during a procedure.[2,3,9] Therefore, devising strategies to minimize radiation dose is an important goal.

In May 2011, the pediatric cardiac catheterization/hybrid suite was opened at the Children's Hospital at Montefiore (CHAM), New York, USA. As part of a quality improvement initiative, "as low as reasonably achievable (ALARA)" protocols were designed and enacted to reduce radiation dosage and tailor the dose to the particular type of study being performed with a goal of using the minimum radiation dose that would allow for adequate visualization of the heart and the blood vessels in order to minimize radiation dose to the patient and staff. Most of these protocols consisted of reducing fluoroscopy time in addition to frame rates and dose per frame.[10,11]

In addition to the aforementioned measures for reduction in radiation exposure, the air gap technique (AGT) was also introduced for all patients with weight <20 kg. In a smaller child, radiation is less scattered and removal of the antiscatter grid [Figure 1] with an air gap between the patient and the detector allows for dissipation of much of the scatter without compromising the primary beam [Figure 2].[12] The resultant image is magnified but not by more than one step in the ordinary intensifier or detector electronic magnification.[13] This technique has not previously been described for use in children during cardiac catheterization.

The aim of this study was to retrospectively review the radiation exposure data for pediatric patients weighing <20 kg during diagnostic or interventional cardiac catheterizations using "AGT" and a standard "ALARA" radiation reduction protocol.

PATIENTS AND METHODS

Patient selection

All patients weighing <20 kg who underwent cardiac catherization, diagnostic or interventional, in the hybrid cardiac catheterization laboratory at CHAM, New York, USA from May 1, 2011 when the new catheterization laboratory at CHAM was opened to July 31, 2013 were included. Transplant recipients who underwent routine endomyocardial biopsy and those who had surgical procedures at the time of the catheterization were excluded because of their very short fluoroscopy times.

As low as reasonably achievable protocol and the air gap technique

The protocol, designed with the input and suggestions of Siemens Corp. (Washington, DC, USA) utilized a combination of the AGT and previously described ALARA principles.[11] Operators were instructed to begin with the "low dose" (6 nGy/frame) and adjust upward from this setting as needed to provide acceptable image quality (increased to 8-18 nGy/frame). It should be mentioned that roughly 2/3 to 3/4 of fluoroscopic imaging was performed at this lowest setting. In addition to altering

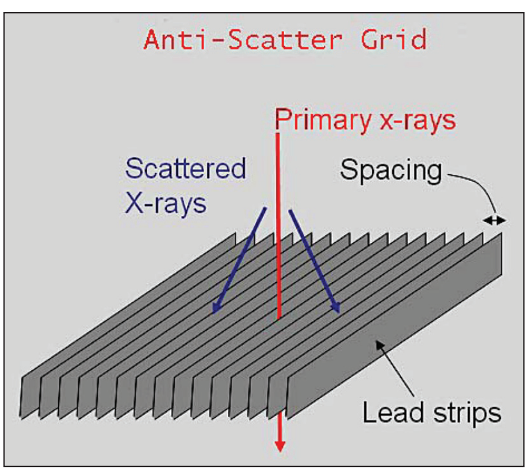

Figure 1: Antiscatter grid
This diagram illustrates some of the x-rays (the primary x-rays) being transmitted and the scattered x-rays absorbed in the grid, thereby leading the grid to attenuation of some of the desired primary x-rays. (Obtained from http://www.upstate.edu/radiology/education/rsna/radiography/scattergrid)

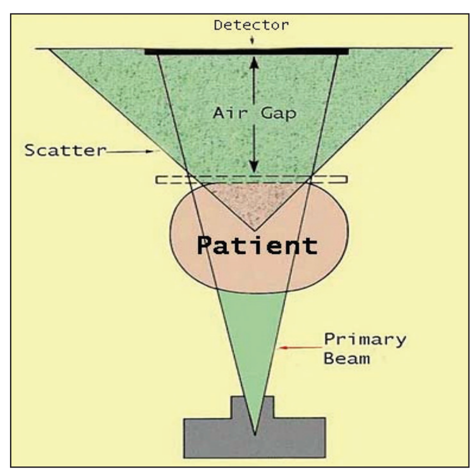

Figure 2: Air gap technique. The antiscatter grid, an air gap between the patient and the detector, allows dissipation of much of the scatter and does not compromise the primary beam. (Obtained from http://www.sprawls.org/ppmi2/SCATRAD. Last date of visit, June, 2014)

the dose per frame, operators were instructed to start at ultra-low frame rates of 2 fps and the frame rates were kept as low as possible to allow visualization with escalation as needed. The majority of fluoroscopic imaging was performed at 2-3 fps with elevations in the frame rate as needed. Most digital acquisition angiograms were taken at typical traditional fast frame rates of 15 fps or 30 fps with more standard dose per frame (of 15-30 nGy/frame). Increased attention was paid to not "stepping on" fluoroscopy when unnecessary. In addition to the ALARA protocol, AGT that includes the removal of the anti-scatter grid and placement of the detector 110 cm in both the posterior-anterior (PA) and lateral projections was utilized for all the patients.

Patient demographics, procedure time, fluoroscopy time, and radiation exposure [measured as air Kerma (K) and dose area product (DAP)] were recorded by the Siemens device and analyzed. Other data collected for analysis included the type of procedures, diagnostic or interventional, type of interventions as well as any untoward outcomes/complication.

Statistical analysis

All outcome measures were skewed continuous variables; therefore nonparametric tools were used. Standard descriptive statistics were used to summarize the data and were expressed as median [with range or interquartile range (IQR)]. The Wilcoxon rank-sum test was used for comparison of the radiation exposure in diagnostic and interventional procedures. Statistical analysis was performed using SPSS software (IBM, Armonk, New York, USA). All P values <0.05 were considered to be statistically significant.

RESULTS

One-hundred and twenty-seven patients under went 151 procedures within the study period with a male predominance of 54%. The patient characteristics are demonstrated in Table 1. The median age was 1.2 years (range: 1 day to 7.9 years), weight was 8.8 kg (range 1.9-19.7 kg), and body surface area (BSA) was 0.07 m^2 (range 0.01-0.14) [Table 1].

Eighty-nine (59%) of the procedures were interventional [22 patent *ductus arteriosus* (PDA) device closure and coil closures, 18 pulmonary angioplasty/stenting, 14 pulmonary valvuloplasties, 10 atrial septal defect (ASD) device closures, 6 coil embolizations, 3 recoarctation dilations, 2 aortic valve dilations, and the rest single cases of dilation of Blalock-Taussig (BT) shunt, atrial septoplasty, inferior *vena cava* (IVC) stenting, superior vena cava (SVC) balloon dilation, device closure of Fontan fenestration, etc.] [Tables 2 and 3). The radiation data were expressed as the median (IQR). The median fluoro time for combined diagnostic and interventional procedures was 13 min (IQR 7.3-21.8); biplane fluoro was used in 127 (84.1%) cases. The median total air K for all procedures was 55.6 mGy (IQR 17.6-94.2) and DAP was 189 Gy.m^2 (IQR 62.6-425.5). The median procedural time was 71.5 min (range: 20-238) [Table 4]. The total air K for only diagnostic procedures was 52.1 mGy (IQR 12.5-83.2) and DAP was 174.8 Gy.m^2 (IQR 42.5-330.0). The median procedural time for only diagnostic procedures was 69.0 min (IQR 47.0-93.0) and the fluoro time was 11.6 min (IQR 6.2-18.7) [Table 4]. There was no difference in radiation exposure between diagnostic or interventional cases in the study (P = 0.2). The radiation data for some of the common interventions in this age group were analyzed as well and are reviewed in Table 4.

There were few complications (4.6%; Table 5). Three had supraventricular tachycardia and 2 of these required DC cardioversion and one resolved spontaneously. The left leg of one the patients was discolored secondary to venous congestion which resolved without intervention. One patient developed VF that required defibrillation and one developed asystole for 6 seconds which resolved spontaneously. One developed a small pericardial effusion and new moderate tricuspid regurgitation during attempt at closure of a coronary fistula to RA [Table 5]. Of the 89 interventions attempted, success was achieved in 88. The single failed intervention was a coronary fistula in a newborn. This could not be closed in the laboratory and the patient was ultimately successfully repaired surgically.

Table 1: Patient characteristics

Total number of patients	127
Males	69 (54%)
Median age (years)	1.2 (range: 1 day-7.9 years)
Median weight (kg)	8.8 (range: 1.9-19.7)
Median height (cm)	70 (range: 40-119)
Median body surface area (m^2)	0.07 (range: 0.01-0.14)

Table 2: Procedural data

Number of catheterizations (*n*)	151
Interventional catheterizations (*n*, %)	89 (59%)
Diagnostic catheterizations (*n*, %)	62 (41%)
Median procedural time (minutes)	71.5 (range: 20-238)

Table 3: Interventions

Type of Interventions (*N* = 89)

Procedure	Number
PDA† device and coil occlusion	22
Pulmonary angioplasty/stenting	18
Balloon pulmonary valvuloplasty	13
ASD‡ device closures	10
Coil embolizations	6
Recoarctation dilation	3
Balloon aortic valvuloplasty	2
Balloon atrial septoplasty	2
Others	13

†PDA: Patent *ductus arteriosus*, ‡ASD: Atrial septal defect

Table 4: Radiation exposure measures by type of procedure

Type of procedure	Air Kerma (mGy)	DAP† (μGy·m^2)	Fluoroscopy time (minutes)	Procedure time (minutes)
Diagnostic and interventions (*n*=151)	55.6 (17.6-94.2)	189 (62.6-425.5)	13 (7.3-21.8)	71.5 (49.0-108.5)
Diagnostic only (*n*=62)	52.1 (12.5-83.2)	174.8 (42.5-330.0)	11.6 (6.2-18.7)	69.0 (47.0-93.0)
Interventions only (*n*=89)	61.3 (17.8-100.5)	202.8 (58.9-486.2)	15.1 (8.3-23.9)	77.0 (49.3-119.3)
PDA§ device and coil closure (*n*=22)	56.9 (35.4-70.9)	120.1 (156.2-32.6)	11.3 (6.7-15.2)	63.5 (55.8-84.0)
Secundum ASD‡ device closure (*n*=10)	2.8 (1.0-3.5)	17.2 (5.2-24.1)	7.5 (5.2-10.0)	37.0 (30.0-44.0)
Balloon pulmonary angioplasty/stenting (*n*=18)	96.6 (69.1-150.3)	486.2 (360.9-726.7)	25.9 (17.7-34.2)	125 (95.5-146.3)
Pulmonary valvuloplasty (*n*=13)	23.1 (15.2-41.3)	67.5 (29.7-192.7)	8.9 (7.8-22.6)	48 (37.5-79.3)

†DAP: Dose area product, §PDA: Patent *ductus arteriosus,* ‡ASD: Atrial septal defect

Table 5: Complications

Type	Number of cases
Supraventricular tachycardia	3
Ventricular fibrillation requiring defibrillation	1
Asystole for 6 s (self-resolved)	1
Leg discoloration due to venous congestion	1
Development of new trace AI†, moderate TR‡, and small pericardial effusion	1

†AI: Aortic insufficiency, ‡TR: Tricuspid regurgitation

When comparing complication rates before and after the ALARA and AGT era, the incidence of complications was 4.6% during the ALARA and AGT period in comparison to 9.4% in the previous 2-year period and this difference was not statistically significant ($P = 0.126$). As illustrated in Figure 3, the quality of the images taken with the radiation grid in place and the ones without the radiation grid and using the "air gap" technique were comparable.

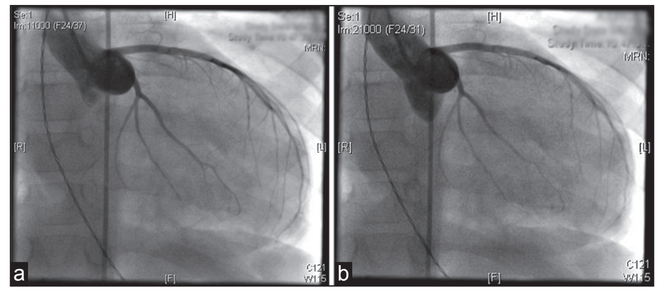

Figure 3: Selective injection in the LCA in the PA view in a 2-year-old s/p orthotopic heart transplant (a) Is taken with the radiation grid in place and the detector immediately above the chest (b) Is taken without the radiation grid using the "air gap" technique. Image quality is comparable between the two

DISCUSSION

In this study, the median air K for all of the catheter-based cardiac procedures, diagnostic and intervention combined, was 55.6 mGy (IQR 17.6-94.2) with a median DAP of 189 Gym^2 (IQR 62.6-25.5). These values are substantially and profoundly lower than any prior published data for diagnostic or interventional catheterizations in children and infants, demonstrating the powerful effects of this combined ALARA + AGT when applied to catheterization of infants and children.[14,15] In a roughly contemporaneous period, the median dose for patients undergoing only diagnostic catheterizations with weight less than 12 kg in the study by Verghese *et al.* was 278 mGy (IQR 146-502) or nearly five times the 55.6 mGy for all of the patients in this study who were physically larger and were undergoing both diagnostic and interventional catheterizations.[15] Additionally, the reported DAP in that study was 1399 Gy.m^2 (IQR 852-2222), which was nearly seven times the median value in this study. Finally, fluoroscopy time in that large single-center study was 26 min, which was double our median 13-min time.

Similarly, Glatz *et al.* reported[14] the median dose for patients undergoing diagnostic catheterizations with weight less than 12.5 kg of 97 mGy (IQR 59-149), compared to 52.1 mGy (IQR 12.5-83.2) for our patients who were physically larger and were undergoing diagnostic catheterizations. The Philadelphia, Pennsylvania, USA group also reported a fluoroscopy time for diagnostic procedures of 16 min, compared to our median 11.6-min time. Additionally, the DAP reported for this weight range was 418 Gy.m^2 (IQR 272-663) compared to our 174.8 Gy.m^2 (IQR 42.5-330.0). According to this study,[14] the median air K for patients undergoing similar interventional catheterizations for patients weighing less than 12.5 kg was 136 mGy (IQR 81-287), which was more than two times our 61.3 mGy (IQR 17.8-100.5) for our interventional cohort who were physically larger. Similarly, the DAP for interventions in that study was 656 Gy.m^2 (IQR 346-1,380) in comparison to our study value of 202.8 Gy.m^2 (IQR 58.9-486.2) for somewhat larger patients (20 kg vs 12.5 kg). Finally, the fluoroscopy time in the Glatz study was 26 min (IQR 14.5-41) compared to our 15.1 min (IQR 8.3-23.9).

It is challenging to ascertain what part of the radiation reduction protocol was most responsible for the significantly low doses observed. A concerted effort to not "step on the pedal" was made by all operators (cardiology fellow and attending staff) because all operators in the laboratory were aware of the quality improvement initiative aimed at radiation reduction that was started upon opening the new hybrid catheterization laboratory at our hospital center. This may account for the relatively low fluoroscopy times, which have been linked in prior studies with reduced total dose.[16] However, addition of AGT in concert with a novel radiation reduction protocol utilizing low frame rates in concert with very low dose of radiation per frame (with the ability to increase as needed at the table side at any time) was likely similarly important in the achievement of these low values.

It should be noted that despite these significant reductions in dose, safety was not obviously compromised in this patient group. There were no deaths during the study period and the complication rate was low (4.6%) and similar to other reports of complications during invasive cardiac catheterization in infants and children.[17-19] When comparing the complication rate during the time period of this study with the prior 2-year period in which a more standard, high dose fluoroscopic technique was utilized at our center, no difference was observed in the complication rate (9.4%; $P = 0.126$). Though the difference was not statistically significant, the apparent reduction in complication rate in the ALARA and AGT period could possibly be attributed to many factors including the introduction of a team of fully qualified and experienced pediatric critical care nurses in the new pediatric hybrid catheterization laboratory and improvement in anesthesia coverage by experienced pediatric cardiac anesthesiologists. Additionally, there was only one "serious" complication in a patient who developed an increase in the degree of tricuspid regurgitation during a failed attempt at the closure of a large coronary fistula. Importantly, this was also the only interventional procedure that was not successful in this patient cohort.

Despite the relatively low doses of radiation used in our patients, the image quality of the images taken with the radiation grid in place and the ones without the radiation grid and using the "air gap" technique were comparable [Figure 3] and the safety of the patients was not compromised.

Limitations

The limitations of this study include the retrospective study design. Additionally, as this study was begun as a quality improvement project, with the baseline assumption that less radiation was superior to more radiation, there was no adequate clinical or theoretical equipoise to have a simultaneous control group for comparison. There was no historical control group because the data on radiation dose was not recorded consistently in the prior adult catheterization laboratory (where cases were previously performed) prior to the new hybrid catheterization laboratory at CHAM, making such a comparison unfeasible. Finally, the cardiac interventionalists were experienced and it is possible that the doses would be higher with less experienced staff.

CONCLUSIONS

The use of a novel ALARA protocol in concert with AGT for diagnostic and interventional cardiac catheterizations in children markedly reduced radiation exposure to levels below recently reported values without negatively affecting the safety or efficacy of these complex procedures. These initial data may provide new benchmarks as a means of comparison for future large scale efforts to reduce radiation dose in catheterizations performed in infants and children. Additionally, these initial data may suggest that the extension of this technique to larger patients (e.g., 20-40 kg) is warranted.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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