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RADIATION SAFETY

Radiation Dose Benchmarks During Cardiac Catheterization for Congenital Heart Disease in the United States

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ABSTRACT

OBJECTIVES The aim of this study was to define age-stratified, procedure-specific benchmark radiation dose levels during interventional catheterization for congenital heart disease.

BACKGROUND There is a paucity of published literature with regard to radiation dose levels during catheterization for congenital heart disease. Obtaining benchmark radiation data is essential for assessing the impact of quality improvement initiatives for radiation safety.

METHODS Data were obtained retrospectively from 7 laboratories participating in the Congenital Cardiac Catheterization Project on Outcomes collaborative. Total air kerma, dose area product, and total fluoroscopy time were obtained for the following procedures: 1) patent ductus arteriosus closure; 2) atrial septal defect closure; 3) pulmonary valvuloplasty; 4) aortic valvuloplasty; 5) treatment of coarctation of aorta; and 6) transcatheter pulmonary valve placement.

RESULTS Between January 2009 and July 2013, 2,713 cases were identified. Radiation dose benchmarks are presented including median, 75th percentile, and 95th percentile. Radiation doses varied widely between age groups and procedure types. Radiation exposure was lowest in patent ductus arteriosus closure and highest in transcatheter pulmonary valve placement. Total fluoroscopy time was a poor marker of radiation exposure and did not correlate well with total air kerma and dose area product.

CONCLUSIONS This study presents age-stratified radiation dose values for 6 common congenital heart interventional catheterization procedures. Fluoroscopy time alone is not an adequate measure for monitoring radiation exposure. These values will be used as baseline for measuring the effectiveness of future quality improvement activities by the Congenital Cardiac Catheterization Project on Outcomes collaborative. (J Am Coll Cardiol Intv 2014;7:1060–9)

A majority of cardiac catheterizations for congenital heart disease (CHD) are performed in children and adolescents who are at a higher risk of long-term adverse effects of radiation (1–3). Over the past 3 decades, a heightened awareness to minimize radiation during all radiological

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studies in children and substantial technical advancements in catheterization equipment have led to relatively lower radiation doses (4). However, over the same period, the complexity and relative number of interventional transcatheter procedures have increased (5–8). Although reference levels for radiation exposure have been widely used outside of pediatric cardiology, limited data are available with regard to radiation exposure in patients with CHD undergoing catheterization and interventions (9–16).

Obtaining benchmark radiation exposure data for congenital cardiac catheterization is challenging due to the wide variation in procedure complexity, which is affected by underlying pathology as well as the type and quality of previously obtained imaging. Varying age, size, equipment specifications, and performer skills add to this heterogeneity. Establishing baseline values is important for assessing the impact of quality measures being undertaken to minimize exposure as well as for intra- and interfacility comparisons. The Quality Metrics Working Group of the American College of Cardiology (ACC) has endorsed a dose metric for CHD catheterizations defined as the proportion of patients who receive radiation doses higher than 95th percentile of a pre-defined dataset (17). Application of this metric has been impeded by a paucity of published radiation data for congenital cardiac catheterization procedures.

The goal of the present study was to analyze radiation exposure for 6 common interventional procedures using the Congenital Cardiac Catheterization Project on Outcomes (C3PO) database. The C3PO collaborative multicenter group was founded in 2006 to better understand case-mix variation and to develop outcome measures for patients undergoing catheterization for CHD (18). The collaborative currently has 15 participating institutions and has initiated a quality improvement (QI) (C3POQI) project with the primary aim of reducing radiation exposure. We aimed to define initial benchmark radiation dose values for C3POQI that will be reassessed biannually (**Figure 1**). With QI initiatives, we expect these benchmark values to decrease over time. The results of the present study will allow application of the ACC-endorsed dose metric and will provide data to assess improvements in the future.

METHODS

All 15 participating centers in the C3PO collaborative were invited to contribute radiation dose data for the following 6 interventions: 1) patent ductus arteriosus (PDA) closure; 2) atrial septal defect (ASD) closure; 3) pulmonary valvuloplasty; 4) aortic valvuloplasty; 5) treatment of coarctation of the aorta; and 6) transcatheter pulmonary valve (TPV) placement. Seven of the 15 centers were able to retrospectively retrieve total fluoroscopy time and dose area product (DAP), and only 5 centers were able to retrieve total air kerma ($K_{a,r}$). Although most modern equipment is capable of reporting delivered dose at the time of the study, in most instances, the values must be recorded in a database or patient report at the time of the study. Unless recorded at the time of the study, these cannot be retrieved retrospectively. Centers that were unable to provide data were those that did not routinely record or report radiation doses during the study period. Technical data about the equipment and procedure were obtained and included the year of purchase of the equipment, equipment vendor, availability and use of the "store fluoro" feature ("store fluoro" is a feature/button on catheterization equipment. Hitting the button stores a fluoroscopic image that otherwise would have been discarded by the system. This feature is often ignored leading to more radiation exposure.), use of digital subtraction angiography, use of antiscatter grid, and use of copper filtration.

The cited procedures are typically performed as isolated cases and were selected to represent a relatively homogeneous case mix. The 5 procedures other than TPV placement are also captured in the IMPACT (Improving Pediatric and Adult Congenital Treatments) registry; however, these data have not been published (19). Procedures performed between January 2009 and July 2013 were included with 1 exception. The Medtronic Melody transcatheter pulmonary valve was approved for use in the United States in January 2010. To account for performer learning curve, data collection for this lesion was commenced in January 2011. Approval was obtained from either institutional review boards or quality improvement committees of the participating centers.

Patients were stratified by age and intervention type. Five age groups were defined based on previous publications to facilitate comparisons (younger than 1 year of age, 1 to 4 years of age, 5 to 9 years of age, 10 to 15 years of age, and older than 15 years of age) (20,21). Although different centers varied with regard to imaging equipment, radiation doses were calculated automatically according to standard existing federal laws. The following variables were analyzed. 1) Total air $K_{a,r}$ expressed in mGy and estimated as the sum of radiation doses in anteroposterior and lateral

ABBREVIATIONS AND ACRONYMS

ACC = American College of Cardiology

ASD = atrial septal defect

CHD = congenital heart disease

C3PO = Congenital Cardiac Catheterization Project on Outcomes

DAP = dose area product

$K_{a,r}$ = total air kerma

PCI = percutaneous coronary intervention

PDA = patent ductus arteriosus

QI = quality improvement

TPV = transcatheter pulmonary valve