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ORIGINAL RESEARCH

CONGENITAL HEART DISEASE

Congenital Cardiac Catheterization in Low- and Middle-Income Countries

The International Quality Improvement Collaborative Catheterization Registry

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ABSTRACT

BACKGROUND No published data are available on the patient, procedural characteristics, and outcomes of congenital heart disease (CHD) cardiac catheterization performed in low- and middle-income countries (LMICs).

OBJECTIVES The objective of this study was to describe procedural characteristics and patient outcomes of CHD cardiac catheterizations in LMICs.

METHODS Cases performed between January 2019 and December 2020 from 15 centers in the International Quality Improvement Collaborative Congenital Heart Disease Catheterization Registry (IQIC-CHDCR) data were included. The Procedural Risk in Congenital Cardiac Catheterization (PREDIC3T) classification was used to stratify risk. Outcomes of interest included mortality, severe adverse events (SAEs), and procedural efficacy. Procedural efficacy, based on technical and safety endpoints, was categorized into optimal, adequate, and inadequate for 5 common interventional procedures.

RESULTS There were 3,287 cases, of which 60% (n = 1,973) were interventional cases. Most of the cases (66%) were in patients between the ages of 1 to 18 years with a median patient age of 4 years. PREDIC3T risk class 1 and 2 were most common in 37% and 38% of cases, respectively. SAEs occurred in 2.8% while the death was reported within <72 hours post catheterization 1%. The majority of device implantation procedures patent ductus arteriosus (67%) and atrial septal defect (60%) had optimal procedure efficacy outcomes.

CONCLUSIONS This study demonstrates that congenital cardiac catheterization is safely performed in LMICs. Future work addressing predictors of SAEs and adverse procedural outcomes may help future quality improvement initiatives. (JACC Adv 2023;2:100344) © 2023 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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ABBREVIATIONS AND ACRONYMS

AE = adverse event

ASD = atrial septal defect

BCH = Boston Children's Hospital

C3PO = Congenital Cardiac Catheterization Project on Outcomes

CHARM II = Catheterization for Congenital Heart Disease Adjustment for Risk Method II

CHD = congenital heart disease

DAP = dose area product

HIC = high-income country

HSAE = high severe adverse event

HVS = hemodynamic vulnerability score

IQIC-CHDCR = International Quality Improvement Collaborative Congenital Heart Disease Catheterization Registry

LMIC = low- and middle-income country

PDA = patent ductus arteriosus

PREDIC3T = Procedural Risk in Congenital Cardiac Catheterization

QI = quality improvement

REC = radiation exposure category

SAE = severe adverse event

The prevalence of congenital heart disease (CHD) is estimated to be approximately 1.8 cases per 100 live births.[1] Rapidly evolving technologies, increased resource availability, and focus on quality improvement (QI), including in congenital cardiac catheterization, have contributed to the overall decline in the annual mortality of CHD.[2-6] Several registries that collect audited data have been established in the United States and have enabled the development of risk adjustment methodologies, benchmarking, and subsequently collaborative QI initiatives.[7-9] However, the prevalence of CHD mortality in the first year of life is markedly different in low sociodemographic index countries as compared to higher sociodemographic index countries.[1] Previously, no such registries have existed for congenital cardiac catheterization in low- and middle-income countries (LMICs), limiting insights into patient and procedural characteristics and outcomes specific to LMICs.

The International Quality Improvement Collaborative (IQIC) has been collecting CHD surgical data from LMICs since 2007 to benchmark outcomes and promote collaborative QI efforts.[10-12] More than 80 sites have participated and involvement has been associated with improvement in morbidity and mortality following CHD surgery.[13] Leveraging these successes, the IQIC-Congenital Heart Disease Catheterization Registry (IQIC-CHDCR) was piloted in 2017 at 7 participating surgical sites with catheterization programs.[14] Feedback from the pilot phase was used to improve the database with the primary objective of harmonizing data elements with the U.S.-based Congenital Cardiac Catheterization Project on Outcomes (C3PO) registry prior to the beginning of open enrollment for IQIC-CHDCR in 2019.[14] This study aims to describe the patient and procedural characteristics and outcomes of CHD cardiac catheterization in LMICs using the audited, cumulative data from the IQIC-CHDCR registry.

METHODS

Participation in IQIC-CHDCR is open to any congenital cardiac catheterization site in an LMIC during the annual enrollment period. IQIC-CHDCR launched with 10 sites in 2019, with an additional 5 sites joining in 2020. The web-based data entry platform was sponsored by Boston Children's Hospital (BCH), U.S., and this study was approved by the BCH Institutional Review Board and supported by data-sharing agreements between BCH and the participating sites as required. All pediatric cardiac catheterizations from January 1, 2019, to December 31, 2020, were included. Only sites that participated and met passing criteria for data completion and accuracy in annual audits were included in the final data set.

DATA VERIFICATION. All sites underwent data audits to confirm complete case capture and 10% or minimum of 20 cases were randomly selected for each site to verify key data elements. Key data elements were determined by experts Kimberlee Gauvreau and Lisa Bergersen for fields related to patient outcomes including age, procedure type, hemodynamic values, description of any adverse events (AEs), total dose area product (DAP) in micro gray times meters square, procedural airway management and sedation types, and death within 72 hours, and, when applicable, procedural efficacy data. Audits were conducted via Zoom videoconferencing and data were compared to the original hospital records.

DATA ELEMENTS. Patient characteristics. Patient demographic variables included age (days, months, or years) and weight (kg) at catheterization, presence of any known or suspected genetic syndrome (yes/no), and any noncardiac comorbidities (coagulation disorder, chronic lung disease, renal insufficiency, or other). Cardiac data collected included single- or biventricle physiology at the time of cath and preprocedure cardiac status category 1 to 3 (Supplemental Table 2).[15,16]

Procedure characteristics. Procedure characteristics included any interventions performed which were used to classify cases as diagnostic only or interventional and to summarize cases by Procedural Risk in Congenital Cardiac Catheterization (PREDIC3T) case type (Supplemental Table 3).[17] Measured hemodynamic elements were recorded as normal or abnormal according to threshold values for single- or biventricle physiology and used to calculate a hemodynamic vulnerability score (HVS) (Supplemental Table 4).[17,18] Procedural clinical resources including highest level of sedation, airway support, and ventilation were collected along with any use of intravenous medications, cardiac mechanical support, drains, and the presence of a central or arterial line. Procedure duration was defined as minutes from first sheath-in to last sheath-out. Radiation data included total fluoroscopy time in minutes and the total DAP in

TABLE 1 Procedural Efficacy Classification

	Class I/Optimal (Must Have All Criteria Below)	Class II/Adequate (Criteria Not Met for Optimal or Inadequate)	Class III/Inadequate (If Any of the Criteria Below)
Aortic valvuloplasty	PSEG <35 mm Hg No new AR Most severe AE level 1	PSEG 35-49 mm Hg New mild aortic regurgitation Most severe AE level 2-3	PSEG ≥50 mm Hg New moderate to severe aortic regurgitation Most severe AE 4-5
Pulmonary valvuloplasty	PSEG <30 mm Hg No new pulmonary regurgitation No new tricuspid regurgitation No MPA/RVOT tear Elective home discharge Most severe AE level 1	New mild pulmonary regurgitation MPA tear not requiring intervention Most severe AE level 2-3	PSEG ≥30 mm Hg New moderate-severe pulmonary regurgitation New tricuspid valve regurgitation MPA/RVOT tear requiring intervention Most severe AE 4-5
ASD device closure	Residual shunt size none No new MV insufficiency Elective home discharge Most severe AE level 1	Residual shunt mild	Residual shunt moderate-severe New MV insufficiency Most severe AE level 4-5
PDA device closure	Residual shunt none No new LPA stenosis No arch obstruction No hemolysis Elective home discharge Most severe AE level 1	Most severe AE level 2-3	Residual shunt moderate-severe New LPA stenosis Arch obstruction Hemolysis Device removed from body and no new device placed Most severe AE level 4-5
Coarctation of aorta stent	Gradient <20 mm Hg No aneurysm No stent migration No vessel jailing	Most severe AE level 2-3	Gradient >30 mm Hg Aneurysm Stent migration requiring intervention Vessel jailing requiring reintervention Most severe AE level 4-5

AE = adverse event; ASD = atrial septal defect; LPA = left pulmonary artery; MPA = main pulmonary artery; PDA = patent ductus arteriosus; PSEG = peak end-systolic gradient; RVOT = right ventricular outflow track.

micro gray times meters square were collected for each case. The presence of any AE and a detailed narrative was also recorded.

Procedure specific variables. Additional data were collected for 5 common isolated procedures: aortic valvuloplasty, pulmonary valvuloplasty, atrial septal defect (ASD) device closure, patent ductus arteriosus (PDA) device closure, and aortic coarctation procedures in accordance with previous publications from the IQIC-CHDCR pilot study (Table 1).[14]

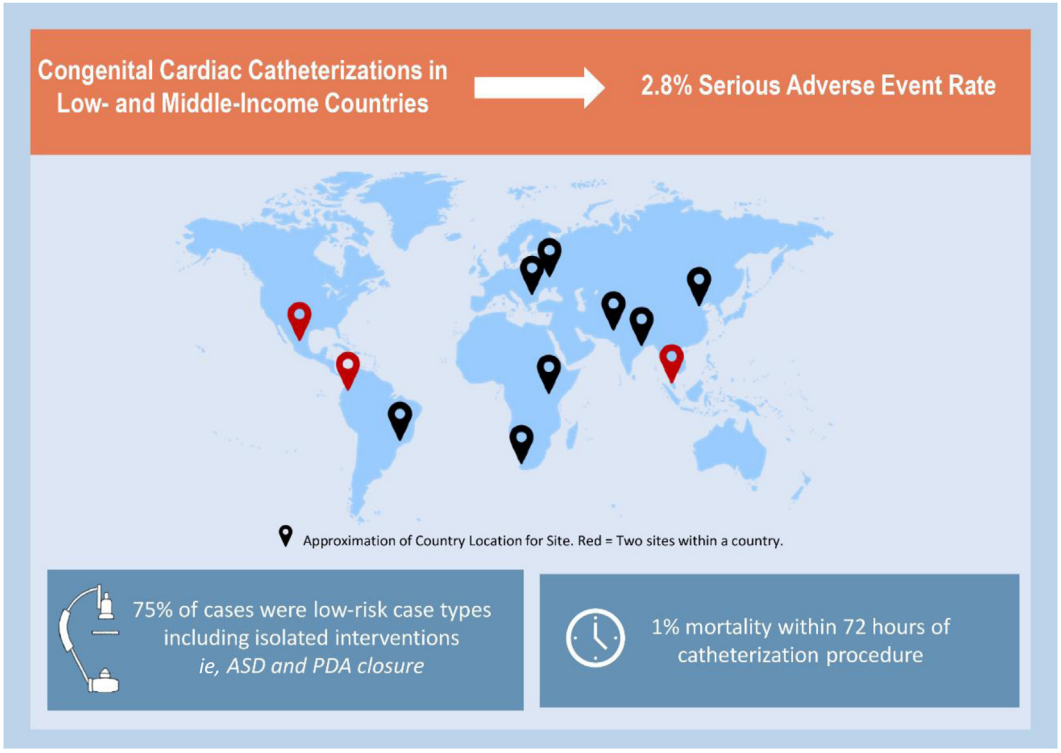
Episode of care. Episode of care characteristics included whether the procedure was considered an elective procedure, whether the patient was admitted >48 hours precath, discharged >48 hours postcath, required an unplanned hospital stay postcath, required a blood transfusion <72 hours post-procedure, or died <72 hours postcath. In addition, the patient location (outpatient, general floor, step-down unit, or intensive care unit) and nursing ratio 6 hours postprocedure were collected.

TABLE 2 Definitions for Adverse Event Severity

Severity Level	Definition	Examples
3-moderate	Transient change in condition may be life-threatening if not treated, condition returns to baseline, required monitoring, required intervention such as reversal agent, additional medication, transfer to the intensive care unit for monitoring, or moderate transcatheter intervention to correct condition.	• Unstable arrhythmia with preserved blood pressure requiring intervention • Vascular damage not life-threatening but requiring intervention • Non-life-threatening arrhythmia requiring intervention
4-major	Change in condition, life-threatening if not treated, change in condition may be permanent, may have required an intensive care unit admission or emergent readmit to hospital, may have required invasive monitoring, required interventions such as electrical cardioversion for life-threatening arrhythmia or unanticipated intubation or required major invasive procedures or transcatheter interventions to correct condition.	• Event requiring cardiopulmonary resuscitation • Event leading to surgery or repeat catheterization • Stroke • ECMO cannulation with subsequent weaning from ECMO
5-catastrophic	Any death. This may include emergent surgery or heart lung bypass support (ECMO) to prevent death with failure to wean from bypass support, if these measures were ultimately unable to prevent death.	• Event resulting in death

ECMO = extracorporeal membrane oxygenation.

CENTRAL ILLUSTRATION **IQIC Catheterization Registry Participating Sites and Cumulative outcomes**



Ali F, et al. JACC Adv. 2023;2(4):100344.

ASD = atrial septal defect; PDA = patent ductus arteriosus.

PATIENT OUTCOMES. Radiation exposure. Total DAP was indexed to weight (DAP/kg) and calculated as a reliable surrogate for radiation exposure, as it accounts for the variability in dose seen among cases of varying patient sizes. In addition, cases were categorized into radiation exposure categories (RECs) by case type based as defined in previous work[19-21] (Supplemental Table 5).

Procedural efficacy. Procedure specific data for 5 common isolated procedures were used to determine procedural efficacy classification (Class I/optimal, Class II/adequate, and Class III/inadequate), which incorporated technical success with procedure-related AEs, as previously developed during the pilot phase of IQIC-CHDCR (Table 1).[14]

Mortality. Mortality was defined as a death during the procedure or within 72 hours postprocedure.

Adverse event. AEs were defined as any predicted or unpredicted event, for which preventable injury could have happened, or did occur, possibly or certainly as a consequence of performing the catheterization. Based on the seriousness of harm caused by the AE, it was categorized into 5 levels of severity, as previously described (Table 2).[18] AE levels 3 to 5 were considered as severe AEs (SAEs) and 4 and 5 were labeled as high severity AEs (HSAEs). AE classification and severity scoring were independently reviewed and for accuracy and consistency.

STATISTICAL ANALYSIS. Categorical variables were described using frequencies and percentages and continuous variables using median (IQR). As no risk adjustment model is available for LMICs, the CHARM II (Catheterization for Congenital Heart Disease Adjustment for Risk Method II) model, developed using the C3PO database and incorporates PREDIC3T case type risk category, age in categories and HVS, was used to determine the expected AE rate for the entire cohort.[17] Standardized AE ratios for any level 3/4/5 AE and any level 4/5 AE were then calculated by dividing the observed AE rate within each institution by the expected AE rate accounting for the cohort's case mix.

TABLE 3 Cohort Characteristics (N = 3,287)

Patient characteristics	
Age (y)	4 (1-10)
≤30 d	188 (6%)
31 d to <1 y	622 (19%)
1-18 y	2,153 (66%)
≥19 y	324 (10%)
Weight (kg)	15 (8-29)
Weight <3 kg	70 (2%)
Sex male	1,559 (47%)
Single ventricle (n = 3,286)	470 (14%)
Genetic syndrome	211 (6%)
Any noncardiac problem	144 (4%)
Coagulation disorder	2 (<1%)
Chronic lung disease	22 (1%)
Renal insufficiency	3 (<1%)
Other	117 (4%)
Preprocedure cardiac status	
Biventricle patients (n = 2,804)	
1	1,736 (62%)
2	612 (22%)
3	456 (16%)
Single-ventricle patients (n = 468)	
1	161 (34%)
2	197 (42%)
3	110 (24%)
Procedure characteristics	
Diagnostic	1,314 (40%)
Interventional	1,973 (60%)
PREDIC3T risk category	
1	1,214 (37%)
2	1,243 (38%)
3	385 (12%)
4	208 (6%)
5	152 (5%)
Not assigned	85 (3%)
Hemodynamic vulnerability score (n = 3,281)	
0	1,571 (48%)
1	896 (27%)
2	382 (12%)
≥3	432 (13%)
Case duration (n = 3,205)	
Case duration (h)	0.9 (0.6-1.3)
Case duration category	
<1 h	1,768 (55%)
1-2 h	1,224 (38%)
2-3 h	186 (6%)
≥3 h	27 (1%)
Clinical management	
Sedation	
General anesthesia	2,481 (75%)
Intravenous sedation	679 (21%)
None or local/oral	127 (4%)
Airway management	
ETT or tracheostomy	2,295 (70%)
Airway support (no ETT)	210 (6%)
Natural airway	782 (24%)
Ventilation (n = 3,273)	
Room air only	1,634 (50%)
Supplemental oxygen	1,602 (49%)
Any nitric oxide^	37 (1%)
IV medications	
Vasoactive - supportive	114 (3%)
Vasoactive - essential	22 (1%)
Antiarrhythmic	8 (<1%)
PGE	22 (1%)
Other continuous medications	124 (4%)
Any cardiac mechanical support	18 (1%)
Any drains	40 (1%)
Central venous or arterial line present	
Episode of care	
Admission	
Elective	3,070 (93%)
Admit >48 h prior to cath	447 (14%)
Postprocedure	
Blood transfusion <72 h after cath	74 (2%)
Discharge >48 h postcath	765 (23%)
Unplanned hospitalization postcath	187 (6%)
Death <72 h post-cath	34 (1.0%)

Values are median (IQR) or n (%).
ETT = endotracheal tube; PGE = prostaglandin E.

Continued in the next column

RESULTS

A total of 15 centers from 12 countries (**Central Illustration**, Supplemental Table 1) entered 3,287 congenital cardiac catheterization cases that met the eligibility criteria from January 1, 2019, to December 31, 2020.

COHORT CHARACTERISTICS. The median patient age at catheterization was 4 years (**Table 3**). A total of 470 (14%) patients had single-ventricle physiology, 211 (6%) had a suspected or confirmed genetic syndrome, and 144 (4%) had a reported noncardiac problem. Most patients with biventricle physiology had a preprocedure cardiac status of 1 (n = 1,736, 62%), while most with single-ventricle physiology patients had a preprocedure cardiac status of 2 (n = 197, 42%).

Procedures were performed in 1,973 (60%) of cases, with the remaining cases serving as diagnostic only (**Table 3**). Most cases were categorized as PREDIC3T category 1 or 2 (n = 1,222 and n = 1,235, respectively) and had a hemodynamic score of 0 (n = 1,571, 48%). Diagnostic catheterizations in patients 1 to 18 years accounted for 32% (n = 1,056) of the cohort (**Table 4**). The most common interventions were PDA device

TABLE 4 Adverse Events by Case Type

	N (%)[a]	Level 3 AE 59 (1.8%)	Level 4 AE 26 (0.8%)	Level 5 AE 8 (0.2%)	Death <72 h 34 (1%)
Category 1					
Pulmonary valvotomy ± procedure, age >30 d	166 (5%)	5	0	0	2
Diagnostic case, age 1-18 y	1,056 (32%)	12	6	1	10
Category 2					
ASD or PFO device closure	343 (10%)	3	3	0	0
Venous collateral device or coil occlusion ± procedure	19 (1%)	0	0	0	0
PDA device or coil closure ± procedure	654 (20%)	8	3	1	0
Fontan fenestration or baffle leak device closure	4 (<1%)	0	0	0	0
Diagnostic case, age >30 d to <1 y	215 (7%)	13	3	1	4
Category 3					
Pulmonary artery (only 1 vessel)	76 (2%)	0	1	1	2
Fontan fenestration or baffle leak device closure + procedure	1 (<1%)	0	0	0	0
Aorta (coarctation) dilation and/or stent	114 (3%)	0	1	0	0
Systemic pulmonary collateral device or coil closure ± procedure	88 (3%)	1	0	0	1
Pulmonary valvotomy ± procedure	25 (1%)	0	0	0	1
RVOT conduit dilation and/or stent + PA (1)	1 (<1%)	0	0	0	0
Atrial septostomy	37 (1%)	1	0	0	0
Diagnostic case, age ≤30 d	43 (1%)	1	1	0	0
Category 4					
Pulmonary artery (only 1 vessel) + procedure	8 (<1%)	0	0	0	0
ASD or PFO device closure + procedure	8 (<1%)	0	0	0	0
Pulmonary vein dilation and/or stent ± procedure	6 (<1%)	0	0	0	0
Pulmonary artery (≥2 vessels) ± procedure	28 (1%)	0	1	0	0
RVOT conduit/no conduit dilation and/or stent ± procedure	32 (1%)	0	0	0	1
PDA dilation and/or stent ± procedure	126 (4%)	11	1	9	9
Category 5					
Aorta (coarctation) dilation and/or stent + procedure	3 (<1%)	0	1	0	0
Aortic valvotomy ± procedure age >30 d	32 (1%)	0	1	0	1
Pulmonary artery (≥2 vessels) ± procedure	2 (<1%)	0	0	1	1
Aortic valvotomy age ≤30 d ± procedure	11 (<1%)	0	0	1	0
VSD device closure + procedure	85 (3%)	0	0	0	0
Mitral valvotomy ± procedure	2 (<1%)	0	0	0	0
Atrial septostomy + procedure	2 (<1%)	0	0	0	0
TPV implantation ± procedure	6 (<1%)	0	0	0	0
Atrial septum static dilation and/or stent placement	3 (<1%)	0	0	0	0
Atretic valve perforation and/or valvotomy ± procedure	6 (<1%)	2	0	0	1
Not assigned	85 (3%)	2	4	1	1

Total number of cases as numerator = 3287. [a]Percentages are calculated by using total number of cases as denominator and fraction as numerator.

ASD = atrial septal defect; PA = pulmonary artery; PDA = patent ductus arteriosus; PFO = patent foramen ovale; RVOT = right ventricular outflow track; TPV = transpulmonary valve; VSD = ventricular septal defect.

closure (n = 654) and ASD device closure (n = 343) (Table 4). Most cases (55%) lasted <1 hour, with a median case duration of 0.9 hours. Half of all cases did not utilize supplemental oxygen or nitric oxide (n = 1,634, 50%) and <5% of cases utilized any intravenous medications, cardiac mechanical support, or drains (Table 3). Most patients were considered elective cases (n = 3,070, 93%) and were discharged within 48 hours after their procedure (n = 2,522, 77%).

RADIATION OUTCOMES. Radiation data were available for 2,550 (77.6%) procedures. Cases were classified as REC 1 in 2,855 (87%) patients (Table 5). For patients with available radiation data, the median radiation exposure for REC 1 was 17 DAP/kg (IQR: 8-37) (n = 2,232) (Table 5).

PROCEDURAL OUTCOMES. In those cases where variables of procedural efficacy were recorded, it was optimal in 10 (67%) isolated aortic valvuloplasty cases, 32 (32%) isolated pulmonary valvuloplasty cases, 124 (67%) isolated ASD device closures, 159 (60%) isolated PDA device closures, and 5 (21%) coarctation procedures. Pulmonary valvuloplasty was considered inadequate in 27 (27%) of cases, with all other procedure types reporting inadequacy levels below 15% (Table 6, Figure 1). The primary cause for

inadequate pulmonary valvuloplasty outcomes was a postprocedure pulmonary valve gradient of ≥30 mm Hg (n = 23).

PATIENT OUTCOMES AND ANALYSES. A total of 34 (1%) patients died within 72 hours of the catheterization procedure. The frequency of death increased among higher PREDIC3T case types with highest mortality seen in PREDIC3T 4% to 4.8% (n = 10). Among those who died, 10 (29%) were diagnostic cases performed on patients 1 to 18 years of age and 9 (26%) were PDA dilation and/or stent procedures. Eight deaths were attributed to an AE.

Overall, 93 (2.8%) cases had any SAEs and 34 (1.0%) had a level HSAE. When stratified by PREDIC3T category, HSAE was observed in 0.6% of category 1 (n = 1,214), 0.9% of category 2 (n = 1,243), 1% of category 3 (n = 385), 1.4% of category 4 (n = 208), and 2.6% of category 5 (n = 152) cases (Figure 2). When using the CHARM II model developed by C3PO, the standardized AE ratio was 0.60 for SAEs and 0.72 for HSAEs. Predominant causes of AEs were catheterization related in 31% (n = 20) and sedation and airway related in 28% (n = 18) of cases.

TABLE 5 Radiation Exposure

Radiation Exposure Category[a]	Total Cases (N = 3,287)	Cases With Radiation Data	Median Dose Area Product/kg and (μGy/m²/kg)
1	2,855 (87%)	2,232 (78.2%)	17 (8–37)
2	359 (11%)	261 (72.7%)	37 (18–87)
3	63 (2%)	57 (90.5%)	67 (39–146)

Values are n (%) or median (IQR) unless otherwise indicated. [a]Radiation data were missing in 22% cases.

DISCUSSION

Using multicenter data from an international registry, this is the first study examining congenital catheterization procedures and outcomes from LMICs centers. The majority of catheterization procedures were low-risk elective cases in patients older than 1 year of age without comorbidities. Device closures (PDA and ASD) were the most commonly performed interventions.

Low rates of SAE and HSAEs (2.8% and 1%, respectively) and a mortality of 1% demonstrate that cardiac catheterization in CHD patients was performed safely in these centers. This was comparable to AE frequency reported in some U.S.-based registries.[22,23] AEs were attributed predominantly to catheterization-related followed by sedation-related problems. Sedation-related airway issues reported in our registry were higher compared to one of the U.S.-based multicenter reports which showed 1.83% sedation- or airway-related AEs of which only 0.69% events were categorized as HSAE.[24] This study identified a weight <4 kg, low mixed venous saturations, and noncardiac comorbidities as predictors of HSAE. Given the high frequency of sedation-related AE, efforts to identify such risk factors will help design risk mitigation strategies in congenital cardiac catheterization laboratories in LMICs.

The IQIC-CHDCR cohort had a higher overall mortality than some U.S. centers which reported a mortality of 0.23%[25] and 0.29%.[23] Procedures that carried the highest mortality were atretic pulmonary valve perforation 1/6 cases and PDA stenting or dilation 9/126 cases (Table 4). Failure to rescue after a complication, especially in such procedures, may be a major cause of mortality. Lack of extracorporeal membrane oxygenation or immediate availability of surgical bailout may contribute to failure to rescue in resource-limited settings.[26] Availability of a biplane cardiac catheterization suite may also affect the outcomes and complications of such procedures. Such patients also require appropriate postprocedure management. Quality of care in the postprocedure period is a significant determinant of survival in CHD patients undergoing complex interventions.[27,28] Further work on understanding the pathway to mortality in such cases may help develop risk mitigation, efficient resource allocation, and QI strategies for such procedures. Use of precase risk prediction tools like Catheterization RISk Score for Pediatrics (CRISP), a publicly available calculator, can also assist in preprocedure planning based on US and international data. Currently, some IQIC-CHDCR participants do use this tool. Similarly, IQIC-CHDCR will be developing risk adjustment methodology and prediction tools specific for this patient population in the future. This will allow centers to anticipate patient risk of AEs and resource utilization to optimize delivery of patient care.

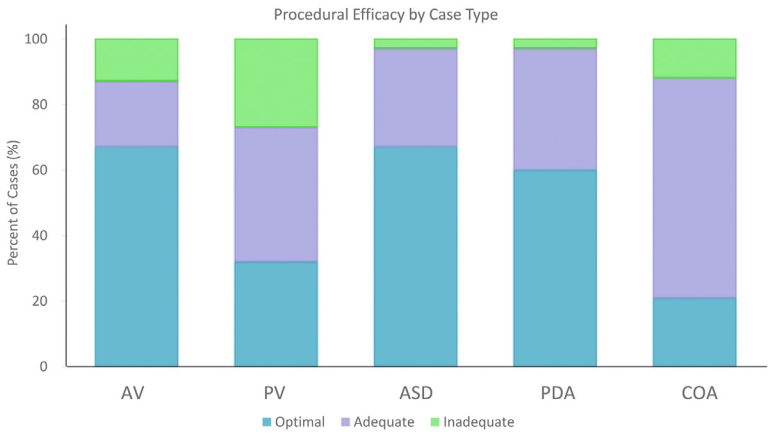
Management of patients with CHD in LMICs is affected by factors unique to that context. These

TABLE 6 Procedural Efficacy

	Valvuloplasty		Device Closure		
	Aortic (n = 15)	Pulmonary (n = 100)	Atrial Septal Defect (n = 185)	Patent Ductus Arteriosus (n = 265)	Coarctation Procedure (n = 24)
Optimal	10 (67%)	32 (32%)	124 (67%)	159 (60%)	5 (21%)
Adequate	3 (20%)	41 (41%)	56 (30%)	98 (37%)	16 (67%)
Inadequate	2 (13%)	27 (27%)	5 (3%)	8 (3%)	3 (12%)

Values are n (%).

FIGURE 1 Procedural Efficacy Stratified by Type of Procedure

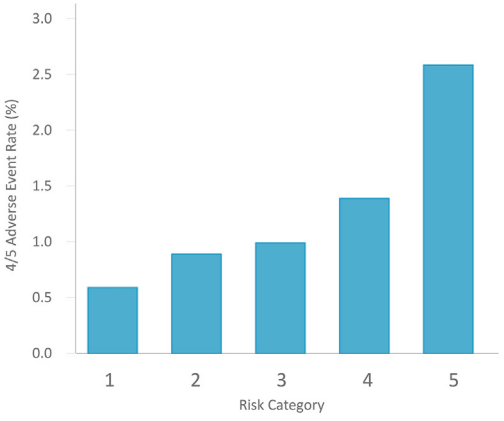


ASD = atrial septal defect; AV = aortic valvuloplasty; COA = coarctation of aorta; PDA = patent ductus arteriosus; PV = pulmonary valvuloplasty.

factors include, but are not limited to, late presentation of patients, significant malnourishment, comorbidities like infections, lack of resources to manage complex lesions (operator and/or team experience), and quality of postprocedure care. These factors can significantly affect the outcomes of cardiac catheterization in LMICs. In order to compare AE rates to benchmark outcomes across centers, it is imperative to adjust for case-mix variables. We used the CHARM II model to determine the expected HSAE for programs participating in IQIC-CHDCR. This model was developed using the C3PO database which only collected data from U.S.-based centers thus may not account for some of the patient and procedural characteristics unique to low-resource settings while standardizing for AEs. Variables that are used in the risk adjustment models may also need to be contextualized given the variation in practice for collecting diagnostic hemodynamics. Observation during the data audits of IQIC-CHDCR has shown that many of the data collected in C3PO, especially hemodynamics during interventional cases, are not gathered among some of the IQIC centers. Many factors may play into such a practice including sharing of resources with other specialties like adult interventional cardiology, interventional radiology, and vascular surgery, etc, thus limiting the time allotted to pediatric cases where the actual intervention becomes a priority above all of collecting hemodynamic data. In such a scenario, the HVS may be falsely low (not reported as abnormal since it was not collected) and therefore HVS may not be a useful tool for risk adjustment for such centers. However, preprocedural cardiac status does not require invasively collected measurements and may serve an important function in future models for international communities. IQIC-CHDCR thus provides a unique opportunity to collect reliable and audited data from LMICs and can help create risk adjustment model specific to LMICs accounting for such variation in practices and other social determinants of health.

Outcomes of intervention in patients with CHD vary among programs in LMICs.[29,30] The arbitrary definition of a cardiac program being "low resourced" is currently based on the country it is in. LMICs are defined on the basis of Gross National Income. Such a

FIGURE 2 High Severity Adverse Event Stratified According to the PREDIC3T Risk Category



4/5 Adverse Event Rates = high severe adverse event rates, PREDIC3T Risk category.[17]

definition may inappropriately label programs that are well equipped and perform complex procedures and are well equipped but reside in countries with low gross national income as being 'low' resourced. This may discourage some of these high functioning programs from joining registries specific to LMIC programs. As IQIC-CHDCR collects variables on resources available and/or utilized in cardiac catheterization, future work using these data may help better characterize (or distinguish between) a 'low' vs a 'high' resourced cardiac catheterization laboratory. Variables in IQIC-CHDCR are harmonized with the C3PO registry and share the same data entry platform as that of C3PO. This provides a unique opportunity to look at differences and similarities of data from high-income countries (HICs) and LMICs. Such a comparison may further help create a more refined definition of a 'high' vs 'low' resource laboratory. Thus a 'low resource lab' may be present in a HIC while a 'high resource lab' may reside in a LMIC. Exchange of ideas through such collaboration may help understand some disparities in CHD care and provide opportunity to create focused innovative care delivery solutions for specific labs as well as addressing health inequity in global CHD care.

The novel approach of determining procedure efficacy using technical and safety results may evolve into a composite outcome metric. Further work through the IQIC-CHDCR registry may help in testing the validity of this approach and thus explore causes of inadequate procedures outcomes, for example, residual gradients in valvuloplasty (pulmonary and aortic) and coarctation. Subsequently, context-specific QI initiatives may be developed to further improve the efficacy of these procedures.

The IQIC surgical data were established in 2007 with the goal of improving outcomes in CHD surgeries in LMICs. Adopting a key driver approach and knowledge transfer through webinars, discussion around audited reports, and mentorship of individual sites have been associated with significant improvement in morbidity (postoperative infections) and mortality in postoperative CHD patients in LMICs. Following the success of IQIC surgery, a similar collaborative was created for congenital cardiac catheterization in LMICs. We believe that providing a user-friendly no-charge platform for data entry, standardized performance reports and knowledge transfer through webinars and individual program mentorship may help overcome some of the barriers (ie, an inundated physician due to patient load, lack of funds for registry memberships, expertise in complex statistical modeling, etc) to data generation in LMICs.[31]

STUDY LIMITATIONS. This report is from the initial 15 centers which entered data in IQIC-CHDCR over a period of 2 years. These 15 centers comprise only ~21% of total IQIC centers and participation is voluntary thus limiting the generalizability of the result and inferences made for programs in LMICs. Experience from the surgical registry suggests that the enrollment will likely increase over time. Being a new registry, completion of data entry has been variable across sites. The routine collection of level 3 AEs has taken time with all new sites, as many of these events have not necessarily been viewed as AE. Therefore, there is much more variation in the reporting of level 3 events. Similarly, data on radiation dosing were missing in 22% of cases as not every center collects radiation doses mainly due to the use of older equipment in capable of displaying exact radiation dose.

CONCLUSIONS

Congenital cardiac catheterization can be safely performed in LMICs. Future work to identify predictors of SAEs and unsatisfactory procedure outcomes may help to define future QI initiatives. Learning from such efforts may also benefit centers in HIC performing with low case volume.

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PERSPECTIVES

COMPETENCY IN PATIENT CARE AND PROCEDURAL SKILLS: The report gives insight into performance of congenital cardiac catheterization laboratories in LMICs. It demonstrates the importance of tracking outcomes and being a part of a registry to benchmark one's performance and collaboratively learn to improve.

TRANSLATIONAL OUTLOOK: The generalizability of the study can get better with efforts to enroll more programs. Future work around creating risk-adjusted models specifics for programs in LMICs. Further work around understanding factors effecting AEs and procedure efficacy can help inform QI initiatives.

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APPENDIX For supplemental tables, please see the online version of this paper.