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Quality Initiative to Reduce Cardiac CT Angiography Radiation Exposure in Patients with Congenital Heart Disease

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Abstract

Background: The use of cardiac computed tomography angiography (CCTA) as a complementary diagnostic modality to echocardiography in patients with congenital heart diseases (CHDs) is expanding in low- and middle-income countries. The adoption of As Low As Reasonably Achievable techniques is not widespread, resulting in significant unintended radiation exposure, especially in children. Simple quality improvement measures geared toward reducing radiation dose can have an impact on patient safety in resource-limited centers in low- and middle-income countries. **Objectives:** To determine how a quality improvement initiative can reduce radiation exposure during CCTA in patients with CHD. **Methods:** We designed a key driver -based quality initiative to reduce radiation dose during CCTA for CHD using protocol optimization, communication, and training and implementation as the drivers for intervention. Preintervention variables (radiation exposure, scanning protocols, and image quality) were collected from September 2012 to July 2016 and compared with variables in the postimplementation phase (February 2017 to July 2017). We compared quantitative and categorical variables using the chi-square test. Linear regression analysis was used to evaluate the effect of various factors on radiation dose. **Results:** We documented a reduction in the effective dose in the postintervention versus preintervention phase (mean, 2.0 versus 21 mSv, $P < 0.0001$, respectively). Linear regression showed that the optimal organizational levels are associated with the same reduction in radiation. This finding shows that the time factor translates a combination of organizational and technical factors that contributed to the reduction in radiations. **Conclusions:** Our project showed a reduction in CCTA-associated radiation exposure. (*Pediatr Qual Saf* 2019;3:e168; doi: 10.1097/pq9.000000000000168; Published online May 16, 2019.)

INTRODUCTION

Cardiac computed tomography angiography (CCTA) is increasingly used as a promising alternative to diagnostic cardiac catheterization in the evaluation of children with

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Supplemental digital content is available for this article. Clickable URL citations appear in the text.

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To cite: Ali F, Rizvi A, Ahmad H, McGonagill P, Khan M, Krishnamurthy R, Jamil Z, Nadeem N, Yousuf M, Hasan B. Quality Improvement Initiative to Reduce Cardiac Computed Tomography Angiography Radiation Exposure in Patients with Congenital Heart Disease. *Pediatr Qual Saf* 2019;3:e168.

Received for publication October 11, 2018; Accepted March 27, 2019.

Published online May 16, 2019.

DOI: 10.1097/pq9.000000000000168



congenital heart disease (CHD).¹ Due to the ionizing radiation associated with CT, the rise of CCTA use in children has been accompanied by concerns over radiation exposure because children are particularly sensitive and have a longer lifespan to manifest radiation-induced cancer.²

CCTA is a complementary diagnostic modality to echocardiography and is expanding as an alternative to diagnostic cardiac catheterization (done for delineation of anatomy) in low- and middle-income countries (LMICs). CCTA is already widely used in developing countries for adult cardiac imaging. However, it has seen increased use in pediatric populations.³ Adoption of As Low As Reasonably Achievable approaches for pediatric CT radiation exposure is not widespread due to the lack of pediatric imaging experts, optimized protocols, training in the appropriate techniques, or effective radiation monitoring.^{4,5} There are no reports from LMIC on quality improvement initiatives to prevent radiation overdosing during CT.

The objective of this manuscript is to demonstrate how a quality improvement initiative can reduce radiation exposure during CCTA in pediatric patients with CHD in an LMIC setting and to elucidate factors associated with high radiation exposure.

METHODOLOGY

We conducted this quality improvement initiative project at Aga Khan University Hospital in 3 phases that took place between September 2012 and July 2017. We compared the preintervention phase (September 2012 to July 2016) with a postintervention phase (February 2017 to July 2017). We implemented interventions between August 2016 and January 2017.

Aga Khan University Hospital is a 644-bed tertiary care teaching hospital in our country and belongs to LMICs catering to all aspects of pediatric and adult diseases. Our center utilizes a Toshiba detector scanner and Aquilion One 640-detector scanner (Canon Medical Corporation, Japan) to perform approximately 15,000–18,000 (combined adult and pediatric) CT scans per year. Our center performs approximately 300 open heart surgeries and 200–250 CCTAs in neonates and adult patients with CHD. At our center, the number of CCTA cases has grown exponentially over the past 2 years.

Identification of Key Drivers

An audit of radiation exposure over a month revealed average pediatric CT radiation dosing at approximately >25 mSv. This finding was significantly higher than the published standard values. Even recent literature from international and national studies showed that median doses of 2.7 mSv⁶ or 3.46 mSv in a Pakistani population were reasonably achievable.^{7,8} Thus, we formed a quality improvement team that included a radiologist, pediatric cardiologist, physicist, CT technicians, and the radiology manager. Group discussions and previously published studies were used to identify factors that possibly contributed to increased radiation dose in our population.^{3,9,10}

1. Despite the availability of a new-generation CT like the 640-detector CT, there was a lack of awareness of the advantages of newer CT techniques like volumetric imaging over helical imaging that has been found to reduce radiation exposure in pediatric populations.³
2. No radiation monitoring system is in place to measure cumulative effective dose (ED) (millisieverts) in patients.
3. Vendor guidance regarding pediatric-specific low radiation protocols and machine settings is ineffective. The available pediatric protocols were not modified for age or indication.
4. Lack of a hospital-wide information system that synchronized with a radiology information system to provide relevant demographic and clinical information at the point of care.
5. Lack of structured communication between the referring and radiology teams. The requisition slips had inadequate information on patient disease/status, often with no indication for the CT, leading to unnecessary multiphasic, comprehensive, or ex-

tended studies.

6. Ineffective sedation and lack of utilization of techniques to avoid cardiac, respiratory, or gross motion resulting in motion artifact necessitating repeat studies.
7. CCTA at nonroutine timings, such as late evenings, nights, and weekends, with junior technologists using nonstandard protocols.
8. Using identical protocols and standard scan lengths for both adult and pediatric patients. An example was the use of a 16-mm scan length in every case irrespective of age and size of the pediatric patient, resulting in unnecessary coverage of the neck and abdomen in neonates and infants.
9. Use of 120 kV for all cardiac studies regardless of patient size, indication, or target organ.
10. Use of dual phase or equilibrium phase of contrast enhancement to opacify arterial and venous structures irrespective of the indication.

We grouped the identified factors into 3 key drivers crucial to reducing radiation exposure: protocol optimization, communication, and training and implementation of interventions to promote these drivers. The key driver diagram is depicted in Figure 1.

Interventions

Details of interventions are described in Table 1.

Data Collection

We collected demographic data (age, sex, and primary cardiac diagnosis) from electronic records. We also collected the following data from the scanner console for effective radiation dose calculation: type of CT scanner (64 slice/640 slice), mode (volumetric/helical), dose length product (DLP), kilovolts, milliamperes, and CT dose index volume. We estimated ED by multiplying DLP by an age/sex-specific conversion factor.¹¹ Radiologists and technologists also collected the following data to identify contributing factors:

1. Indication on requisition slip (complete, defined as both the diagnosis and the indication for the scan with a specific area of concern identified; incomplete, defined as a slip with only the diagnosis but no indication for the scan; and no indication, defined as only being asked to do a CCTA without any other additional information).
2. Sedation status during the study (fully sedated, defined as having no motion; and not sedated, defined as being sedated but agitated during the study or fully awake). A trained sedation nurse or doctor determined sedation status based on the irritability of the child during the procedure.
3. The timing of CCTA (morning, defined as 8 AM to 4 PM; afternoon, from 4 PM to 12 AM; and night shift, from 12 AM to 8 AM).
4. Single- or dual-phase contrast study.
5. We defined the standard scan length from thoracic

inlet to top of the diaphragm; any other scan length was determined as nonstandard until the requisition slip specified a clear indication requiring a larger scan area.

6. Technologist training level: senior (≥ 3 years of experience with adult and pediatric CCTA) or junior (< 3 years of experience with adult and pediatric CCTA).

Assessment of Image Quality and Diagnostic Accuracy

While performing pediatric CT, we made a concerted effort to follow the principles of As Low As Reasonably Achievable which is to use minimum radiation while maintaining image quality, thus not compromising on the diagnostic accuracy of the scan.¹² To assess image quality changes due to the intervention, we attempted to look at diagnostic error qualitatively in a blinded fashion on a subset of patients pre- and postintervention. Approximately 44% (n = 70) of patients preintervention and 40% (n = 30) of patients postintervention underwent cardiac surgery. We considered the anatomical findings on surgery as the gold standard. A pediatric cardiologist and radiologist, blinded to the surgical findings, reviewed the presurgical CCTA images of all these patients. We defined an accurate diagnosis when the anatomical details as read by the cardiology and radiologist were found to be the same during surgery. The report was labeled inaccurate if there were any discrepancy in the findings.

Study of Interventions

Majority of the interventions done were process-level changes (ie, appropriate requisition, pediatric scanning protocols, daytime scans, senior technologist scans, etc). These changes were brought about after meetings and buy-in from the radiology and cardiology colleagues. Thus, all the process-level changes were enabled simultaneously. The effect of individual process changes is thus difficult to discern. For analysis, process-level changes (as a group) are treated as a single intervention.

Statistical Analysis

Due to the categorical nature of all predictor variables, we reported frequency and proportions over time and compared via chi-square test or Fisher’s exact test as appropriate. Nonparametric Kruskal–Wallis test was used to compare outcomes over time owing skewed nature of these variables. We performed multivariable linear regression analysis to evaluate the effect of various factors on radiation dose. The outcome variable was radiation exposure in millisievert, while the independent factors include age, gender, initial diagnosis, protocol (standard/nonstandard), scan length (focused/unlimited), CT scanner type (64/640 slice), slice mode (volumetric/helical), kilovolts (80–100/120), arterial and venous phase (single/double), indication (complete/incomplete), sedation during scan (yes/no), timing of scan (morning, evening, night), and technologist level (junior/senior). Details of linear regression are described in Appendix B (available as Supplemental Digital Content at <http://links.lww.com/PQ9/A83>). Radiation

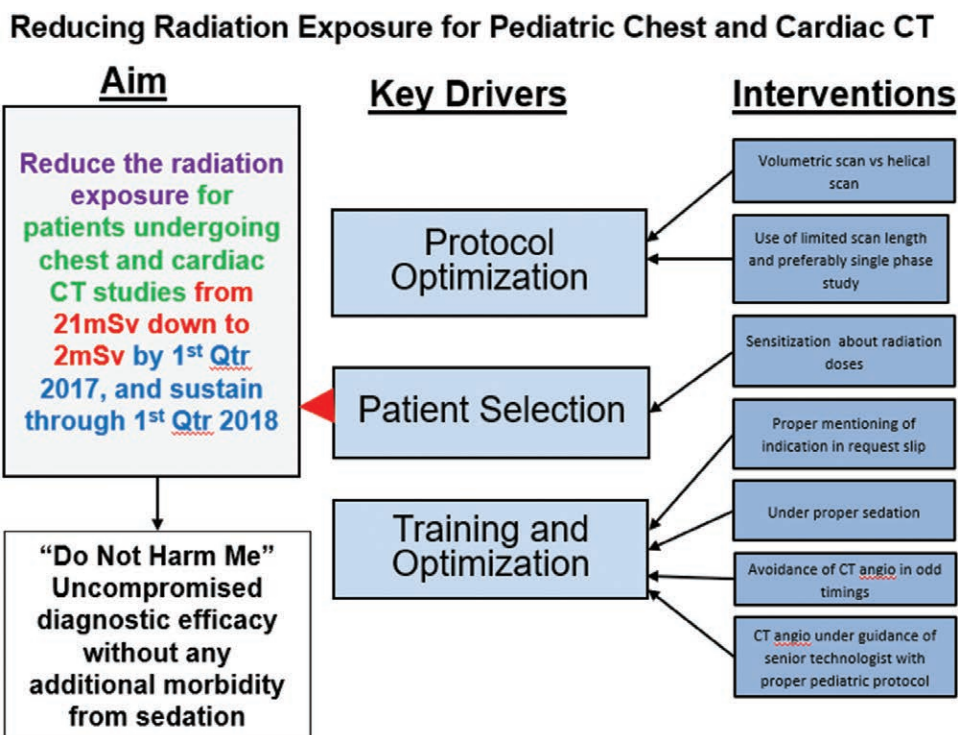


Fig. 1. Key driver diagram.

Table 1. Details of Interventions for Key Drivers

Key Drivers	Interventions
Protocol optimization	Meetings between the vendor and the radiology team were arranged to reset pediatric protocols. The radiology team implemented pediatric protocols with indication-based scan length and appropriate sedation. Protocol attached in Appendix A (available as Supplemental Digital Content, http://links.lww.com/PQ9/A85). We made use of the 320-detector scanner with volumetric mode mandatory for pediatric imaging. The 64-detector scanners were only used in situations when the 640-detector scanners were not operational. Helical mode use was restricted to cases needing a scan length >16 cm.
Communication	Protocols with routine kilovolt settings between 80 and 100 based on patient size were implemented. We arranged bimonthly meetings between the radiology team (comprising a cardiac radiologist, a manager, a physicist, and a senior technician) and the cardiology team (comprising a pediatric cardiologist and a senior cardiology fellow). We began by sensitizing the residents, fellows, and faculty in resident sessions and faculty meetings. We arranged Grand rounds at the institution level to discuss radiation burden and methods of decreasing radiation exposure in children.
Training and implementation	Clear indication of scan on requisite slips made mandatory by communicating to cardiology team. Technician was enforced to enquire about indication (in case of incomplete requisition slip) before to proceed for scan. Scan initiation was accomplished with a manual real-time bolus-tracking method. We trained the technologists to initiate an acquisition when sufficient contrast medium opacification was achieved in the target vessel or chamber, or when both the aorta and pulmonary vessels were opacified. Nonionic, low, or iso-osmolar iodinated contrast agents were used. We made checking the intravenous cannula for leakage with test injections mandatory, and cannulation was preferentially done to plan contrast transit away from the area of suspected pathology to prevent streak artifacts from iodinated contrast medium.

Table 2. Demographic Data

	Pregroup Count (%) Total # 160	Postgroup Count (%) Total # 76	P*
Age in groups			0.176
≤1 mo	32 (20)	12 (15.8)	
1 mo to 5 y	71 (44.4)	33 (43.4)	
5–16 y	30 (18.8)	23 (30.3)	
>16 y	27 (16.9)	8 (10.5)	
Gender			0.842
Male	99 (61.9)	46 (60.5)	
Female	61 (38.1)	30 (39.5)	
Diagnosis categories			0.004
TOF	47 (29.4)	30 (39.5)	
CoA	15 (9.4)	15 (19.7)	
TGA	10 (6.3)	2 (2.6)	
Complex CHD	26 (16.3)	2 (2.6)	
Others	62 (38.8)	27 (35.5)	

*P used to compare pre- and postgroups obtained through chi-square test.

dose was tracked statistically by control charts using X-bar and S-charts.

RESULTS

We included CT scan data from a total of 236 patients (160 in preintervention and 76 in postintervention) in this study. Patients 1 month to 5 years old comprised the highest proportion of cases included in both phases. The majority of patients were male in both pre- and postintervention phases (61.9% and 60.5%, respectively) (Table 2).

There was a significant reduction in the ED (combined 64- and 640-slice CT scanner) in the postintervention versus preintervention phase (mean, 2.0 versus 21 mSv, $P < 0.0001$, respectively). There is also significant decrease in total DLP, milliamperes, and CT dose index after the intervention ($P < 0.0001$; see Figure 1A–D, Supplemental Digital Content, <http://links.lww.com/PQ9/A81>). An X bar and S control chart in Figures 2 and 3, respectively, illustrates the tracking of average quarterly radiation dosage (measured in millisievert) from the start of initiative till now showing the success of project and sustainability.

Effect of Intervention on Key Driver Components

The effect of the quality improvement initiative on factors contributing to radiation dose is shown in the Supplemental Digital Content available at <http://links.lww.com/PQ9/A82>.

The analysis considered the period before the 640-slice scanners were available (before July 2014) and the period when the 640-slice scanner was available but before the interventions occurred (before January 2017). In the pre-intervention phase, helical scans were conducted 100% of the time before the availability of 640-slice scanners and 83.2% of the time after 640 scanners were available. The proportion of helical scans used decreased significantly from 88.8% to 25% of the time ($P < 0.0001$) postintervention, whereas the proportion of 120-kV tube voltage decreased from 100% to 21.1% ($P < 0.0001$). There was a significant improvement in the timing of the scan (more often in the morning), completeness of requisition slips and sedation, and the presence of senior technologists. The use of standard protocol increased from 50% to 97.4% ($P < 0.0001$) as did use of 640-slice scanner (55.0% preintervention to 98.7% postintervention, $P < 0.0001$).

There were no diagnostic errors seen in both pre- and postintervention subset of patients with surgical confirmation. Because image quality was adequate, no patients required repeat scans.

Factors Associated with CCTA Radiation Exposure

In a linear regression analysis of radiation exposure with 3 independent variables, time, age, gender, and initial diagnosis (model A of Table 3), time had a statistically significant association with outcome. The radiation exposure reduced 16 mSv in January to July 2017 compared with January to December 2016 adjusting for age, gender, and initial diagnosis ($\beta = -16.0$; 95% confidence interval, -20.8 to -11.2). This model explained 32.5% variation in the outcome variable. In the model B organizational factors, that is, an indication of request slip, sedation

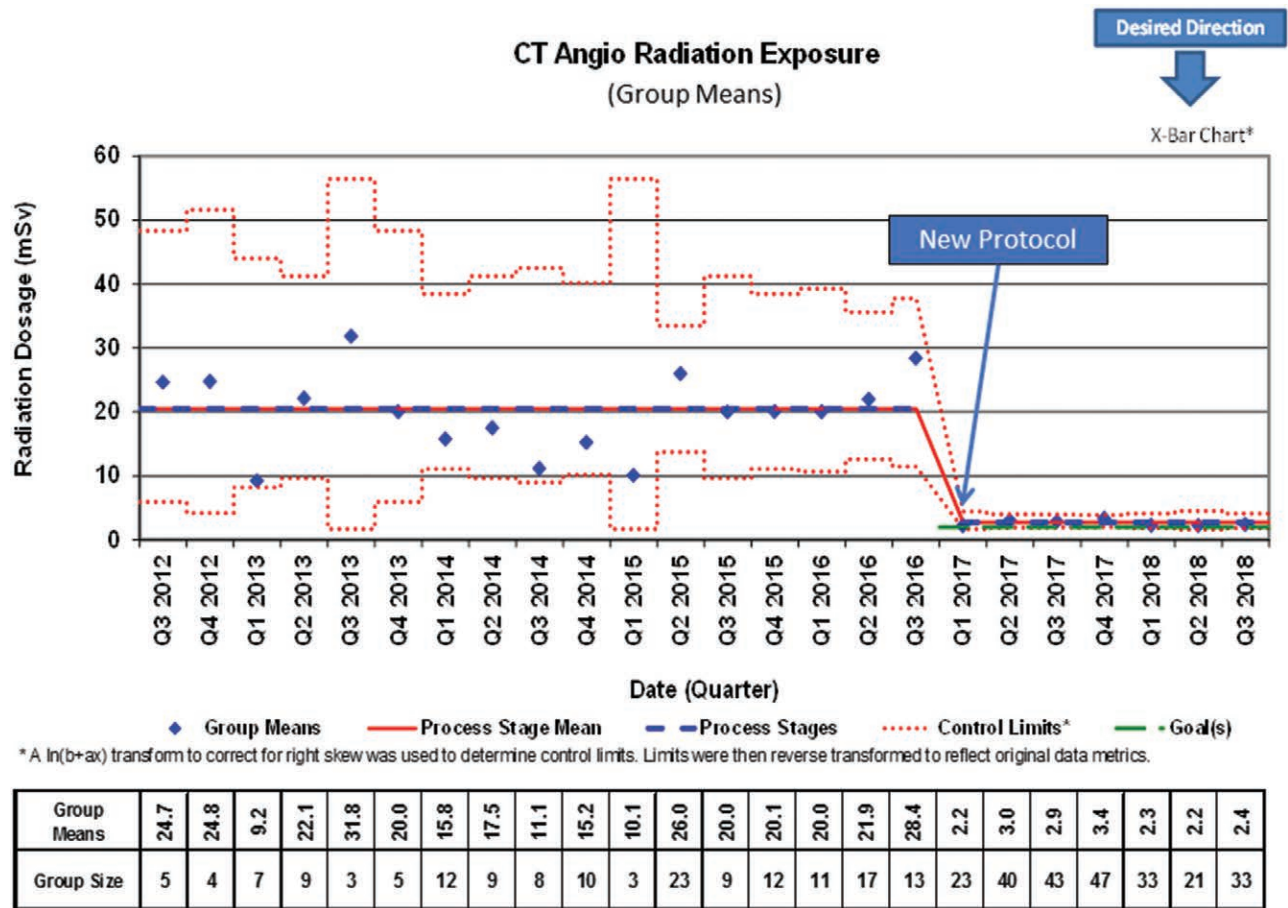


Fig. 2. CCTA radiation exposure pre- and postintervention (control X bar chart by quarter).

status during the scan, time of scan, and technologist level were added in the model with patient characteristics. The indication on the request slip and technologist experience level was associated with a significant reduction in radiation. The share of explained variation remains the same. The model C included technical factors with patient characteristics. This model included volume, kilovolts, protocol, scan length, arterial and venous phase, and CT scanner type. All of the variables except arterial and venous phase were statistically significant and associated with a reduction in radiation exposure. The share of explained variation increased to 48.6%. This finding shows that technical factors are more important in explaining the variation in the outcome. Details of the regression analysis including the 3 models A, B, and C are shown in Appendix B, available as **Supplemental Digital Content**, <http://links.lww.com/PQ9/A83>.

We also estimated the adjusted mean radiation (millisieverts) for significant factors from model A to C (available as **Supplemental Digital Content**, <http://links.lww.com/PQ9/A84>). The greatest reduction observed was with time, that is, 2.8 mSv (seconds: 0.2). The optimal organizational and technical levels were also associated with the same reduction in radiation. This result shows that the time factor translates a combination of

organizational and technical factors that contributed to the reduction in radiations.

DISCUSSION

This study demonstrates how a tertiary care center catering to a mixed adult-pediatric population in an LMIC can adopt a key driver-based quality improvement initiative to reduce radiation exposure in patients undergoing CCTA for CHD without compromising the diagnostic accuracy of the scan. We identified the use of helical mode, nonstandard protocols, and lack of sedation as the major contributors to an excess effective radiation dose. Furthermore, we noted that although the 320-detector scanner reduced radiation exposure, its availability alone was not sufficient. The systematic implementation of a quality improvement initiative was necessary.^{12,13}

Using a key driver-based quality initiative is effective in multiple aspects of management related to patients with CHD. The congenital cardiac catheterization project outcome quality initiative demonstrated a significant reduction in radiation during cardiac catheterization of patients with CHD among 17 centers in the United States.^{14,15} This initiative used a key driver-based approach to bring about system-level change through education, awareness,

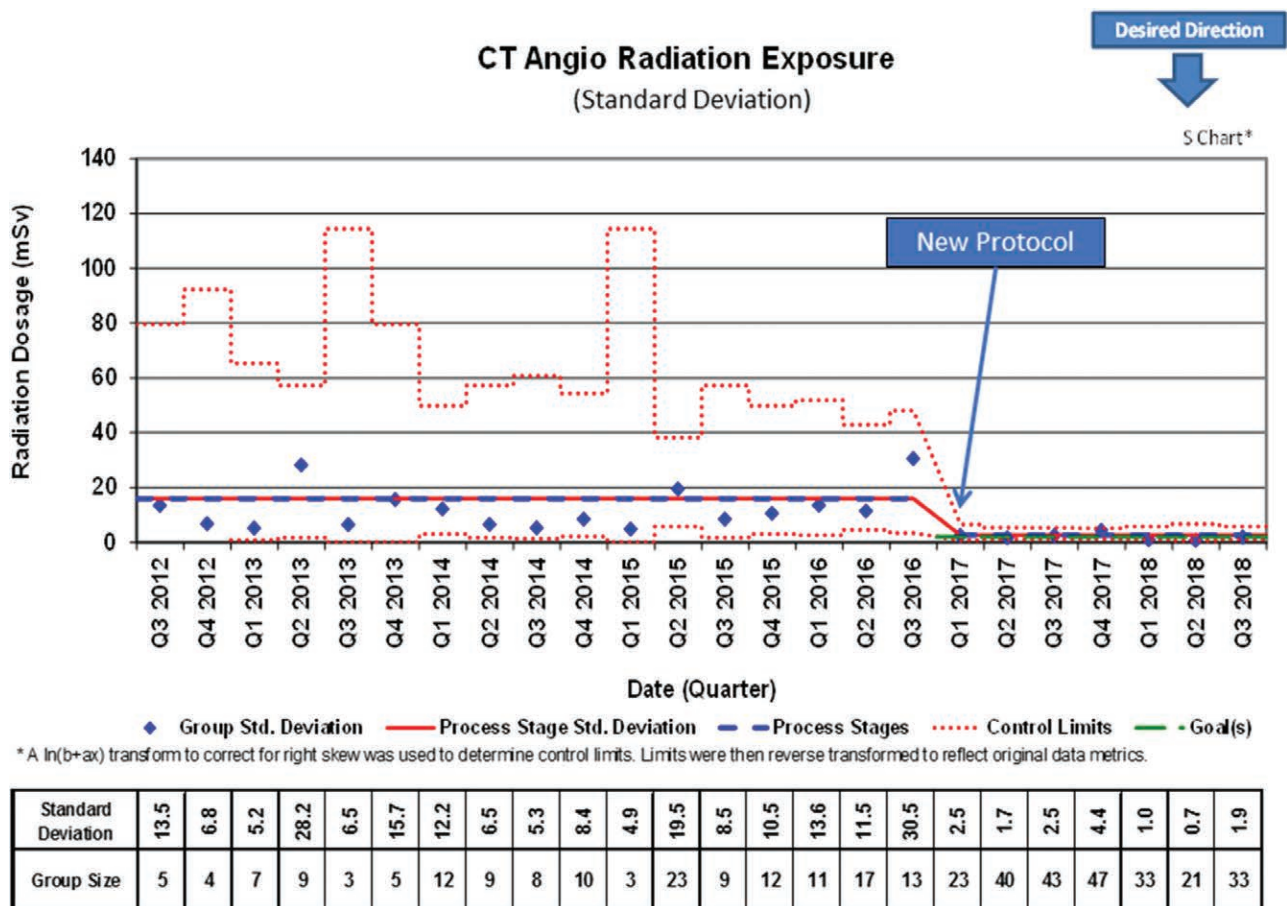


Fig. 3. CCTA radiation exposure pre- and postintervention (control S chart by quarter).

and systematic data tracking. Similarly, the international quality improvement initiative used a key driver-based quality improvement approach to help reduce morbidity and mortality post-CHD surgeries in LMICs.¹⁶ Adapting a similar methodology, we demonstrated the utility of such an approach in addressing underlying factors contributing to high radiation exposure during CCTA at our center.

The new-generation 256- to 640-detector CT scanners have approximately 0.3-second rotation times and allow for a radiation exposure 50%–70% less than the 64-detector CT scanners.^{12,13,17,18} As demonstrated by our findings, just acquiring the technology was not enough to reduce reduction. Our center possessed the 320-detector CT scanner for 2 years before the initiation of this quality improvement initiative. During these 2 years, we exposed children to similar doses of radiation when compared with before our acquisition of these scanners. This observation should signal to institutions in LMIC with limited resources that solely rely on the acquisition of new technology does not guarantee improved outcomes. Introducing established technology to a new environment like a developing country, otherwise known as contextually new technology, requires regulation, surveillance, and other special considerations. Capacity development and education of technologists are key to the safe and effective use of CT scanners in the pediatric population.^{19,20}

Additionally, establishing protocols specific to pediatric patients who utilized the technical innovation to address the specific clinical question had far-reaching positive impacts. (Details of Protocols in Appendix A, **Supplemental Digital Content** <http://links.lww.com/PQ9/A85>). Studies have shown that a significant proportion of institutions in LMIC use the same protocol and radiation exposure for both adult and pediatric patients.⁷ As previously shown,²⁰ educating physicians and technicians regarding pediatric-specific protocols helped decrease radiation exposure. These protocols involve prospective electrocardiogram (ECG) gating,²¹ use of volume scan versus helical modes,²² reduction in tube current and voltage,^{23,24} and using appropriate scan lengths.²⁵ An appropriately generated requisition addressing specific clinical question and indication for CCTA helped in communication.²⁶

Limitations

The postintervention period was short and comparing data to a much longer preintervention period may create a selection bias. Thus, the generalizability of these findings to a long-term sustainable outcome is not possible. We hope that introducing radiation dosing as a key point indicator for CCTA will help with the sustainability of this initiative. The 640-detector scanner is an advanced piece of equipment that may not be available in many

Table 3. Estimated Associations Between Radiation Exposure (Millisieverts) and Patient Characteristics and Initial Diagnosis (Model A), Organizational Factors (Model B), and Technical Factors (Model C)

	Model A		Model B		Model C	
	Coefficient (95% CI)	P	Coefficient (95% CI)	P	Coefficient (95% CI)	P
Time (reference: September 2012 to June 2014)						
July 2014 to December 2016	2.3 (−3.1 to 7.7)	0.389	—	—	—	—
January 2017 to July 2017	−16 (−20.8 to −11.2)	<0.0001	—	—	—	—
Age	0.1 (−0.1 to 0.4)	0.213	0.2 (−0.04 to 0.4)	0.115	0.1 (−0.11 to 0.4)	0.286
Sex (reference: male)						
Female	0.4 (−2.9 to 3.8)	0.812	−0.4 (−4.1 to 3.3)	0.823	−0.5 (−3.5 to 2.5)	0.746
Diagnosis						
TOF	−3.1 (−6.7 to 0.6)	0.103	−4.7 (−8.6 to −0.8)	0.018	−3.4 (−6.7 to −0.1)	0.043
CoA	0.9 (−6.4 to 8.2)	0.803	−0.7 (−7.9 to 6.5)	0.842	1.7 (−4.8 to 8.1)	0.612
TGA	9.6 (−0.6 to 19.9)	0.065	12.2 (2.9–21.4)	0.01	11.3 (3.9–18.8)	0.003
Complex CHD	−2.6 (−7.7 to 2.5)	0.308	−0.8 (−5.9 to 4.4)	0.773	−3 (−8.2 to 2.2)	0.263
Indication of request slip (reference: no indication)						
Complete	—	—	−16.4 (−22.9 to −9.8)	<0.0001	—	—
Incomplete	—	—	−13.6 (−20.3 to −6.9)	<0.0001	—	—
Sedation status during scan (reference: not sedated)						
Fully sedated	—	—	−2.9 (−17.1 to 11.1)	0.677	—	—
Partially sedated	—	—	−10.9 (−24.1 to 2.3)	0.105	—	—
Time of scan (reference: night)						
Morning	—	—	−2.1 (−9.5 to 5.3)	0.58	—	—
Evening	—	—	1.7 (−6.1 to 9.5)	0.667	—	—
Technologist level (reference: junior)						
Senior	—	—	−11.1 (−15.8 to −6.2)	<0.0001	—	—
Volume (reference: helical)						
Volumetric	—	—	—	—	−3.6 (−6.6 to −0.5)	0.022
Kilovolts (reference: 8–100)						
120	—	—	—	—	5.4 (2.3–8.8)	0.002
Protocol (reference: nonstandard)						
Standard	—	—	—	—	−7.7 (−12.9 to −2.6)	0.003
Scan length (reference: unlimited)						
Focused and standard	—	—	—	—	−6.9 (−11.2 to −2.7)	0.001
Arterial and venous phase (reference: single)						
Double	—	—	—	—	−3.4 (−7.7 to 0.9)	0.123
CT scanner (reference: 64 slice)						
640 slice	—	—	—	—	−15.9 (−21.9 to −10)	<0.0001
N	236	—	236	—	236	—
Explanatory value R ²	32.5	—	32.3	—	48.6	—

CI indicates confidence interval.

LMIC hospitals. As demonstrated by our results, these centers can target other key drivers primarily affecting communication and education to reduce radiation exposure in children undergoing CCTA. Such interventions have implementation resource requirements and can lead to a significant improvement in service delivery. Although we reported diagnostic errors as a surrogate to assess changes in image quality, we did not perform exact image quality measurement parameters, such as measuring noise as the SD of Hounsfield units. Diagnostic accuracy statistics were also not performed because the gold standard (surgical confirmation) was not available in all patients.

CONCLUSIONS

Significant reduction in radiation doses during CCTA can be achieved using a simple, practical, and low resource key driver quality initiative approach.

ACKNOWLEDGMENTS

The authors recognize the study coordinators and personnel who have made this project possible: Ms. Jessica Morrison, Ms. Sonia Qureshi, and Ms. Sana Noorani.

DISCLOSURE

The authors have no financial interest to declare in relation to the content of this article.

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