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ORIGINAL INVESTIGATIONS

Procedural Results and Safety of Common Interventional Procedures in Congenital Heart Disease

Initial Report From the National Cardiovascular Data Registry

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ABSTRACT

BACKGROUND The National Cardiovascular Data Registry (NCDR) launched the IMPACT (Improving Pediatric and Adult Congenital Treatment) Registry in 2010. By 2013, its patient enrollment exceeded that of other current and historical congenital catheterization registries.

OBJECTIVES This study sought to describe procedural results and safety of 6 common congenital interventions performed in patients enrolled during the IMPACT Registry's initial periods.

METHODS With specified exclusions, we compiled registry data from patients enrolled in the IMPACT Registry from January 2011 through March 2013 who underwent 1 of the following isolated procedures: device closure of atrial septal defect (ASD); device closure of patent ductus arteriosus (PDA); pulmonary valvuloplasty; aortic valvuloplasty; coarctation of the aorta angioplasty and stenting; and pulmonary artery stenting. Patient data, procedural data and results, and adverse events (AEs) were reviewed and described.

RESULTS In 4,152 catheterizations, 1 isolated procedure was reported. There were 1,286 single-ASD procedures, 1,375 PDA procedures, 270 "typical" pulmonary valve procedures, 305 aortic valve procedures, 671 aortic procedures, and 245 pulmonary artery procedures. The reported procedure was performed in >95% of catheterizations. Stated outcomes were accomplished in >98% of ASD and PDA procedures, but less commonly in the others, with coarctation angioplasty procedures being the least successful (51%). Reported major AE rates ranged from 0% to 3.3%; total AE rates ranged from 5.3% to 24.3%.

CONCLUSIONS Contemporary community practice, procedural outcomes, and safety for 6 common congenital interventional procedures are reported. These benchmarks may be compared with individual center results and historical single-center and multicenter results. (J Am Coll Cardiol 2014;64:2439–51) © 2014 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

ADO = Amplatzer duct occluder

AE = adverse event(s)

ASD = atrial septal defect

ASO = Amplatzer septal occluder

AV = aortic valvuloplasty

Coarct = coarctation of the aorta

FDA = U.S. Food and Drug Administration

MAE = major adverse event(s)

NCDR = National Cardiovascular Data Registry

PA = pulmonary artery

PDA = patent ductus arteriosus

PV = pulmonary valvuloplasty

Qp/Qs = pulmonary flow/systemic flow

Most previous reports of interventional procedures in congenital heart disease have been single-center or single-device studies. Although there have been some registry-based studies, historically, congenital catheterization registries have been physician initiated and limited. The Michigan and the European PDA Coil Registries (1,2) and the VACA (Valvuloplasty and Angioplasty of Congenital Anomalies) Registry (3) closed decades ago and reported on procedures using somewhat dated technologies. The MAGIC (Mid-Atlantic Group of Interventional Cardiology) Registry (3) and the Congenital Cardiovascular Interventional Study Consortium (CCISC) (4) are active, but have limited scopes. The C3PO (Congenital Cardiac Catheterization Project on Outcomes) Registry (5), which generated several groundbreaking studies, involves a relatively limited number of study centers.

The IMPACT (Improving Pediatric and Adult Congenital Treatment) Registry, 1 registry in the National Cardiovascular Data Registry (NCDR), was launched in 2010 (6). As of October 2013, the IMPACT Registry had 81 participating centers and enrolled >26,000 catheterization episodes of care. Because of wide congenital heart center participation, the IMPACT Registry has the potential to define community practice and contemporary practice benchmarks. Moreover, its sophistication, size, and scope give IMPACT Registry the potential to support better powered, more nuanced reviews and analyses than previous studies.

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In this report, we describe the procedural results and safety of 6 common congenital interventions performed in patients enrolled in the IMPACT Registry during its initial periods. These procedures are device closure of an atrial septal defect (ASD), device closure of patent ductus arteriosus (PDA), pulmonary valvuloplasty (PV), aortic valvuloplasty (AV), coarctation of the aorta (Coarct) angioplasty and stenting, and pulmonary artery (PA) stenting.

METHODS

NATIONAL CARDIOVASCULAR DATA REGISTRY. The IMPACT Registry is an initiative of the American College of Cardiology Foundation and was previously described (7). The Registry collects data for use in development of performance and quality metrics, quality improvement programs, and peer-reviewed outcomes research focused on patients with congenital heart disease undergoing cardiac catheterizations. Demographic, clinical, procedural, and institutional data elements are collected at participating centers, entered via a Web-based platform, and collected in a secure, centralized database. A description of IMPACT Registry data elements and definitions is available online (8). When not pre-specified, definition of other aspects of data elements was left to the discretion of participating centers.

The IMPACT Registry has a data quality program consistent with that described for the NCDR (9). The program ensures data completeness, consistency, and accuracy. In this study, all reported data met Registry criteria for completeness and consistency. During data collection for this study, IMPACT Registry auditing procedures were under development. Therefore, data accuracy was not verified by audits. Patient consent forms of centers enrolled in the IMPACT Registry include the provision that parties agree to allow use of clinical data in deidentified quality review. Because patient information is collected anonymously and without unique patient identifiers, the IMPACT Registry research studies meet the definition of research not requiring specific informed consent.

THIS STUDY. This study focuses on describing IMPACT Registry data pertaining to procedural elements and results in patients who underwent 1 of the following procedures: device closure of ASD, device closure of PDA, PV, AV, Coarct angioplasty and stenting, and PA stenting. Data from January 2011 to March 2013 were collected from a total of 4,152 catheterization laboratory visits that included 1 of the aforementioned procedures.

Only patients who had "isolated" procedures were eligible for inclusion; patients undergoing more than

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1 of the 6 common interventional procedures or undergoing 1 of the common procedures and another interventional procedure were excluded. Further exclusion criteria included the following: 1) ASD procedures having multiple devices implanted; 2) pulmonary valve procedures, with highly dysplastic valves, supravalve stenosis, or significant infundibular stenosis; and 3) aortic valve procedures using dual-balloon catheters.

Data regarding patient characteristics, procedural indications (including hemodynamic data), procedural elements and results, and adverse events (AEs) are included in this report. An AE was defined as occurrence of any of the following: cardiac arrest; air embolus; arrhythmia; arrhythmia requiring cardioversion, antiarrhythmic medication; permanent or temporary pacemaker; new heart valve regurgitation; tamponade; embolic stroke; new requirement for dialysis; airway event requiring intubation; event requiring extracorporeal membrane oxygenation or left ventricular assist device; bleeding event; bleeding event at access site; hematoma at access site; retroperitoneal, gastrointestinal, or genitourinary bleeding; red blood cell/whole blood transfusion; device malposition; device thrombus; device embolization; unplanned surgery; or subsequent cardiac catheterization due to a catheterization-related complication. Major adverse events (MAEs) were defined as need for permanent or temporary pacemaker, cardiac arrest, cardiac tamponade (requiring pericardial drainage), embolic stroke (within 72 h), and unplanned cardiac surgery (due to catheterization complication). Reported AEs occurred during the catheterization or the hospitalization during which the procedure was performed (episode of care) and were attributable to the catheterization procedure. Deaths occurring during the episodes of care are reported; however, registry data do not specify whether death was attributed to the catheterization procedure. Reported deaths may be complications of catheterization or attributable to other procedures occurring during the episodes of care (e.g., cardiac surgery) or unrelated patient comorbidities.

STATISTICAL ANALYSIS. Descriptive statistics for all patients undergoing 1 of the 6 major interventional procedures are presented. Continuously distributed variables are reported as mean ± SD and categorical variables are reported as frequencies.

RESULTS

DEVICE CLOSURE OF A SINGLE ASD. Device occlusion or attempt to occlude a single isolated ASD was reported in 1,286 patients. (Table 1). Only 19 patients

TABLE 1 ASD Procedures

	Total	Age <30 Days (Neonates)	Age 30 Days to 1 Year (Infants)	Age 1-18 Years (Children)	Age >18 Years (Adults)
No. of procedures*	1,286	2	17	939	328
Indication					
RV volume overload	1,038 (81.0)	1	8 (47.0)	861 (92)	168 (51.5)
Stroke prevention	165 (13.0)	0	1 (6.0)	35 (3.8)	129 (39.6)
Qp/Qs	1.8 ± 0.8 1.7 (1.3-2.1)	2.9 ± 1.5 2.9 (1.8-3.9)	2.2 ± 1.0 1.9 (1.6-2.2)	1.8 ± 0.7 1.7 (1.3-2.1)	1.8 ± 1.2 1.5 (1.1-2.0)
ASD size, mm	13.1 ± 6.3	13.0 ± 7.1	8.3 ± 2.7	13.0 ± 5.5	13.5 ± 8.2
Device implanted	1,228 (95.7)	2 (100.0)	15 (88.2)	897 (95.7)	314 (96.0)
Amplatzer	852 (69.3)	2	13	639	198
HELEX	352 (28.6)		2	239	111
Other	23 (1.9)				
Not specified	1				
Residual >3 mm	22 (1.8)	0	0	18 (2.0)	4 (1.3)
Death					
Procedural	0				
Episode of care	2	0	1 (respiratory)	0	1 (cardiac)
AE (any)	1,280 73 (5.7)	1 (50.0)	2 (11.8)	937 53 (5.7)	326 17 (5.2)
MAE	15 (1.2)	0	1 (5.9)	8 (0.9)	6 (1.8)
Tamponade (erosion)	3	0	0	1	2
Embolization	22 (1.7)	0	0	17 (1.8)	5 (1.5)
Unplanned cardiac surgery	10 (0.8)	0	0	7 (0.7)	3 (0.9)

Values are n, n (%), mean ± SD, or median (interquartile range). *Number of procedures reporting this individual data element.
AE = adverse event; ASD = atrial septal defect; MAE = major adverse event; Qp/Qs = pulmonary flow/systemic flow; RV = right ventricular.

were neonates (<30 days old) or infants (30 days to 1 year old). There were 939 children (73%) (between 1 and 18 years of age), and 328 adults (26%) (older than 18 years of age).

The primary reported indication for ASD closure was right ventricular volume overload in 1,038 patients (81.2%), followed by stroke prevention in 165 patients (12.9%). Additional primary indications in small numbers (from 0.4% to 1.8%) included chronic lung disease, failure to thrive, recurrent respiratory infections, cyanosis, and migraines. When reported, hemodynamic measurements at catheterization yielded a mean pulmonary flow/systemic flow (Qp/Qs) ratio of 1.8 ± 0.8 and median of 1.7 (interquartile range: 1.3 to 2.1). These data were not reported in 133 adult patients (41%) and in 98 children (10%). Mean ASD size was 13.1 ± 6.3 mm, and ASD sizes were similar in children and adults, but was smaller (8.3 mm) in infants.

Balloon sizing was performed in 82.3% of patients, more commonly in those older than 1 year. Among patients having balloon sizing, the stop-flow technique, when specified, was performed in 89.0% of cases. Only 56% of cases reported ASD rim measurement. Rim measurement was less common in adults (36.9%) than in children (62.4%).

An ASD device was implanted in 95.7% of catheterizations (1,228 of 1,283). Amplatzer septal occluders (ASOs) were implanted in 852 patients (69.3%), whereas HELEX occluders (W. L. Gore & Associates, Flagstaff, Arizona) were implanted in 352 patients (28.6%). Insufficient ASD rim was given as the reason for failure to implant devices in 48.1% of patients (26 of 54). Significant residual shunts (≥3 mm) immediately after device placement were noted in 1.8% of patients (22 of 1,226).

The mean length of hospital stay (LOS) from admission to discharge was 1.6 ± 7.9 days; median was 1.0 days. There were no deaths in the catheterization laboratory. However, 2 patients died during the episode of care: 1 adult from a cardiac cause and an infant from a pulmonary cause. AEs were reported

TABLE 2 PDA Procedures

	Total	Age <30 Days (Neonates)	Age 30 Days to 1 Year (Infants)	Age 1–18 Years (Children)	Age >18 Years (Adults)
No. of procedures*	1,375	10	359	962	44
Indication					
LV volume overload	751 (54.8)	6	241 (67.5)	488 (50.9)	16 (36.4)
SBE prevention	517 (37.7)	2	48 (13.4)	443 (46.2)	24 (54.5)
Pulmonary HTN	102 (7.4)	2	68 (19.0)	28 (2.9)	4 (9.1)
Qp/Qs	1.7 ± 1.3 1.3 (1.1–1.8)	3.4 ± 3.1 1.9 (1.8–4.0)	2.3 ± 2.1 1.9 (1.4–2.7)	1.4 ± 0.6 1.2 (1.0–1.5)	1.5 ± 0.8 1.4 (1.1–1.6)
PDA type	1,333	9	346	936	42
A (conical)	829 (62.2)	8	187 (54.0)	608 (65.0)	26 (61.9)
B (window)	20 (1.5)		2 (0.6)	17 (1.8)	1 (2.4)
C (tubular)	257 (19.3)		97 (28.0)	152 (16.2)	8 (19.0)
D (complex)	66 (5.0)		16 (4.6)	47 (5.0)	3 (7.1)
E (elongated)	161 (12.1)	1	44 (12.7)	112 (12.0)	4 (9.5)
PDA-treated	1,357 (98.8)	9 (90)	348 (97.2)	956 (99.5)	44 (100.0)
Coil	216 (15.9)				
Device	501 (36.9)				
Not reported	640 (47.1)				
Residual >3 mm	14 (1.0)	1	3	10	0
Death					
Procedural	0				
Episode of care	6	1 (resp)	5 (4 resp)	0	0
AE (any)	1,366 72 (5.3)	4 (40.0)	358 29 (8.1)	954 39 (4.1)	0
MAE	1,370 3 (0.2)	1	1	1	0
Embolization	1,371 16 (1.2)	0	3 (0.8)	958 13 (1.4)	0
Unplanned cardiac surgery	1,370 2 (0.1)	1 (10.0)	1 (0.3)	0	0

Values are n, n (%), mean ± SD, or median (interquartile range). *Number of procedures reporting this individual data element.
HTN = hypertension; LV = left ventricular; PDA = patent ductus arteriosus; resp = pulmonary cause; SBE = subacute endocarditis; other abbreviations as in Table 1.

in 5.7% of patients (73 of 1,281). MAEs were noted in 1.2% of patients (15 of 1,281). Cardiac tamponade (due to device erosion) occurred in 0.2% of patients (3 of 1,285). Device embolization occurred in 1.7% (22 of 1,285). Catheter retrieval was performed in 72.7% (16 of 22). Unplanned cardiac surgery was performed in 10 patients, including those with tamponade or device embolization.

DEVICE CLOSURE OF PDA. Device occlusion or attempt to occlude PDA was reported in 1,375 patients (Table 2). There were only 10 neonates. Most patients were infants (26.1%) or children (69.9%).

The primary reported indication for PDA closure was left ventricular volume overload in 751 patients (55%), followed by subacute endocarditis prevention in 517 patients (37.7%) and pulmonary hypertension in 102 (7.4%). In spite of controversy with respect to use of standard oximetry for Qp calculation in PDA, for consistency with prior datasets, measurements at catheterization were reported with mean Qp/Qs ratio of 1.7 ± 1.3 and median ratio of 1.3 (IQR: 1.1 to 1.8). These data were not reported in 204 children (21%), 49 infants (14%), and 12 adults (27%).

PDA were classified as Type A (conical) in 62% (829 of 1,333), Type B (window) in 1.5% (20 of 1,333), Type C (tubular) in 19.3% (257 of 1,333), Type D (complex) in 5.0% (66 of 1,333), and Type E (elongated) in 12.1% (161 of 1,333). Type A was the most common in all age groups.

A coil or a device was implanted in 98.8% of catheterizations (1,357 of 1,373). Devices were used in 70.0% and coils were used in 30.0%. In all age categories, device implant was more common than coils. Significant residual shunts (≥3 mm), PA obstruction, and aortic obstruction immediately after device and/or coil implant were each noted in about 1.0%.

Mean patient length of hospital stay was 4.3 ± 21.8 days, and the median was <1 day. There were no deaths in the catheterization laboratory. However, 6 patients died during the episode of care: none attributed to a cardiac cause, and 5 attributed to a pulmonary cause. AEs were reported in 5.3% of patients (72 of 1,366), whereas MAEs occurred in 0.2% (3 of 1,370). Device embolization occurred in 1.2% of patients (16 of 1,371). Catheter retrieval was performed in 69% of patients (11 of 16). Unplanned cardiac surgery was performed in only 2 patients.

PULMONARY VALVULOPLASTY. Balloon PV in patients with isolated "typical" valve morphology

TABLE 3 Pulmonary Valvuloplasty Procedures

	Total	Age <30 Days (Neonates)	Age 30 Days to 1 Year (Infants)	Age 1-18 Years (Children)	Age >18 Years (Adults)
No. of procedures*	270	78	93	83	16
Indication					
Resting gradient	223 (82.6)	52 (66.7)	86 (92.5)	75 (90.4)	10 (62.5)
Right-to-left shunting	16 (5.9)	15 (19.2)	1 (1.1)	0	0
RV dysfunction	14 (5.2)	7 (9.0)	4 (4.3)	2 (2.4)	1 (6.3)
Symptoms	17 (6.3)	4 (5.1)	2 (2.2)	6 (7.2)	5 (31.3)
Pre-procedural PV gradient, mm	47.0 ± 19.7 45.0 (33.0-60.0)	75 52.9 ± 24.1 54.0 (40.0-70.0)	49.8 ± 17.2 50.0 (37.0-61.0)	39.4 ± 15.3 38 (30.0-46.0)	42.2 ± 19.2 40 (36.5-41.0)
PS treated	268 (99.3)	78 (100)	93 (100)	82 (98.8)	15 (93.8)
Balloon technique	268			82	15
Single	249 (92.9)	75 (96.2)	92 (98.9)	70 (85.4)	12 (80.0)
Double	17 (6.3)	2 (2.6)	1 (1.1)	11 (13.4)	3 (20.0)
Both	2 (0.7)	1 (1.3)	0	1 (1.2)	0
Post-single-balloon systolic gradient, mm Hg	249 16.1 ± 11.6 14.0 (9.0-20.0)	75 13.0 ± 11.8 10.0 (6.0-16.0)	92 17.8 ± 11.4 15.0 (10.0-20.0)	70 16.7 ± 10.9 15.0 (10.0-21.0)	12 19.0 ± 13.5 14.5 (10.0-21.0)
<20	181 (73.0)	64 (85.3)	65 (70.7)	44 (63.8)	8 (66.7)
Post-single-balloon pulmonary insufficiency ≥2+	224 14 (6.2)	69 7 (10.1)	85 3 (3.5)	59 3 (5.1)	1 1 (9.1)
AE (any)	267 19 (7.1)	77 11 (14.3)	92 6 (6.5)	82 2 (2.4)	0
MAE	0	0	0	0	0
Unplanned cardiac surgery	0	0	0	0	0

Values are n (%), n, mean ± SD, or median (interquartile range). *Number of procedures reporting this individual data element.

PS = pulmonary stenosis; PV = pulmonary valvuloplasty; other abbreviations as in Table 1.

was reported in 270 patients. (Table 3): 78 neonates (29%), 93 infants (34%), 83 children (31%), and 16 adults (5.9%).

The primary reported indication for valvuloplasty was resting gradient (83% of patients). Right-to-left shunting, a common criterion for critical pulmonary stenosis, was cited in 15 neonates (19%). Right ventricular dysfunction or symptoms were noted in a small number of older patients.

The mean pre-procedure pulmonary valve systolic gradient was 47.0 ± 19.7 mm Hg, and the median was 45.0 mm Hg across all age groups. The mean and median gradients among neonates (53 mm Hg and 54 mm Hg, respectively) and infants (50 mm Hg and 50 mm Hg, respectively) were higher than those observed among children (39 mm Hg and 38 mm Hg, respectively) and adults (42 mm Hg and 40 mm Hg, respectively).

Balloon dilation of the pulmonary valve was performed in 268 patients or in 99.3% of patients reported for PV. The single-balloon technique was used in the majority (93%) of patients in all age groups. Among patients having single-balloon valvuloplasty, the mean post-procedure systolic gradient ranged from 13.0 mm Hg in infants to 19.0 mm Hg in adults (mean of 16.1 ± 11.6 mm Hg across all groups). A post-procedure gradient <20 mm Hg was attained in 73% of patients.

Pulmonary insufficiency ≥2+ was observed in ≤10% of the single-balloon patients in all groups after valvuloplasty. AEs were recorded in 19 episodes of care (7.1%), most commonly among infants 11 (14.3%). There were no MAEs or unplanned surgeries.

AORTIC VALVULOPLASTY. Single-balloon AV was reported in 305 patients (Table 4): 101 neonates (33%), 76 infants (25%), 106 children (34.8%), and 22 adults (7.2%).

In most patients (252 or 83%), the primary indication for valvuloplasty was resting gradient. Left ventricular dysfunction, a common criterion for critical aortic stenosis, was cited in 21 neonates (21%) and in 8 infants (10.5%). Symptoms were cited in 5 additional neonates (5.0%), expanding the critical group to 26% of enrolled neonates. Symptoms were also cited in 6 (27.3%) of the adults enrolled.

The pre-procedure mean aortic valve systolic gradient was 62.6 ± 23.3 mm Hg, and the median was

TABLE 4 Aortic Valvuloplasty Procedures (Single-Balloon Technique)

	Total	Age <30 Days (Neonates)	Age 30 Days to 1 Year (Infants)	Age 1–18 Years (Children)	Age >18 Years (Adults)
No. of procedures*	305	101	76	106	22
Indication					
Resting gradient	252 (82.6)	75 (74.3)	67 (88.2)	94 (88.7)	16 (72.7)
LV dysfunction	35 (11.5)	21 (20.8)	8 (10.5)	6 (5.7)	0
Symptoms	18 (5.9)	5 (5.0)	1 (1.3)	6 (5.7)	6 (27.3)
AV gradient, mm Hg	302 62.6 ± 23.3 60.0 (48.0–75.0)	99 68.1 ± 22.3 70.0 (55.0–80.0)	75 59.7 ± 19.5 60.0 (45.0–73.0)	59.1 ± 19.6 59 (46.0–70.0)	64.2 ± 44.4 51.5 (36.0–70.0)
AS treated	305 (100.0)	101 (100.0)	76 (100.0)	106 (100.0)	22 (100.0)
Post-single-balloon systolic gradient, mm Hg	299 26.1 ± 15.0 25.0 (15.0–35.0)	97 24.5 ± 13.0 24.0 (15.0–33.0)	75 26.0 ± 15.9 20.0 (15.0–35.0)	105 27.4 ± 14.3 25.0 (15.0–35.0)	27.8 ± 22.5 23.0 (9.0–36.0)
<30	184 (61.5)	63 (64.9)	48 (64.0)	60 (57.1)	13 (59.1)
Post-single-balloon aortic insufficiency					
<2+	252 (82.6)	83 (82.2)	63 (82.9)	87 (82.1)	19 (86.4)
2+	46 (15.1)	16 (15.8)	11 (14.5)	16 (15.1)	3 (13.6)
>2+	7 (2.3)	2 (2.0)	2 (2.6)	3 (2.8)	0
Death					
Catheterization lab	0	0	0	0	0
Episode	6	5 (4 cardiac)	0	1 (not cardiac)	0
AE (any)	301 73 (24.3)	29 (29.0)	25 (33.3)	104 14 (13.5)	5 (22.7)
MAE	302 10 (3.3)	100 3 (3.0)	75 2 (2.7)	105 5 (4.8)	0
Unplanned cardiac surgery	304 3 (1.0)	1 (1.0)	1 (1.3)	105 1 (1.0)	0

Values are n (%), n, mean ± SD, or median (interquartile range). *Number of procedures reporting this individual data element.

AS = aortic stenosis; AV = aortic valvuloplasty; other abbreviations as in Table 1.

60.0 mm Hg across all age groups. Systolic gradients ranged from 59.1 ± 19.6 mm Hg among children to 68.1 ± 22.3 mm Hg among neonates. The median gradients ranged from 51.5 mm Hg in adults to 70.0 mm Hg in neonates.

Single-balloon dilation of the aortic valve was performed in 305 patients or 100% of those reported for this procedure. The mean post-procedure systolic gradient was 26.1 ± 15.0 mm Hg and was similar across all groups. The median gradients ranged from 20.0 mm Hg in infants to 25.0 mm Hg in children. However, only 61.5% of patients attained a post-procedure gradient <30 mm Hg.

Aortic insufficiency of 2+ was observed in 46 patients (15.1%). Aortic insufficiency >2+ was seen in 7 patients (2.3%).

AEs were recorded in 73 patients (24.3%). MAEs were reported in 10 patients (3.3%), and unplanned cardiac surgery was reported in 3 patients (1.0%). There were no catheterization laboratory deaths. However, there were 6 deaths, 4 attributed to cardiac causes during the episodes of care.

ANGIOPLASTY AND STENTING OF THE COARCT. Balloon dilation and/or stenting of the Coarct were reported in 671 patients (Table 5): 267 infants (39.8%), 300 children (44.7%), and 92 adults (13.7%), but only 12 neonates (1.8%).

The primary indication was reported to be resting gradient in 351 patients (52.4%), hypertension in 143 patients (21.4%), angiographic appearance in 108 patients (16.1%), and ventricular dysfunction or failure in 68 patients (10.2%). The mean systolic gradient ranged from 24.3 mm Hg in neonates to 33.1 mm Hg in infants. Children and adults had similar mean gradients (25.7 mm Hg and 25.8 mm Hg, respectively).

TABLE 5 Coarctation Angioplasty and Stenting Procedures

	Total	Age <30 Days (Neonates)	Age 30 Days to 1 Year (Infants)	Age 1–18 Years (Children)	Age >18 Years (Adults)
No. of procedures*	671	12	267	300	92
Indication	670		266		
Resting gradient	351 (52.4)	6 (50.0)	166 (62.4)	158 (52.7)	21 (22.8)
Hypertension	143 (21.4)	1 (8.3)	17 (6.4)	70 (23.4)	55 (59.8)
Angio appearance	108 (16.1)	2 (16.7)	40 (15.0)	56 (18.7)	10 (10.9)
Ventricular dysfunction/failure	68 (10.2)	3 (25.0)	43 (16.2)	16 (5.3)	6 (6.5)
Pre-procedure systolic gradient, mm Hg	669 28.6 ± 17.4 25.0 (16.0–39.0)	 24.3 ± 18.6 20.0 (13.0–33.5)	265 33.1 ± 19.6 30.0 (18.0–45.0)	 25.7 ± 13.6 24.0 (16.0–33.0)	 25.8 ± 19.0 20.0 (15.0–31.5)
Coarctation treated	670 663 (99.0)	 12 (100.0)	266 266 (100.0)	 294 (98.0)	 91 (98.9)
Technique	663		266	294	91
Balloon	335 (50.5)	6 (50.0)	252 (94.7)	75 (25.5)	2 (2.2)
Stent	251 (37.9)	5 (41.7)	8 (3.0)	171 (58.2)	67 (73.6)
Both	77 (11.6)	1 (8.3)	6 (2.3)	48 (16.3)	22 (24.2)
Post-balloon systolic gradient, mm Hg	334 11.3 ± 10.4 9.0 (4.0–16.0)	5 6.2 ± 5.8 5.0 (3.0–6.0)	252 11.1 ± 10.6 8.0 (3.0–16.0)	75 12.5 ± 10.3 10.0 (5.0–18.0)	2 4.5 ± 0.7 4.5 (4.0–5.0)
<10	170 (50.9)	4 (80.0)	131 (52.0)	33 (44.0)	2 (100.0)
>20	64 (19.2)	0	47 (18.7)	17 (22.7)	
Post-stent systolic gradient, mm Hg	251 5.4 ± 10.9 2.0 (0.1–6.0)	5 4.8 ± 7.1 2.0 (0.1–5.0)	8 3.7 ± 4.2 3.0 (0.6–4.5)	171 4.7 ± 6.5 2.0 (0.1–6.0)	67 7.5 ± 18.3 2.0 (0.1–7.0)
<10	210 (83.7)	4 (80.0)	7 (87.5)	143 (83.6)	56 (83.6)
>20	15 (6.0)	0	0	9 (5.3)	6 (9.0)
Death					
Procedural	1	0	0	1 (vascular)	0
Episode of care	12 (7 cardiac)	2	8 (6 cardiac)	1 (vascular)	1 (cardiac)
AE (any)	663 115 (17.3)	17 6 (35.3)	258 65 (25.2)	296 36 (12.2)	8 (8.7)
MAE	667 8 (1.2)	 3 (17.6)	258 1 (0.4)	 3 (1.0)	 1 (1.1)
Unplanned cardiac or vascular surgery	668 5 (0.7)	0	265 2 (0.8)	299 2 (0.7)	 1 (1.1)

Values are n, n (%), mean ± SD, or median (interquartile range). *Number of procedures reporting this individual data element.
Angio = angiography; other abbreviations as in Table 1.

Angioplasty and/or stent implantation were performed in 663 patients or 99.0% of patients reported for angioplasty or stent implantation. Angioplasty alone was performed in 335 patients (50.5%) including 252 infants (94.7% of the infants). Stent implantation was more commonly performed in children (n = 171, 58.2%) and adults (n = 67, 73.6%). The mean post-angioplasty systolic gradient was 11.3 ± 10.4 mm Hg, whereas the mean systolic gradient post-stent implantation was 5.4 ± 10.9 mm Hg. The median systolic gradients were 9.0 mm Hg in angioplasty patients and 2.0 mm Hg in stent patients.

AEs were recorded in 115 patients (17.3%), MAEs were reported in 8 patients (1.2%), and unplanned surgeries were reported in 5 patients (0.7%). One catheterization laboratory death attributed to a vascular cause occurred in a child, and there were 12 deaths during episodes of care, 7 attributed to cardiac causes.

PA STENOSIS STENTING. Stent implantation to address proximal PA stenosis stenting was reported in 245 patients with biventricular physiology (Table 6). Only 2 were neonates (0.8%), and there were 39 infants (15.9%), 175 children (71.4%), and 29 adults (11.8%).

The primary indication was reported to be resting gradient in 96 patients (39.2%), PA flow discrepancy in 55 patients (22.4%), angiographic appearance in 44 patients (18.0%), right ventricular dysfunction in 39 patients (15.9%), and pulmonary valve insufficiency in 11 patients (4.5%).

Two stenoses (both right and left PA) were present in 42 patients, and 1 stenosis was present in 203 patients. Of 287 total stenoses reported for stent implantation, 285 implantations were successful (99.3%).

The mean ratio of post-stent minimal vessel diameter to pre-stent minimal vessel diameter was 2.1 ± 0.9. This ratio was higher among the younger age groups (1.6 in adults and 2.5 in infants). Side-branch jailing was reported in 30 patients (10.5%).

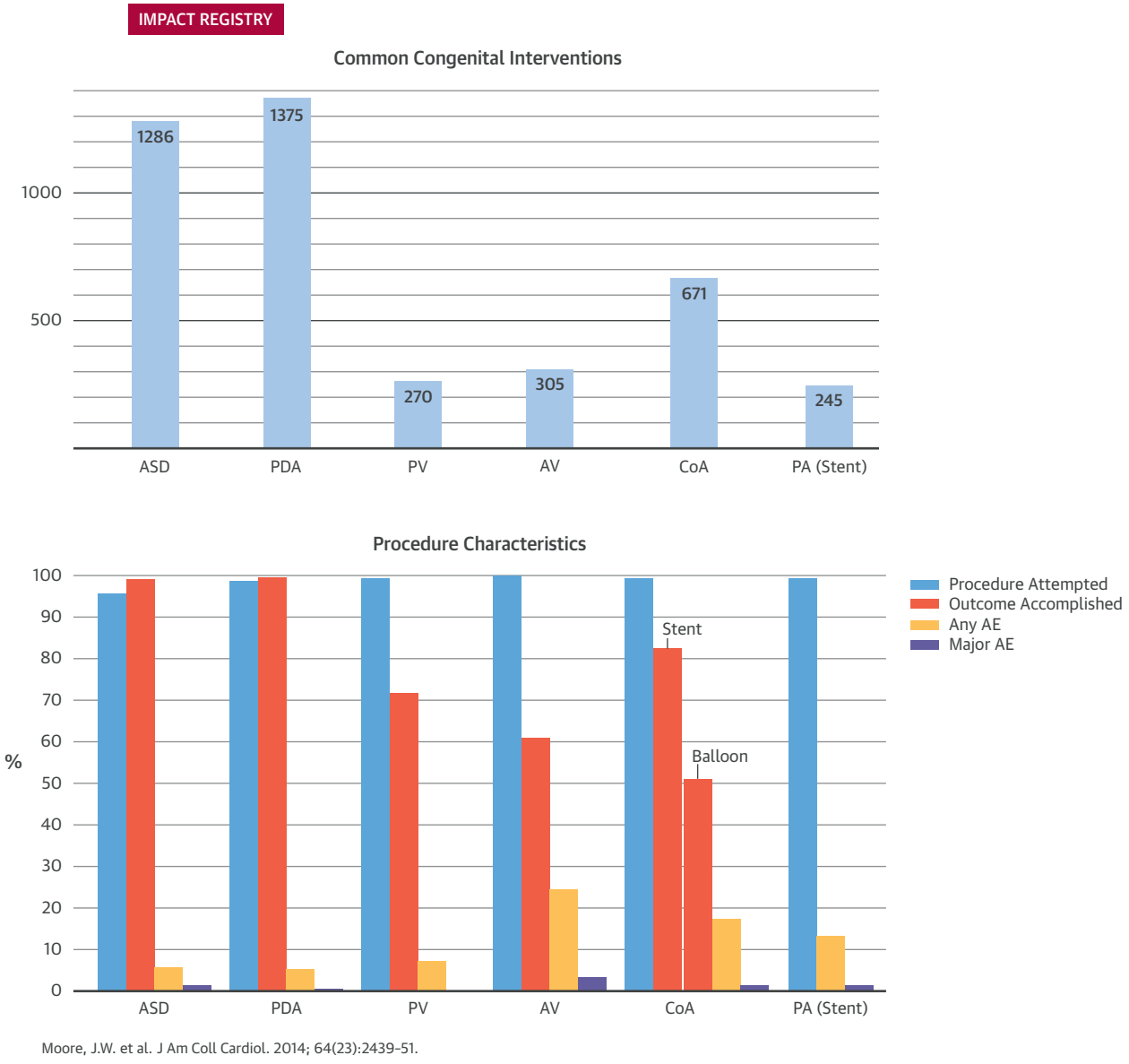
AEs were recorded in 32 patients (13.2%). There were MAEs in 3 (1.2%), and unplanned surgery in 1 patient (0.4%). There were no catheterization laboratory deaths and 3 deaths during the episodes of care, 2 attributed to cardiac causes and none to a vascular cause.

TABLE 6 Pulmonary Artery Stenting Procedures

	Total	Age <30 Days (Neonates)	Age 30 Days to 1 Year (Infants)	Age 1–18 Years (Children)	Age >18 Years (Adults)
No. of procedures*	245	2	39	175	29
Indication					
Resting gradient	96 (39.2)	2 (100.0)	14 (35.9)	68 (38.9)	12 (41.4)
PA flow discrepancy	55 (22.4)	0	10 (25.6)	38 (21.7)	7 (24.1)
Angio appearance	44 (18.0)	0	4 (10.3)	37 (21.1)	3 (10.3)
RV dysfunction/HTN	39 (15.9)	0	10 (25.6)	25 (14.3)	4 (13.8)
Pulmonary insufficiency	11 (4.5)	0	1 (2.6)	7 (4.0)	3 (10.3)
RVSP/LVSP	151 0.6 ± 0.2 0.6 (0.5–0.7)	1 0.8 (0.8–0.8)	20 0.7 ± 0.2 0.7 (0.5–0.8)	114 0.6 ± 0.2 0.6 (0.5–0.8)	16 0.5 ± 0.2 0.5 (0.4–0.6)
No. of stenoses/procedure					
1	203	1	28	149	25
2	42	1	11	26	4
PA stenoses treated	287 285 (99.3)	3 3 (100.0)	50 50 (100.0)	201 201 (100.0)	33 31 (93.9)
Post-/pre-procedure minimal vessel diameter, mm	214 2.1 ± 0.9 2.0 (1.6–2.5)	 2.8 ± 2.3 2.0 (1.0–5.3)	33 2.5 ± 0.8 2.6 (2.0–3.0)	153 2.1 ± 0.9 2.0 (1.5–2.5)	25 1.6 ± 0.6 1.6 (1.3–2.1)
PA side-branch jailing	286 30 (10.5)	1 (33.3)	49 2 (4.1)	24 (11.9)	3 (9.1)
Death					
Episode of care	3 (2 cardiac)	0	2 (1 cardiac)	1 (cardiac)	0
AE (any)	244 32 (13.2)	3 1 (33.3)	38 10 (26.3)	174 16 (9.2)	 5 (17.2)
MAE	3 (1.2)	0	1 (2.6)	1 (0.6)	1 (3.4)
Unplanned cardiac or vascular surgery	1 (0.4)	0	0	1 (0.6)	0

Values are n (%), n, mean ± SD, or median (interquartile range). *Number of procedures reporting this individual data element.
LVSP = left ventricular systolic pressure; PA = pulmonary artery; RVSP = right ventricular systolic pressure; other abbreviations as in Tables 1, 2, and 5.

CENTRAL ILLUSTRATION **Congenital Interventional Procedures and Outcomes**



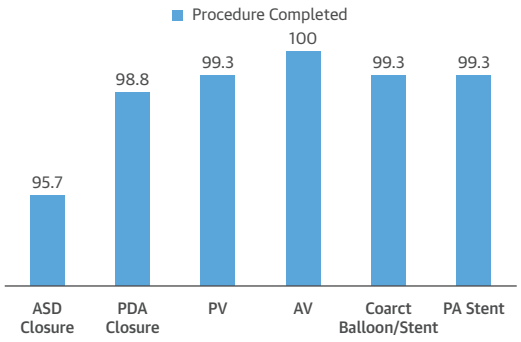
Moore, J.W. et al. J Am Coll Cardiol. 2014; 64(23):2439-51.

The number of isolated common interventional procedure episodes reported to the IMPACT Registry between January 2011 and March 2013, as well as their outcomes. AE = adverse event; ASD = atrial septal defect; AV = aortic valvuloplasty; CoA = coarctation of the aorta; PA = pulmonary artery; PDA = patent ductus arteriosus; PV = pulmonary valvuloplasty.

DISCUSSION

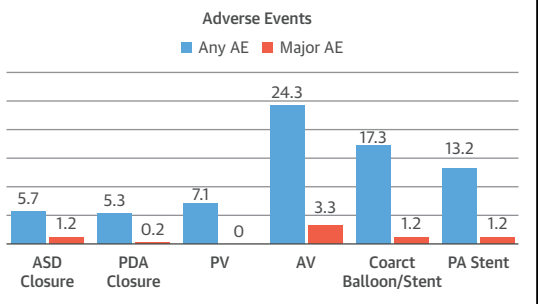
As described here, in only 9 quarters during the Registry's startup, IMPACT accumulated procedural and safety data about large numbers of patients undergoing 6 common congenital interventional procedures (Central Illustration). Percentage of procedures completed and primary outcome accomplished (Figures 1 and 2), as well as AEs (Figure 3) were reported. Numerous earlier single-center reports described only relatively small numbers of patients with procedures performed over fairly extended periods of time. Previous multicenter studies have been more substantial, and some describe datasets comparable in size to the IMPACT data reported here. This discussion briefly reviews these studies, including their procedural/

FIGURE 1 Procedures Completed



Percentages of intended procedures completed: atrial septal defect (ASD) or patent ductus arteriosus (PDA) device or stent implanted, valve, or vessel balloon dilation performed. AV = aortic valvuloplasty; Coarct = coarctation of the aorta; PA = pulmonary artery; PV = pulmonary valvuloplasty.

FIGURE 3 Adverse Events

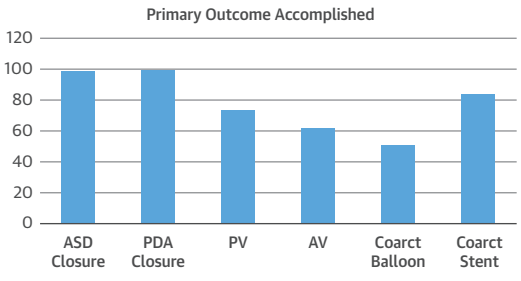


Percentage of procedure episodes having adverse events (AEs); other abbreviations as in Figure 1.

technical elements and AE rates, juxtaposed with IMPACT Registry data. Note that definitions of technical/procedural success and AEs used in the various multicenter studies differ from those in this report.

DEVICE CLOSURE OF A SINGLE ASD. We described procedural elements and safety data for 1,286 patients undergoing ASD device occlusion. Other contemporary registries reported similar data for 478 patients (MAGIC, 12 centers) (10) having ASD closure with the ASO and in 688 patients (C3PO, 8 centers) having ASD closure with a mix of occluders (11). Other substantial multicenter studies include the U.S. Food and Drug Administration (FDA) sentinel studies of the ASO and the HELEX septal occluder. These were prospective follow-up studies, which included patient data to 1 year post-implantation. The ASO study reported data for 442 patients at 29 centers (12), and the HELEX study reported data for 119 patients at 14 centers (13). A successful ASD device implant rate of 95.7% was reported to the IMPACT Registry, similar to procedural success rates of 96% in the MAGIC report, 95% in the C3PO report, and 95.7% (ASO) and 88.1% (HELEX) in the FDA studies. MAE and total AE rates were 1.2% and 5.7%, respectively, in IMPACT patients. These rates compare with 1.1% and 5.9%, respectively, in MAGIC patients and with 4.7% and 11.5%%, respectively, in C3PO patients. AE rates in the FDA studies include events occurring up to 1 year post-implantation. These rates were 1.6% and 7.2%, respectively, in ASO patients, and 5.9% and 33.6%, respectively, in HELEX patients.

FIGURE 2 Procedure Success



Percentage of completed procedures resulting in <3-mm residual leak for ASD and PDA closures, <20 mm residual systolic gradient for PV single balloon, <30 mm residual systolic gradient for AV single balloon, and <10 mm residual gradient for Coarct balloon and stent. Abbreviations as in Figure 1.

DEVICE CLOSURE OF PDA. With regard to PDA occlusion, we described procedural elements and safety data for 1,375 patients reported to the IMPACT Registry. The Michigan PDA Coil Registry, an early attempt to accumulate a large dataset describing use of coils, was not published beyond abstract form. The European PDA Registry retrospectively reported on 1,291 intended PDA coil occlusion procedures from 30 centers. Contemporary registries reported data for 496 patients (C3PO, 8 centers) (14) and for 359 patients (MAGIC, 12 centers) (15). In addition, the FDA study of the Amplatzer Duct Occluder (ADO) was a multicenter prospective study that reported efficacy and safety results for 439 patients enrolled at 25 centers (16). This study also included 1-year post-implantation follow-up data. The FDA sentinel study of the recently approved Nitocclud PDA device included data for 357 patients enrolled at 15 centers, including 1-year follow-up data (17).

Successful PDA occlusion device implantation in 98.8% was reported to IMPACT. In the European Registry, procedure success was 94.3% in patients having a PDA minimal diameter <6.2 mm. The MAGIC and C3PO studies also used both devices and coils, with reported procedure success rates of 99.4% and 96.8%, respectively. FDA sentinel studies for the ADO and the Nitocclud PDA device reported on subsets of larger or smaller PDAs. Procedure success rates in the context of specific PDA size-related selection criteria were 99% in the ADO study and 97.2% in the Nitocclud study. AE rates reported to IMPACT were 0.2% (MAEs) and 5.3% (total AEs). In the European Coil Registry, the rate of suboptimal outcomes (failed procedures and AEs) was 10%. In the MAGIC study, these rates were 2.3% and 4.6%, respectively, and in the C3PO study, these rates were 2.0% and 9.0%, respectively. The FDA studies reported MAE rates of 2.3% and 0 and total AE rates of 7.1% and 4.7% in the ADO and Nitocclud studies, respectively.

PULMONARY VALVULOPLASTY. This report describes 270 patients undergoing balloon valvuloplasty for "typical" pulmonary valve stenosis. The C3PO Registry recently reported similar data for 211 patients from 8 centers (18). Before the C3PO report, the VACA Registry provided the only available (although somewhat dated) multicenter data for 822 patients treated in 26 centers (19). Among IMPACT patients, balloon dilation of the valve was performed in all but 2 patients (99.2%); however, only 73% achieved a residual gradient <20 mm Hg. In the C3PO study, all patients had valve dilation, and 91% achieved procedure success, defined primarily as gradient reduction to ≤25 mm Hg. Similarly, all VACA study patients had valve dilation, but only 91.9% achieved gradient reduction to <30 mm Hg. There were no MAEs reported in IMPACT patients; however, the total AE rate was 7.1%. In C3PO patients, the MAE rate was 3%, and the total AE rate was 12%. The VACA report cited a MAE rate of 0.6% and a total AE rate of 4.5%.

AORTIC VALVULOPLASTY. We described procedural elements and safety information for 305 patients having a single-balloon AV. There are no contemporary multi-institutional reports of balloon AV in pediatric patients or in patients with congenital aortic stenosis. VACA Registry, originally published in 1990, reported data on 204 patients (20). In 1996, an expanded VACA report analyzed 606 patients from 23 participating institutions (21). Except for a small Japanese study (22), the VACA reports provide the only multicenter data available before IMPACT Registry data. Aortic valve dilation was performed in all IMPACT patients; however, only 61.5% of procedures achieved a residual gradient <30 mm Hg. Balloon dilation was not possible in 4.1% of VACA patients. Of those in whom balloon dilation was performed, 83% achieved a residual gradient <60 mm Hg or a residual left ventricular/aorta pressure ratio <1.6. MAEs were reported in 3.3% and AEs were reported in 24.3% of IMPACT patients. In VACA patients, MAE and total AE rates were 5% and 17%, respectively.

ANGIOPLASTY AND COARCT STENTING. We report 671 catheterization laboratory visits for balloon angioplasty or Coarct stenting. Of 663 reported patients, 335 had angioplasty and 328 had either primary stent implantation (n = 251) or stent implantation after balloon angioplasty (n = 77). In 1996, the VACA investigators reported 970 procedures in 907 patients treated with angioplasty in the 1980s and early 1990s (23). A contemporary study, CCISC, reported on 350 patients enrolled from 36 institutions (24), comparing patients having stent implantation (n = 217) with those having angioplasty (n = 61) or surgery (n = 72) to treat Coarct. Balloon dilation and/or stent implantation was performed in 99.0% of IMPACT patients. Among patients having only balloon dilation, 80.9% achieved a residual systolic gradient <20 mm Hg, whereas only 50.9% achieved a gradient <10 mm Hg. In patients having stent implantation, 83.7% had residual gradients <10 mm Hg. In the VACA study, all patients had angioplasty, but only 78% achieved a residual gradient <20 mm Hg. In the CCISC study, 56% of patients having only angioplasty and 76% of patients having stent implantation achieved a residual gradient ≤10 mm Hg. In IMPACT, the reported MAE rate was 1.2%, whereas the reported total AE rate was 17.3%. In VACA patients, the MAE rate was 2.7%, and the total AE rate was 14%. Among CCISC patients, the reported total AE rate for both stent and angioplasty patients was 4%, and no MAEs were reported.

PA STENOSIS STENTING. We describe results from 245 catheterization laboratory visits for placement of 287 proximal PA stents. Historically, there were no multicenter reports describing results of PA stenting procedures. However, the C3PO Registry recently reported data from 8 centers for balloon angioplasty and stenting of branch PAs in 1,314 procedures, of which 335 were proximal PA stents (25). Among IMPACT patients, stent implantation in branch PAs was reported in 99.3%; MAEs in 1.2%, and AEs in 13.2%. In C3PO, among patients having either angioplasty or stent implantation in proximal or more

distal branches, the MAE rate was 10% and the total AE rate was 22%. C3PO did not specify these rates for patients undergoing only stent implantation in proximal branch PAs.

STUDY LIMITATIONS. Weaknesses and limitations of this report reflect those of the IMPACT Registry itself. Data are self-reported and, in this study, unaudited. Self-reporting leads to possible reporting bias and may result in missing data elements and incomplete data for reported cases. The IMPACT/NCDR data quality program prohibits analysis and reporting of cases with inconsistent data and/or with significant missing data. However, cases with 1 or only a few missing data elements may be considered adequate for analysis and are included (9). Although NDCR Data Quality Programs typically include an annual audit, an auditing procedure for IMPACT is still under development. Finally, aside from AEs recorded during the entire episode of care, the Registry does not collect longitudinal data.

CONCLUSIONS

This report provides the first description from the IMPACT Registry of procedural data and AEs in patients undergoing 6 common congenital interventional procedures. This information is both current and broadly representative of community practice. Furthermore, the numbers of patients described in the individual cohorts of this report exceed or rival those reported in other registry and multicenter studies. When IMPACT Registry procedural success and AE rates are juxtaposed with those of other studies, there are some similarities, but also a number of discrepancies, which pose obvious opportunities for future analytic reports from IMPACT.

The data reported here also provide some insights into how commonly the interventions are performed relative to each another and to the total catheterization pool.

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PERSPECTIVES

COMPETENCY IN MEDICAL KNOWLEDGE: Procedures directed at PDA and ASD closure are among the safest and most successful procedures for congenital heart disease in the United States compared with aortic valvuloplasty and coarctation angioplasty and/or stenting, which are generally less successful and are associated with greater risk.

COMPETENCY IN PATIENT CARE: The IMPACT database provides measures and predictors of procedural success that may be considered in evaluating patients with congenital heart disease for common interventional procedures.

TRANSLATIONAL OUTLOOK: Longitudinal data are needed to define the long-term effectiveness, safety, and risk of mortality associated with interventional procedures in patients with congenital heart disease.

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KEY WORDS ASD closure, congenital cardiac interventions, congenital valvuloplasty, large-vessel stenting, PDA closure, registry