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Adverse Events Rates and Risk Factors in Adults Undergoing Cardiac Catheterization at Pediatric Hospitals—Results From the C3PO

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Objective: Determine the frequency and risk factors for adverse events (AE) for adults undergoing cardiac catheterization at pediatric hospitals. Background: Adult catheterization AE rates at pediatric hospitals are not well understood. The Congenital Cardiac Catheterization Project on Outcomes (C3PO) collects data on all catheterizations at eight pediatric institutions. Methods: Adult (≥18 years) case characteristics and AE were reviewed and compared with those of pediatric (<18 years) cases. Cases were classified into procedure risk categories from 1 to 4 based on highest risk procedure/intervention performed. AE were categorized by level of severity. Using a multivariate model for high severity AE (HSAE), standardized AE rates (SAER) were calculated by dividing the observed rates of HSAE by the expected rates. Results: 2,061 cases (15% of total) were performed on adults and 11,422 cases (85%) were performed on children. Adults less frequently underwent high-risk procedure category cases than children (19% vs. 30%). AE occurred in 10% of adult cases and 13% of pediatric cases ($P <$ 0.001). HSAE occurred in 4% of adult and 5% of pediatric cases ($P = 0.006$). Procedure-type risk category (Category 2, 3, 4 OR = 4.8, 6.0, 12.9) and systemic ventricle end diastolic pressure ≥ 18 mm Hg (OR 3.1) were associated with HSAE, *c* statistic 0.751. There were no statistically significant differences in SAER among institutions. Conclusions: Adults undergoing catheterization at pediatric hospitals encountered AE less frequently than children did. The congenital heart disease adjustment for risk method for adults with congenital heart disease is a new tool for assessing procedural risk in adult patients.

Key words: heart defects; congenital; outcome assessment; complications

INTRODUCTION

Adults receive cardiac care at pediatric hospitals for a variety of reasons. Most patients with congenital heart disease (CHD) are diagnosed in childhood. With considerable progress in medical knowledge and technology, ever-increasing numbers of these patients are surviving into adulthood [1]. Patients with CHD may choose maintain care with their childhood providers. Alternatively, some CHD lesions may not be diagnosed until late adolescence or adulthood. Regardless of the

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age at presentation, the 2008 ACC/AHA guidelines [2] recommend referring patients with moderate to severe CHD to an adult congenital heart disease (ACHD) center. In many communities within the United States, ACHD centers reside within free-standing pediatric hospitals. In addition to patients with CHD, patients with forms of inherited or acquired heart disease that initially present during childhood may maintain continuity of care with a pediatric hospital after the age of 18. Greater insight into the potential complications of treating adults with congenital or pediatric acquired heart disease may guide quality improvement and ultimately reduce future complication rates.

Although the experience of a single center can be valuable, multicenter studies allow for greater generalizability of outcomes by reducing the effect of institutional or region-specific variations in care and patient mix. Although several multi-institution registries for patients with CHD (e.g., IMPACT, MAGIC, CCISC) [3–5] are ongoing, studies specifically investigating the outcomes of adult patients undergoing cardiac catheterization at pediatric hospitals have been rare to date [6]. The Congenital Cardiac Catheterization Project on Outcomes (C3PO) collaborative multicenter group was founded in 2006 to better understand case mix variation and to develop outcome measures. The C3PO group recently developed a risk-adjusted method for calculating expected adverse event (AE) rates for all patients undergoing catheterization at pediatric heart centers [7]. In this study, we sought to explore what patient and procedural characteristics were associated with adverse outcomes in the adult population and develop a multivariate model that would allow equitable comparisons among physicians and centers treating adult patients.

METHODS

Data collection, validation, and auditing methods were previously reported [8]. In brief, data were collected prospectively at each participating site using a web-based data entry tool to record patient characteristics, procedural data, and associated AE. Data collection began at six centers and later expanded to eight. All interventional cardiologists who contributed to the data set presented in this manuscript reviewed and approved the document before peer review submission.

This study is an analysis of prospectively acquired data on all diagnostic, interventional, and biopsy cases between February 1st, 2007 and June 30th, 2010. All cases were performed by pediatric cardiologists. Patients undergoing less common procedure types such as hybrid-surgical procedures, combined electrophysiology procedures, or isolated nontrans-catheter interventions (e.g., pericardiocentesis, thoracentesis) were excluded.

Patient and Procedural Characteristics

Recorded variables include age, weight, diagnosis, presence of a genetic syndrome or comorbid noncardiac condition, history of catheterization or surgery, and any cardiac surgery within 30 days of catheterization. Indicators of hemodynamic vulnerability previously developed by C3PO [7] include cardiac index <2.8 L/min/m^2, mixed venous saturation $<60\%$, systemic ventricle end diastolic pressure ≥ 18 mm Hg, systemic arterial oxygen saturation $<95\%$ for two ventricle physiology and $<78\%$ for single ventricle physiology, and main pulmonary artery systolic pressure ≥ 45 mm Hg for two ventricle physiology and ≥ 17 mm Hg for single ventricle physiology. Cases were categorized according to previously established procedure-type risk categories [9] from 1 (lowest risk) to 4 (highest risk) based on highest risk procedure/intervention performed. Interventions were summarized in the cohort. Additional case data include admission source (elective or nonelective), mechanical cardiovascular support before starting the case (e.g., ECMO), anesthesia or sedation with spontaneous respirations, inotropic support, case time, contrast dose, and fluoroscopy time.

Adverse Events and High Severity Adverse Events

AE were defined as any anticipated or unanticipated event, for which avoidable injury could have occurred, or did occur, potentially or definitely as a consequence of performing the catheterization [8]. All AEs were recorded either immediately following the case or at the time of identification if the AE was not apparent during the procedure. Information regarding the AE included: event name, a brief narrative description, time of identification, symptoms, and interventions. AEs were classified by type, attributability, and severity. AE type reflects the nature of the AE (e.g., a hematoma is a vascular type AE) and AE attributability reflects aspect of the case most likely leading to the AE (e.g., access). Previously established definitions for AE severity were used, classifying the severity level of an AE from 1 to 5 [1—none, 2—minor, 3—moderate, 4—major, 5—catastrophic] [10]. High severity AE (HSAE) are defined as any level 3, 4, or 5 AE. The term AE is inclusive of all AEs from level 1 to 5.

All events in the database underwent independent review by two interventional cardiologists for appropriate severity level categorization.

Statistical Analysis

Categorical data are summarized using the frequency and percent, and continuous variable using the median

TABLE I. Age Distribution of Cases in the C3PO Database by Age

Institution	Total	<18		18–29		30–39		40–49		≥50	
		n	%	*n*	%	*n*	%	*n*	%	*n*	%
Total	13,483	11,422	85	1,347	10	291	2	232	2	191	1
A	1,943	1,796	92	118	6	15	1	11	1	3	0
B	4,462	3,640	82	537	12	109	2	85	2	91	2
C	1,338	1,209	90	106	8	16	1	6	0	1	0
D	1,196	952	80	120	10	46	4	39	3	39	3
E	1,166	1,095	94	49	4	8	1	10	1	4	0
F	1,828	1,462	80	216	12	63	3	53	3	34	2
G	1,365	1,135	83	185	14	26	2	15	1	4	0
H	185	133	72	16	9	8	4	13	7	15	8

and interquartile range. Age group was tabulated by institution, physiologic diagnosis, and procedure risk category. Patient and procedural characteristics were summarized for patients <18 years of age and ≥18 years of age, and compared using the chi-square test for categorical variables and the Wilcoxon rank sum test for continuous variables. AEs were tabulated for patients greater than 18 years of age including frequency, percent of total cases, and attributability by category. Comparisons of proportions of patients with AEs for age <18 versus ≥18 were also performed. The frequency and percent of cases with high severity (level 3, 4, or 5) AE were calculated by institution.

Multivariate Model

A multivariate model with outcome any high severity AE was built by forward stepwise logistic regression considering variables significant at $P < 0.1$ in univariate analysis. The multivariate model was built using data collected between September 1st, 2007 and June 30th, 2010 because of incomplete data on the hemodynamic vulnerability indicators before September 1st, 2007. The following variables were considered for inclusion: age, genetic syndrome (yes/no), co-morbidities (yes/no), procedure-type risk category, case type, individual indicators of hemodynamic vulnerability, the sum total of indicators of hemodynamic vulnerability present, and cardiac output. Variables were retained in the model if significant at $P < 0.05$, until no additional variables added additional independent explanatory value. Discrimination of the final model was measured by the *c* statistic. The congenital heart disease adjustment for risk method for adults with congenital heart disease (CHARM-ACHD) model was then used to calculate an expected event rate given the case distribution for each participating C3PO institution. Standardized AE rates (SAER) were calculated by dividing the observed AE rate for each institution by expected AE rate calculated from the multivariate model. The 95% confidence intervals of the SAER were calculated for each institution.

RESULTS

Patient and Procedural Characteristics of the Adult Population

Among 13,483 total cases performed at the participating sites, 2,061 (15%) were in patients 18 years of age or older; frequency by site ranged from 6.1% to 28.1%, median 17.6%, Table I. The majority 11,422 cases (85%) were performed on children less than 18 years of age. Among adult patients, the most common physiologic diagnoses were complex defects with two ventricle physiology ($n = 681$, 33%) and no structural heart disease (e.g., myopathy or after heart transplant) ($n = 675$, 33%), Table II. Half the adult population had previously undergone a prior surgery or catheterization before the index case. Lower risk procedures (Categories 1 and 2) were performed more commonly than higher risk procedures (Categories 3 and 4) throughout the adult age ranges ($P < 0.001$), Table I. The most common interventional procedures in the adult patients were cardiac biopsy (29%), implantable device placement (15%), stent placement (12%), stent redilation (5%), and balloon angioplasty (12%). Most procedures (92%) were classified as elective cases. Thirty-five percent of adult patients had at least one hemodynamic indicator of vulnerability. More than one-third of adult patients had a low cardiac index less than 2.8 L/min/m^2 and approximately one-fifth had systemic arterial desaturation.

Similarities and Differences in Patient and Procedural Characteristics Between the Pediatric and Adult Population

A history of previous catheterization was similar in both adult and pediatric groups (53% vs. 55%, $P = 0.10$). Adults were more likely to have noncardiac comorbid conditions (36% vs. 26%, $P < 0.001$); genetic

TABLE II. Patient and Procedural Characteristics by Age Group—Pediatric Versus Adult

Patient Characteristics *n* **(%) or Median [IQR]**	**Total (*n* = 13,483)**	**<18 years (*n* = 11,422)**	**≥18 years (*n* = 2,061)**	***P* value**
Weight (kg) (*n* = 2,061, 11,417)	17.2 [8.2–49.0]	14.0 [7.0–30.6]	68.0 [56.1–82.4]	<0.001
Diagnosis (*n* = 2,060, 11,419)				<0.001
No structural heart disease (e.g., heart transplant)	3,718 (28)	3,043 (27)	675 (33)	
pulmonary hypertension	386 (3)	321 (3)	65 (3)	
Isolated defects	2,708 (20)	2,258 (20)	450 (22)	
Complex defect with two ventricles	4,072 (30)	3,391 (30)	681 (33)	
Complex defect with one ventricle	2,595 (19)	2,406 (21)	189 (9)	
Genetic syndrome (*n* = 2,060, 11,412)	1,644 (12)	1,511 (13)	133 (6)	<0.001
Noncardiac problem (*n* = 2,057, 11,392)	3,657 (27)	2,920 (26)	737 (36)	<0.001
Prior catheterization	7,367 (55)	6,275 (55)	1,092 (53)	0.10
Prior surgery	7,774 (58)	6,681 (58)	1,093 (53)	<0.001
Prior surgery within 30 days	804 (6)	785 (7)	19 (1)	<0.001
Hemodynamic indicators of vulnerability				
Cardiac index <2.8 L/min/m^2	2,389 (18)	1,610 (14)	779 (38)	<0.001
Mixed venous saturation <60%	1,770 (13)	1,664 (15)	106 (5)	<0.001
Systemic ventricle end diastolic pressure ≥18	692 (5)	504 (4)	188 (9)	<0.001
Systemic arterial saturation (<95% or <78%)	3,511 (26)	3,064 (27)	447 (22)	<0.001
Main pulmonary artery pressure (≥45 or ≥17)	1,990 (15)	1,700 (15)	290 (14)	0.35
Any hemodynamic indicator				<0.001
0	8,191 (61)	6,846 (60)	1,345 (65)	
1	3,144 (33)	2,661 (23)	483 (23)	
≥2	2,148 (16)	1,915 (17)	233 (11)	
Procedure Characteristics				
Case type				<0.001
Biopsy	3,183 (24)	2,581 (23)	602 (29)	
Diagnostic	3,563 (26)	2,972 (26)	591 (29)	
Interventional	6,737 (50)	5,869 (51)	868 (42)	
Admission source (*n* = 2,061, 11,421)				<0.001
Elective	10.832 (80)	8,933 (78)	1,899 (92)	
Nonelective	2,650 (20)	2,488 (22)	162 (8)	
Transferred on ECMO support (*n* = 2,047, 11,311)	182 (1)	174 (2)	8 (<1)	<0.001
Spontaneous respiration (*n* = 2,061, 11,421)	4,065 (30)	2,867 (25)	1,198 (58)	<0.001
Interventions				
Balloon angioplasty	2,142 (16)	1,904 (17)	238 (12)	<0.001
Valvotomy	802 (6)	756 (7)	46 (2)	<0.001
Balloon atrial septostomy	171 (1)	170 (1)	1 (<1)	<0.001
Stent placement	1,415 (10)	1,169 (10)	246 (12)	0.02
Stent redilation	665 (5)	555 (5)	110 (5)	0.35
Implantable device	1,708 (13)	1,391 (12)	317 (15)	<0.001
Coil	1,276 (9)	1,218 (11)	58 (3)	<0.001
Biopsy	3,269 (24)	2,672 (23)	597 (29)	<0.001
Other intended hemodynamic alterations	576 (4)	480 (4)	96 (5)	0.35
Balloon occlusion	215 (2)	193 (2)	22 (1)	0.04
Procedure-type risk category (*n* = 1,967, 11,148)				<0.001
Category 1	5,559 (42)	4,380 (39)	1,179 (60)	
Category 2	3,779 (29)	3,366 (30)	413 (21)	
Category 3	2,426 (19)	2,170 (19)	256 (13)	
Category 4	1,351 (10)	1,232 (11)	119 (6)	
Inotropic support during case (*n* = 2,046, 11,333)	1,516 (11)	1,405 (12)	111 (5)	<0.001
Case duration (*n* = 2,055, 11,393)				<0.001
<1 hr	4,827 (36)	4,050 (36)	777 (38)	
≥1 hr, <2 hr	5,494 (41)	4,739 (42)	755 (37)	
≥2 hr, <3 hr	2,163 (16)	1,826 (16)	337 (16)	
≥3 hr	964 (7)	778 (7)	186 (9)	
Contrast dose (cc/kg) (*n* = 2,061, 11,409)	2.4 [0.5 to 4.6]	2.9 [0.7 to 5.0]	1.0 [0.1 to 2.1]	<0.001
Fluoroscopy time (min) (*n* = 2,057, 11,378)	19 [10 to 35]	18 [10 to 34]	19 [10 to 38]	0.38
Transfusion (*n* = 2,046, 11,324)	967 (7)	943 (8)	24 (1)	<0.001

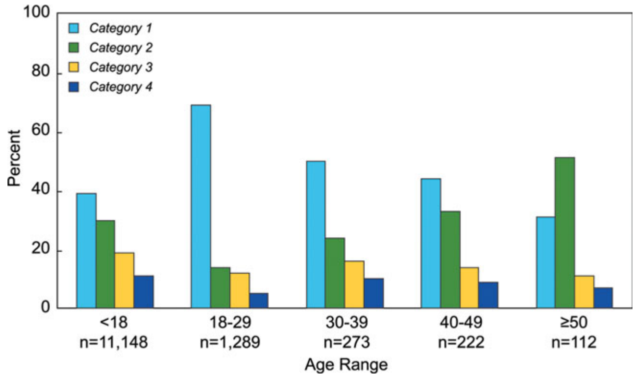

Fig. 1. Procedure risk category by age range. (*368 not assigned risk category.) [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

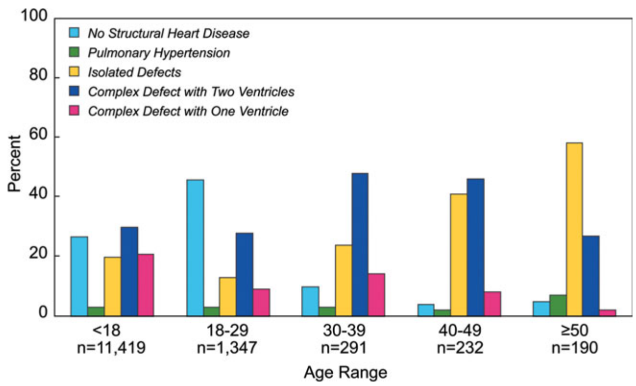

Fig. 2. Physiologic diagnosis by age range. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

syndromes were more common in pediatric patients (13% vs. 6%, $P < 0.001$). A lower percentage of the adult population was classified as having single ventricle physiology when compared with the younger cohort (9% vs. 21%, $P < 0.001$), Fig. 2. Adult cases were less frequently classified as nonelective as compared with pediatric cases (8% vs. 22%, $P < 0.001$). Pediatric cases were also more likely to be classified in a higher risk procedural category ($P < 0.001$). Among hemodynamic indicators of vulnerability, systemic arterial desaturation was more common in children (27% vs. 22%, $P < 0.001$), whereas elevated systemic end diastolic pressure (9% vs. 4%, $P < 0.001$) and a cardiac index less than 2.8 L/min/m^2 (38% vs. 14%, $P < 0.001$) were more common in adults. Hemodynamic risk factors were overall more common in children than adults (40% vs. 35%, $P < 0.001$) and children more commonly had two or more indicators (17% vs. 11%, $P < 0.001$). Radial or brachial access was used very rarely (0.25% of all cases). Excluding biopsy cases, 83% of the remaining cases involved both arterial and venous access.

TABLE III. Select Adverse Events for Adult Patients

	n (% of total cases)
Vascular/cardiac trauma	30 (1)
confined tear	13
Unconfined tear	1
Aneurysm/pseudoaneurysm	1
Heart perforation	3
Other vessel trauma	12
Technical AE	19 (1)
Balloon rupture	11
Stent malposition/embolization	7
Other stent related problem	2
Arrhythmias	60 (3)
Atrial arrhythmia	35
Heart block, resolved	8
Ventricular arrhythmia	17
Hemodynamic AE	22 (1)
Asystole/cardiac arrest	2
Bradycardia (sinus)	1
Hypotension (inotropes or volume)	12
Hypoxia	3
Nonspecific ST/T-wave changes	4
Vascular entry site AE	39 (2)
Local hematoma	21
Pulse loss	1
Rebleed	11
Other problem	7
Sedation/anesthesia/airway	31 (2)
Other	7 (<1)
Allergic reaction	3
Neurological problem	4

Differences in Outcomes Between the Pediatric and Adult Population

When comparing adults to children, there was a lower incidence of any AE (10% vs. 13%, $P < 0.001$) as well as HSAE (4% vs. 5%, $P = 0.006$). Three adult patients and 24 pediatric patients died directly related to the case. Arrhythmias and vascular access related events were the most common AE observed in both populations. Arrhythmias occurred in 3% of all adult cases and were 25% (60 of 239) of the total AE in adults, Table III. Blood transfusions were administered in 8% of pediatric patients in contrast to only 1% of adults ($P < 0.001$). Average fluoroscopy times were not significantly different (19 vs. 18 min, $P = 0.38$). Adults received a median dose 1.0 cc/kg of contrast compared with 2.9 cc/kg ($P < 0.001$) for children ($P < 0.001$).

Risk Factors in the Adult Population

In a multivariable model for HSAEs in adult patients, independent risk factors included procedure-type risk category and systemic ventricle end diastolic pressure greater than or equal to 18 mmHg, Table IV. Each increase in procedure risk category was associated with an increased rate of HSAE. Category 1

TABLE IV. High Severity Events (Level 3, 4, and 5)—Patients ≥18 Years of Age

	n	Any level 3, 4, 5 event		*P* value
		Any Level 3, 4, 5 event, *n* (%)	Multivariate odds ratio (95% CI)	
Systemic ventricle end diastolic pressure ≥18				
No	1,873	61 (3.3%)	1.0	–
Yes	188	17 (9.0%)	3.1 (1.7, 5.6)	<0.001
Procedure-type risk category				
Category 1	1,179	15 (1.3%)	1.0	–
Category 2	413	22 (5.3%)	4.8 (2.5, 9.4)	<0.001
Category 3	256	19 (7.4%)	6.0 (3.0, 12.1)	<0.001
Category 4	119	17 (14.3%)	12.9 (6.2, 26.8)	<0.001
Not assigned	94	5 (5.3%)	4.5 (1.6, 12.7)	0.005

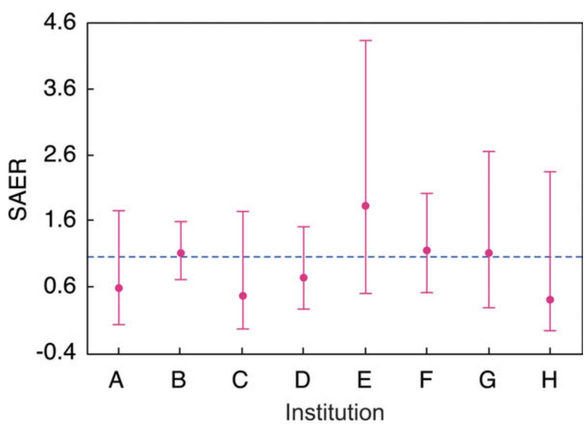

Fig. 3. Standardized ratios for HSAE (severity level 3, 4, and 5) by institution in patients ≥18 years of age. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

procedures were associated with a comparatively low risk of HSAE, 1.3%. Category 2 procedures were associated with a rate of 5.3% HSAE. Category 3 procedures further increased to 7.4%. Category 4 procedures carried the highest risk at 14.3% HSAE rate. Among the 188 adult patients with systemic ventricle end diastolic pressure ≥18 mmHg, there were 17 HSAEs (9.0%), whereas patients with a systemic ventricle end diastolic pressure <18 mmHg, HSAE occurred in only 3.3% of cases.

In the multivariate risk assessment of adults, in comparison with Category 1 procedures, the odds ratio for HSAE in Category 2 procedures was 4.8 (CI 2.5–9.4, $P < 0.001$), Category 3 was 6.0 (95% CI 3.0–12.1, $P < 0.001$) and Category 4 12.9 (95% CI 6.2–26.8, $P < 0.001$). The odds ratio for HSAE with a systemic ventricle end diastolic pressure ≥18 mm Hg was 3.1 (CI 1.7–5.6, $P < 0.001$). The other hemodynamic variables (e.g., arterial or mixed venous desaturation) did not reach significance in CHARM-ACHD. The *c* statistic of the final model incorporating procedure-type risk category and systemic ventricle end diastolic pressure ≥18 was 0.751.

Case Mix and Event Rate Differences by Institution

At all institutions, the great majority of the cases were performed on pediatric patients (85%) with an overall trend of decreasing frequency with increasing age, Table I. There was variation between institutions in the relative proportion of adults among the total case mix. Institution E has only 4% of their total cases performed on patients 20 years of age or older. In contrast, Institution D performed 19% of their cases on patients 20 years or older, with 3% of cases on patients 50 years and older. Although there was variation in the observed (range 1.55–7.04) and expected (range 1.95–4.72) AE rates among adults at institutions, there were no statistically significant differences in the SAER, range 0.41–1.82, with 95% confidence interval spanning 1 for all institutions, Fig. 3.

DISCUSSION

To our knowledge, this is the largest multicenter study to date examining adults undergoing catheterization at pediatric hospitals. Adults represented a substantial portion of the total case volume, approximately one in seven cases. In addition to the expected adults with CHD, 33% had nonstructural heart disease (e.g., cardiomyopathy or heart transplant) with nearly one-third (29%) of all cases in the series, including myocardial biopsy, almost exclusively performed on cardiac transplant recipients.

Despite this sizable number of patients, treating an adult at a pediatric hospital raises certain challenges. Pediatric health care providers may be less comfortable treating adult patients and their comorbid conditions. Pediatric catheterization laboratories may be less equipped than adult facilities to perform coronary interventions if the need arises. Given potential benefits for bleeding risk and earlier mobility, radial/brachial access is increasingly being performed in U.S. adult laboratories but is exceedingly rare in this series. Legal and institutional challenges may exist, such as ensuring staff has certification in adult resuscitation. Even if cardiologists and support personnel are comfortable to take care of adults, if a complication such as a stroke, severe vascular injury requiring surgery, or acute renal insufficiency occurs, the patient may be seen and treated by pediatric subspecialists or warrant urgent transferred to an adult facility.

Evaluating which patients may be at a higher risk for AE can allow for better patient selection and preparation for potential complications. The interventionist, an ACHD trained cardiologist, the anesthesiologist, and support staff should all participate in thorough pre-procedure planning to help anticipate potential issues and their responses. For instance, if a pediatric laboratory is not well equipped to perform coronary interventions, an ACHD trained cardiologist can help determine if stress testing, CT angiography and/or catheterization in an adult laboratory should be performed before congenital catheterization. If an AE occurs that requires resources or expertise not routinely present at a pediatric institution, planning the logistics of either bringing the adult specialist to the pediatric hospital or transferring the patient to an adult facility can save valuable time.

Across this adult study population, high severity AEs were most closely associated with the nature of the procedure (i.e., procedure risk category) and elevated systemic ventricle end diastolic pressure. Arrhythmias were the most common AEs among all adults, most commonly atrial arrhythmias.

Adverse Event Rates

Among adults, 4% of cases were associated high severity adverse events (HSAE), in contrast to 5% in children. When including all low severity AEs, the total AE rate increases to 10% for adults and 13% for children. There are several factors that may affect this difference in AE rates beyond age alone. Beyond differences in procedure types and underlying diagnoses, the cohort of patients who survive to adulthood does not include the most vulnerable patients who do not survive childhood. While there are potential hazards in any cardiac catheterization, certain technical considerations can often be more challenging in smaller patients.

The results of this series are similar to prior single center studies of adults with CHD undergoing catheterization. Garekar et al. [6] reported the results of the Children's Hospital of Michigan's experience with adult patients consisting of 576 procedures on 436 patients 18 years or older with a median age of 26. The overall adult AE/HSAE rate of 10%/5% within the C3PO experience is comparable with the Michigan experience of a 10.6% complication rate and a 3.2% major complication rate (defined as unanticipated complications within 24 hr that required intervention, close observation, or resulted in death). Phillips et al. [11] recently reported the combined congenital cardiac catheterization experience of the Mayo Clinic with adults and children including 561 of 903 procedures performed on patients 18 years of age and older (mean age of 29 $\pm$ 22 years). The combined adult and pediatric Mayo Clinic series reported an overall complication rate of 11% with HSAE (Grade 3 or higher) rate of 3.9%.

In the C3PO series, arrhythmias were the most common AE (n = 60, 3% of total cases) among adults with atrial arrhythmias being the most common (n = 35, 2%). This is similar to the Mayo Clinic experience of 2% (18 of 903) and the Michigan experience 1.4% (5 major, 3 minor of 576 cases). The incidence of vascular access complications among adults was 1.9% (39 of 2,061). This compares with an incidence of 3.6% observed in a single tertiary referral center retrospective analysis of ACHD patients [12], a 3.7% vascular access complication rate in the Mayo Clinic series [11] and a 3.4% hematoma rate reported by Garekar et al. [6].

Risk Adjustment

Adult survivors of CHD are distinct from both children with CHD and patients with more common adult onset acquired heart disease. It is very important that risk adjustment tools specific to this population be developed to better understand their procedural risks. Risk adjustment is challenging given such a wide array of congenital heart lesions with varying surgical history.

Despite this diversity, two factors are demonstrably associated with an increased risk of AE: the procedure risk category and the presence of elevated systemic end diastolic pressure $\geq$18 mmHg. While the nature of a particular procedure is intuitively associated with risk, understanding the magnitude of this risk may help better inform patients and practitioners. For instance, the odds ratio for high level AE for a risk category 4 procedure such as a closure of a perivalvar leak is nearly 13 times greater than that for a diagnostic catheterization, Table IV.

A systemic ventricular end diastolic pressure $\geq$18 mmHg is associated with a threefold increase in AE rate in adults. Increased systemic ventricle end diastolic pressure was previously found to be a risk factor across the entire cohort [7]. There was a wide variety of underlying cardiac diagnoses among the patients with elevated systemic ventricle end diastolic pressure and high severity AE, with no single diagnosis group predominating. Khairy et al. [13] demonstrated that elevated left ventricle end diastolic pressure correlates with an increased risk for arrhythmia in adults with Tetralogy of Fallot. Increased end diastolic pressure has also been demonstrated to correlate with fibrosis/scar burden in CHD [14].

Limitations

There are several potential limitations of this study. Despite audits, exception reports and internal AE reviews [8], inaccuracies and variations in reporting could have occurred. Possible under-reporting of low severity events not requiring intervention may have occurred, perhaps accounting for a lower observed groin complication rate. Comparisons between pediatric and adult cases with factors such as sheath size are difficult to make given the wide variety of patient size in the pediatric cohort. Specific indications for each case were not recorded. Although difficult to quantify, ideally the frequency and severity of AEs should ideally be measured against the efficacy of the interventions producing a positive and durable clinical improvement. Operators that are very conservative in percutaneous interventions or institutions that more readily opt for surgical intervention may have lower catheterization AE rates. Long-term sequelae including difficulties with future vascular access following serial catheterization [11,12] and cumulative radiation exposure of radiographs and CT imaging [15,16] were not examined.

Children undergoing catheterizations at the same institutions are a convenient but ultimately imperfect comparison group for adult patients. The axiom "children are not small adults" [17] also holds true in reverse: adults are not large children. Even with the same disease, the pathophysiology and technical challenges can change dramatically over life. For instance in Tetralogy of Fallot, the young child with severe pulmonary stenosis is different than the surgically palliated adult who has developed severe pulmonary regurgitation.

CONCLUSIONS

The AE rates in adults undergoing cardiac catheterization at pediatric hospitals occur at a lower frequency than in children with in this series. Systemic end diastolic pressure $\geq$18 mmHg and procedure risk category are the most significant risk factors increased complications related to cardiac catheterization. The CHARM-ACHD model is a significant development in our understanding of AE rates for adults undergoing catheterization at pediatric hospitals. This model has considerable promise as a tool for both institutional quality control and future academic study. With the continued experience of the C3PO registry and other registries, additional refinement of risk adjustment models will continue to further the ultimate goal of improved patient safety.

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