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Stefanescu Schmidt, Ada

Armstrong, Aimee

Kennedy, Kevin

et al.

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Original Research

Procedural Characteristics and Outcomes of Transcatheter Interventions for Aortic Coarctation: A Report From the IMPACT Registry

Ada C. Stefanescu Schmidt, MDCM, MSc [a], Aimee Armstrong, MD [b], Kevin F. Kennedy, MS [c], Ignacio Inglessis-Azuaje, MD [a], Eric M. Horlick, MDCM [d], Ralf J. Holzer, MD [e], Ami B. Bhatt, MD [a,*]

[a] Division of Cardiology, Massachusetts General Hospital, Boston, Massachusetts; [b] The Heart Center, Nationwide Children's Hospital, Columbus, Ohio; [c] Saint Luke's Hospital, Kansas City, Missouri; [d] Toronto Congenital Cardiac Centre for Adults, Peter Munk Cardiac Centre, University Health Network, Toronto, Ontario, Canada; [e] Department of Pediatrics, NewYork-Presbyterian/Weill Cornell Medical Center, New York, New York

ABSTRACT

Background: Although surgical repair was the traditional first-line treatment for native coarctation of the aorta (CoA), balloon angioplasty (BA) and stenting are now increasingly being performed. We aimed to determine the practice patterns and acute outcomes of transcatheter interventions for native coarctation in the largest multicenter registry for congenital catheterization.

Methods: CoA interventions from the IMPACT (IMproving Pediatric and Adult Congenital Treatment) National Cardiovascular Data Registry were analyzed. The procedure choice and acute outcomes were compared among patients with no prior interventions on the aortic isthmus (native CoA). Procedural success was defined as no major adverse events (MAEs) and a final peak gradient of <20 mm Hg and optimal outcome as no MAEs and a final gradient of <10 mm Hg.

Results: Over the 8-year study period, 5928 CoA procedures were performed, of which 1187 were performed in patients with native CoA. In this group, stenting was performed in more then half of children aged >1 year and >90% of those aged >8 years. Procedural success was achieved in >90% of stenting procedures but in only 69% of BAs. Stent implantation was associated with a higher likelihood of optimal gradient (<10 mm Hg) after adjustment for age and baseline characteristics. MAEs were most common in children aged <1 year (14%), occurred in 2% to 2.5% of those aged 1 to 18 years and in 6.6% of adults ($P < .001$), and were more likely after BA than after stenting (odds ratio, 0.5; 95% CI, 0.28-0.9; unadjusted $P = .02$).

Conclusions: Catheter interventions for native coarctation are performed safely in older children and adults, with a high degree of immediate procedural success, particularly with stenting.

Introduction

Coarctation of the aorta (CoA), whether treated surgically or through a transcatheter approach, is significantly associated with long-term morbidity and mortality.[1-3] Although surgical repair is usually preferred for infants, balloon angioplasty (BA) and stent implantation are increasingly being performed in older children, with similar effectiveness in some centers,[4] although with a higher risk of requiring reintervention. However, the long-term effects of BA or stenting on vascular mechanics and inflammation are not well known.[5] The incidence of acute aortic wall injury requiring treatment, a complication of BA and of stenting, has been reduced by the introduction of covered stents (which require a larger sheath size), though aortic aneurysms requiring reintervention have also been described after covered stenting,[6-8] in particular, in long-term follow-up.[9] Stent implantation is more often performed in patients weighing >20 kg, although in experienced centers and with favorable anatomy, it has been safely performed in smaller patients[10] to avoid recoil and achieve better postprocedural gradients than those with BA. Retrospective, single-center studies; a prospective registry; and 2 prospective stenting trials suggested >80% procedural success of transcatheter interventions for coarctation (a final peak gradient, or arm-to-leg blood pressure difference, of <10-20 mm Hg, depending on the study), with a 5% to 10% incidence of major complications (aortic wall injury, stent migration or malposition, and access site complications) in selected centers[4,6-8,11-17] and a higher incidence of adverse events in patients with associated defects.[16,18-20]

Abbreviations: BMI, body mass index; CoA, coarctation of the aorta; CHD, congenital heart disease; ECMO, extracorporeal membrane oxygenation; IMPACT, IMproving Pediatric and Adult Congenital Treatment; LVAD, left ventricular assist device; MAE, major adverse event.

Keywords: adult congenital heart disease; aortic coarctation; balloon angioplasty; neonatal interventions; stenting.

* Corresponding author: abhatt@mgh.harvard.edu (A.B. Bhatt).

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We aimed to determine the practice patterns and acute outcomes of CoA interventions in the largest multicenter registry for congenital heart catheterization. In particular, in patients with native coarctation, we compared the patient characteristics and outcomes based on angioplasty and stenting across different weight and age groups.

Methods

The IMPACT (IMproving Pediatric and Adult Congenital Treatment) Registry, developed by the National Cardiovascular Data Registry of the American College of Cardiology in 2011, contains data from >80,000 congenital cardiac catheterizations performed at >120 centers in the United States. We performed a retrospective review of transcatheter interventions for CoA by collecting baseline information, detailed procedural data, and data on postprocedural events at the time of hospital admission (the data elements captured are available at https://cvquality.acc.org/NCDR-Home/Data-Collection/What-Each-Registry-Collects). Versions 1.0 (from January 2011 to March 2016) and 2.0 (after April 1, 2016) of data collection forms were used.

Study population

The inclusion criteria were CoA interventions between January 2011 and 2019 for 2-ventricle circulation with native CoA and no prior aortic arch interventions. Patients who had previously undergone cardiac surgeries (field 3080 in the data collection form) or catheterizations (field 3045) were excluded. The details of the angiographic appearance of coarctation were not available. We excluded infants aged <90 days and weighing ≥1 kg above the 99th percentile for age and those with a final CoA diameter greater than the Boston Z-score[21] of +10; as such, outliers are expected to be erroneous data entries.

Procedure type and end points

In subjects with native CoA, the procedural outcomes were compared based on procedure type and defined as BA alone, BA and stenting, balloon compliance testing and stenting, and direct stenting (stenting without preceding BA or compliance testing). Compliance testing vs BA was defined by the operator. Stents were categorized as bare-metal vs covered based on the reported stent manufacturer and type in field 7135 of the data collection form.

The primary composite outcome of major adverse events (MAEs) during hospitalization was defined as intraprocedural death or cardiac arrest; death in the hospital; an urgent surgery or procedure because of a complication of catheterization; device malposition; thrombosis; embolization requiring retrieval; embolic stroke within 72 hours of the procedure; unplanned need for a left ventricular assist device or extracorporeal membrane oxygenation; or serious vascular events, defined as confined vascular tear, arterial thrombosis or tear with flow obstruction, aortic dissection, or vessel rupture. The cause of the events, particularly in version 1.0, with the exception of an urgent procedure performed because of a complication of catheterization, cannot be attributed to catheterization with certainty. Procedural deaths were defined as deaths occurring on the day of or the calendar day after the index procedure. Procedural success was defined as no MAE and a final CoA peak systolic gradient of <20 mm Hg based on the threshold used in initial studies of coarctation treatment.[4,6,22,23] As a secondary end point that represented the clinical target of gradient reduction more closely, an optimal outcome was defined as no MAE and a final gradient of <10 mm Hg. Pediatric patients were categorized into weight groups (weight <10, 10-20, and >20 kg) because these thresholds are commonly used to determine candidacy for transcatheter interventions and options for vascular access. The predicted risk of the procedure in adolescents and adults was calculated based on the IMPACT risk model.[24] Data on reported indications, procedure characteristics, and hemodynamics were recorded from the coarctation module of the IMPACT data collection forms. Bleeding episodes were defined by the IMPACT data forms as a suspected or confirmed bleeding event associated with a hemoglobin drop of ≥3 g/dL, transfusion, or intervention at a bleeding site (such as angioplasty or surgical exploration).

Statistical analysis

Summary statistics were performed using the *t* test for continuous variables and the χ^2 test for categorical variables. A multivariable model of baseline and procedural characteristics associated with MAEs was developed via stepwise selection, retaining variables with a *P* value of ≤.2. The candidate variables included baseline demographics and procedural indications. All the analyses were performed using SAS, version 9.4 (SAS Institute).

Results

Demographic and clinical data

Over the 8-year study period, 5928 CoA procedures were attempted (Supplemental Table S1). The median age of adults was 30.9 ± 12.7 years, and half of them had undergone prior cardiac surgeries. There were 1187 patients who had not undergone prior cardiac surgery or catheterization, and they were defined as having "native CoA" (Table 1). In patients with native CoA, the indications for transcatheter interventions varied by age and were supported by hemodynamic data. Hypertension was the most common indication in adolescents and adults, and abnormal ventricular function or heart failure was more common in patients aged <1 year. Despite a median age of 34 years, 3.3% of adults were diabetic and 3.8% had renal insufficiency. Antihypertensive medications were prescribed for 2% to 10% of children aged <8 years, 19% of children aged 8 to 17 years, and 53.8% of adults (Table 2). A median of 17 (IQR, 10.6-26.3) total annual CoA procedures were reported by each center (including procedures in patients with recurrent or postsurgical CoA), with a median of 19.2 (IQR, 13.8-26.3) and 19.2 (IQR, 14.5-26.3) for those aged 91 to 365 days and 1 to 7 years, respectively. Many centers joined the registry after 2017, and the volumes at individual centers varied from year to year.

Procedural characteristics

Most procedures in infants aged <3 months were urgent, emergency, or salvage, whereas >95% of procedures in children aged >1 year and in adults were elective. The access site was the femoral artery in 98% of cases overall, with the carotid and umbilical arteries also being used in neonates (13% and 2%, respectively). Most patients were electively intubated for the procedure, although 19.5% of procedures in adults were performed with the patients under conscious sedation (Table 2).

BA alone was the most common procedure in those aged <3 months (73%) and 3 to 12 months (85%) (Central Illustration); 41 children (19%) weighing ≤10 kg and 57 children (43%) weighing 10 to 20 kg underwent stent implantation. Half of patients aged 1 to 7 years and >90% of patients aged >8 years underwent stent implantation as their primary procedure, most commonly, direct stenting with a bare-metal stent (66% of all stents). The prevalence of stenting in the age group of 1 to 7 years increased from 44% in 2011 to 2013 to 63% in 2016 to 2018; in the age group of 8 to 17 years, it remained stable at 91% to 94%. Compliance testing was performed in <6% of stenting procedures overall.

BA alone was performed using 4- to 6-F sheaths in most cases (ranging from 3 to 12 F), with 10- to 12-F sheaths typically used for bare-metal stenting and 12- to 14-F for covered stenting (range, 5-20 F). Of 850

Table 1. Baseline demographics and clinical characteristics of patients with native coarctation of the aorta.

	Total	Age groups					
	N = 1187	≤90 d *n* = 90	91-365 d *n* = 115	1-7 y *n* = 240	8-17 y *n* = 530	≥18 y *n* = 212	*P* value
Female	407 (34.3%)	42 (46.7%)	49 (42.6%)	68 (28.3%)	146 (27.5%)	102 (48.1%)	<.001
Weight							<.001
≤10 kg	213 (18.1%)	89 (100.0%)	112 (99.1%)	12 (5.1%)	0	0	
10-20 kg	132 (11.2%)	0	0	129 (54.4%)	2 (0.4%)	1 (0.5%)	
>20 kg	831 (70.7%)	0	1 (0.9%)	96 (40.5%)	525 (99.6%)	210 (99.5%)	
Age-adjusted BMI							<.001
Underweight	11.7%	71.6%	28.8%	9.7%	1.7 %	4.8%	
Normal	56.3%	22.7%	58.6%	67.5%	62.3%	41.1%	
Overweight	14.87%	3.4%	3.6%	10.1%	14.7%	31%	
Obese	17.2%	2.3%	9.0%	12.7%	21.2%	22.9%	
Shone syndrome	12 (1.0%)	1 (1.1%)	2 (1.8%)	3 (1.3%)	4 (0.8%)	2 (1.0%)	.9
Genetic/congenital condition[a]	37 (3.1%)	6 (6.7%)	7 (6.1%)	6 (2.5%)	8 (1.5%)	10 (4.7%)	.008
Procedure status							<.001
Elective	1053 (88.5%)	32 (35.6%)	62 (54.4%)	232 (97.1%)	519 (97.9%)	202 (96.2%)	
Urgent	109 (9.2%)	40 (44.4%)	44 (38.6%)	7 (2.9%)	10 (1.9%)	8 (3.8%)	
Emergency	22 (1.9%)	13 (14.4%)	8 (7.0%)	0 (0.0%)	1 (0.2%)	0	
Salvage	5 (0.4%)	5 (5.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0	
IMPACT-predicted risk[24]							<.001
Low: <7 points	847 (71.4%)	5 (5.6%)	29 (25.2%)	165 (68.8%)	483 (91.1%)	165 (77.8%)	
Medium: 7-11 points	207 (17.4%)	29 (32.2%)	33 (28.7%)	66 (27.5%)	40 (7.5%)	39 (18.4%)	
High: ≥12 points	133 (11.2%)	56 (62.2%)	53 (46.1%)	9 (3.8%)	7 (1.3%)	8 (3.8%)	
Preprocedural medications							
Anticoagulants	37 (3.1%)	9 (10.0%)	7 (6.1%)	3 (1.3%)	6 (1.1%)	12 (5.7%)	<.001
Antihypertensives	250 (21.1%)	2 (2.2%)	12 (10.4%)	21 (8.8%)	101 (19.1%)	114 (53.8%)	<.001
β-Blockers	111 (9.4%)	3 (3.3%)	5 (4.3%)	9 (3.8%)	43 (8.1%)	51 (24.1%)	<.001
Indication							<.001
Abnormal ventricular function	77 (6.5%)	23 (25.6%)	30 (26.1%)	5 (2.1%)	11 (2.1%)	8 (3.8%)	
Congestive heart failure	25 (2.1%)	9 (10.0%)	11 (9.6%)	3 (1.3%)	1 (0.2%)	1 (0.5%)	
Exercise hypertension	20 (1.7%)	0 (0.0%)	0 (0.0%)	2 (0.8%)	11 (2.1%)	7 (3.3%)	
Systemic hypertension	407 (34.3%)	2 (2.2%)	8 (7.0%)	60 (25.0%)	228 (43.0%)	109 (51.4%)	
High resting gradient	528 (44.5%)	38 (42.2%)	48 (41.7%)	143 (59.6%)	230 (43.4%)	69 (32.5%)	
Angiographic appearance	130 (11.0%)	18 (20.0%)	18 (15.7%)	27 (11.3%)	49 (9.2%)	18 (8.5%)	

Values are n (%). BMI, body mass index; IMPACT, IMproving Pediatric and Adult Congenital Treatment.

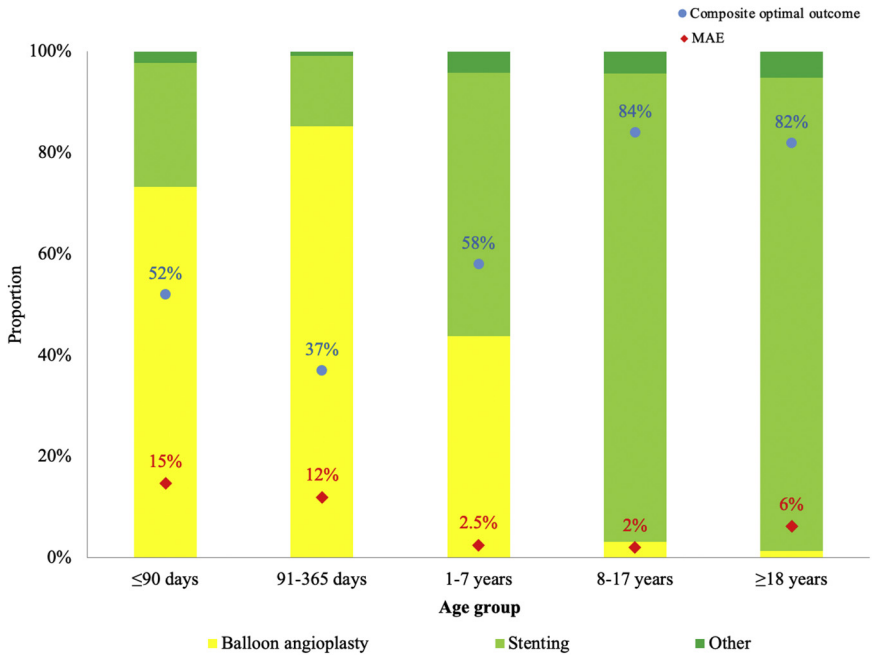
[a] Genetic/congenital conditions in the IMPACT Registry defined as 22q11 deletion syndrome, Alagille syndrome, congenital diaphragmatic hernia, Down syndrome, heterotaxy, Marfan syndrome, Noonan syndrome, congenital rubella, trisomy 13, trisomy 18, Turner syndrome, Williams-Beuren syndrome.

Table 2. Procedural characteristics of patients with native coarctation of the aorta.[a]

	Total *N* = 1187	Age groups					
		≤90 d *n* = 90	91-365 d *n* = 115	1-7 y *n* = 240	8-17 y *n*= 530	≥18 y *n* = 212	*P* value
Conscious sedation with spontaneous respiration	42 (5.7%)	1 (1.6%)	4 (4.7%)	3 (2.0%)	8 (2.6%)	26 (19.5%)	<.001
Elective intubation prior to procedure	1042 (88.8%)	61 (67.8%)	79 (68.7%)	226 (95%)	503 (96.0%)	173 (84.0%)	<.001
Patient intubated prior to arrival to catheterization laboratory	57 (4.9%)	28 (31.1%)	25 (21.7%)	3 (1.3%)	0 (0.0%)	1 (0.5%)	<.001
Procedure type							<.001
Balloon angioplasty only	289 (24.3%)	66 (73.3%)	98 (85.2%)	105 (43.8%)	17 (3.2%)	3 (1.4%)	
Stenting	850 (71.6%)	22 (24.4%)	16 (13.9%)	125 (52.1%)	489 (92.3%)	198 (93.4%)	
Hemodynamic data							
Preprocedural peak CoA gradient, mm Hg	31.6 ± 15.6	29.5 ± 17.7	31.7 ± 19.7	31.5 ± 13.3	31.1 ± 13.3	34.0 ± 19.5	.10
Median preprocedural CoA diameter, mm	4.1 (2.7-7.0)	2.3 (1.6-2.6)	2.5 (1.9-3.2)	3.7 (2.5-5.0)	5.0 (3.2-7.8)	8.0 (4.7-10.0)	<.001
Preprocedural CoA diameter							<.001
<3 mm	330 (28.2%)	70 (78.7%)	79 (62.2%)	78 (33.3%)	88 (16.8%)	25 (11.8%)	
3-5.9 mm	485 (41.5%)	19 (21.3%)	41 (36.9%)	128 (54.7%)	235 (44.8%)	62 (29.4%)	
6-11.9 mm	315 (26.9%)	0 (0.0%)	1 (0.9%)	26 (11.1%)	183 (34.9%)	105 (49.8%)	
≥12mm	39 (3.3%)	0 (0.0%)	0 (0.0%)	2 (0.9%)	18 (3.4%)	19 (9.0%)	
Postprocedure hemodynamics							
Postprocedure peak CoA gradient, mm Hg	6.8 ± 9.8	8.8 ± 6.9	13.5 ± 13.6	10.3 ± 10.7	4.4 ± 7.1	4.7 ± 10.3	<.001
Postprocedure peak CoA gradient							<.001
<10 mm Hg	847 (74.0%)	50 (61.0%)	43 (40.2%)	138 (59.0%)	437 (84.9%)	179 (86.5%)	
≥20 mm Hg	107 (9.3%)	9 (11%)	22 (20.6%)	45 (19.2%)	21 (4.1%)	10 (4.8%)	
Postprocedure CoA diameter, mm	11.5 (7.0-14.6)	4.0 (3.4-4.5)	4.3 (3.6-5.1)	8.0 (6.0-10.0)	13.0 (11.0-15.0)	16.0 (14.0,-18.0)	<.001
Fluoroscopy time, min	18.9 ± 12.2	15.8 ± 10.8	18.1 ± 13.8	17.0 ± 12.6	19.3 ± 11.3	21.7 ± 13.2	<.001

Values are n (%), mean ± SD, or median (IQR). CoA, coarctation of the aorta.

[a] Continuous variables were compared using 1-way analysis of variance, except for postprocedural diameter, which was compared using the Kruskal-Wallis test. Categorical variables were compared using the χ^2 test.



Central Illustration. Procedure type by age in patients with native coarctation. The combined optimal outcomes were procedural success, a final coarctation gradient of <10 mm Hg, and no major adverse events (MAEs).

patients who underwent stent implantation, 180 (21%) received a covered stent; in 155 patients, it was the only stent implanted. Bare-metal stents were used in 80% of stenting procedures, including in 86% to 90% of cases in which BA or compliance testing was also performed. One stent was placed in 93% of patients, with 2 stents in 53 (6%) and 3 or 4 stents in 4 (0.5%) patients. There were only 6 patients with a known aortic aneurysm prior to the procedure, and they were all treated with a covered stent.

Hemodynamic and angiographic data

The median preprocedural gradient was 31.6 ± 15.6 mm Hg, and the postprocedural gradient was 6.8 ± 9.8 mm Hg, with 74% of all patients achieving a postprocedural gradient of <10 mm Hg (Table 2) and 88% of all patients achieving a postprocedural gradient of <20 mm Hg. Despite a lower preprocedural peak aortic gradient, patients who underwent BA alone had, on average, a higher postprocedural gradient than those who received a stent (14.2 vs 4.4 mm Hg in those who underwent BA vs those who underwent stenting, respectively). The postprocedural peak gradient was >20 mm Hg in 25.8% of patients after BA compared with 4% in those who underwent stenting (7.2% for BA and stenting, 0% for compliance testing and stenting, 4.2% for direct bare-metal stenting, and 2.6% for covered stenting, $P < .001$ for comparison across all the groups).

The median preprocedural diameter was 2.3 mm in neonates and up to 8 mm in adults, and the median postprocedural diameter was 4.0 mm in neonates and 16 mm in adults. In 22 infants who underwent stenting, the mean final stent diameter was 4.4 ± 1 mm; bare-metal coronary stents (diameter, 3.5-5 mm), Palmaz Genesis (Cordis), and IntraStent LD (Medtronic) biliary stents were used.

Predictors of procedural success

Thus, the procedural success was overall lower in patients treated with BA alone (68.5%) and >90% in those who received a stent (with the

Table 3. Outcomes in patients with native coarctation of the aorta.

	Total	Age groups					
	N = 1187	≤90 d *n* = 90	91-365 d *n* = 115	1-7 y *n* = 240	8-17 y *n* = 530	≥18 y *n* = 212	*P* value
Composite procedural success (no MAE, postprocedural gradient <20 mm Hg)	1030 (86.8%)	69 (76.7%)	80 (69.6%)	190 (79.2%)	500 (94.3%)	191 (90.1%)	<.001
Composite procedural optimal outcome (no MAE, postprocedural gradient <10 mm Hg)	846 (71.3%)	47 (52.2%)	42 (36.5%)	140 (58.3%)	444 (83.8%)	173 (81.6%)	<.001
Combined MAEs	58 (4.9%)	14 (14.7%)	14 (12.2%)	6 (2.5%)	10 (1.9%)	14 (6.6%)	<.001
Death on the day of or day after the procedure	5 (0.4%)	3 (3.3%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	<.001
Intraprocedural cardiac arrest	6 (0.5%)	4 (4.5%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	<.001
Intraprocedural ECMO	1 (0.1%)	0	0	0	0	1 (0.5%)	.3
Death during hospitalization	20 (1.7%)	10 (11.1%)	8 (7.0%)	0	0	2 (0.9%)	<.001
Other vascular complications requiring treatment	22 (1.9%)	4 (4.5%)	4 (3.5%)	5 (2.1%)	5 (0.9%)	4 (1.9%)	.1
Unplanned cardiac surgery	3 (0.3%)	0	1 (0.9%)	1 (0.04%)	0	1 (0.5%)	.4
Unplanned vascular surgery	11 (0.9%)	1 (1.1%)	0	1 (0.4%)	3 (0.6%)	6 (2.8%)	.027
Bleeding event	36 (3.0%)	2 (2.2%)	2 (1.7%)	2 (0.8%)	18 (3.4%)	12 (5.7%)	.039
Possible aortic injury	16 (1.3%)	0 (0.0%)	5 (4.3%)	3 (1.3%)	3 (0.6%)	5 (2.4%)	.01
Possible access complication	17 (1.4%)	4 (4.4%)	4 (3.5%)	5 (2.1%)	1 (0.2%)	3 (1.4%)	.003

Values are n (%). ECMO, extracorporeal membrane oxygenation; MAE, major adverse event.

Table 4. Predictors of final peak gradient <10 mm Hg.

Risk factors	Univariate OR (95% CI)	Univariate *P* value	Multivariate OR (95% CI)	Multivariate *P* value
Age group			Age (reference group 8-17 y)	
0-3 mo vs 8-17 y	0.24 (0.15-0.37)	<.001	0-3 mo	
3-12 mo vs 8-17 y	0.12 (0.07-0.21)	<.001	1.99 (0.9-4.39)	.09
1-7 y vs 8-17 y	0.67 (0.38-1.17)	.001	3-12 mo	
≥18 y vs 8-17 y	1.17 (0.73-1.88)	.5	0.8 (0.4-1.6)	.5
			1-7 y and weight <20 kg	
Weight			0.7 (0.4-1.2)	.2
10-20 kg vs <10 kg	1.0 (0.64-1.57)	1.0	1-7 y and weight ≤20 kg	
>20 kg vs <10 kg	4.85 (3.46-6.79)	<.001	0.8 (0.4-1.5)	.5
			≥18 y	
			1.15 (0.7-1.9)	.6
Female sex	0.84 (0.64-1.11)	.2		
Nonelective procedure	0.43 (0.29-0.63)	<.001	0.95 (0.5-1.7)	.9
Genetic syndrome	0.53 (0.26-1.07)	.08	0.47 (0.2-1.13)	.09
IMPACT risk score				
Intermediate (7-11) vs low risk (<7 points)	0.46 (0.33-0.64)	<.001		
High (≥12) vs low risk (<7 points)	0.34 (0.23-0.51)	<.001		
Baseline peak gradient (mm Hg)				
20-30 mm Hg vs <20 mm Hg	0.61 (0.38-0.96)	.03	0.39 (0.23-0.68)	<.001
≥30 mm Hg vs <20 mm Hg	0.31 (0.2-0.48)	<.001	0.16 (0.09-0.29)	<.001
Minimal preprocedural CoA diameter (mm)				
3-5.9 mm vs <3 mm	2.41 (1.77-3.27)	<.001	1.68 (1.14-2.48)	.009
6-11.9 mm vs <3 mm	5.95 (3.92-9.02)	<.001	2.02 (1.16-3.51)	.01
≥12 mm vs <3 mm	4.93 (1.87-12.99)	.001	1.29 (0.42-3.96)	.7
Procedure type				
Stent vs balloon angioplasty	9.11 (6.68-12.43)	<.001	12.8 (7.62-21.5)	<.001
Annual center volume of CoA procedures (per y)				
5-10 vs <5	2.03 (1.05-3.93)	.035	1.5 (0.7-3.4)	.3
>10 vs <5	2.47 (1.34-4.53)	.004	2.44 (1.12-5.29)	.02

CoA, coarctation of the aorta; IMPACT, IMproving Pediatric and Adult Congenital Treatment; OR, odds ratio.

exception of 10 patients who received both a covered and a bare-metal stent because 3 out of the 10 patients in that group had an MAE, Table 3). The factors associated with a lower likelihood of achieving a final peak gradient of <10 mm Hg included younger age (<8 years), lower weight (<10 vs >20 kg), nonelective procedures, intermediate or high IMPACT-predicted procedural risk, higher baseline peak gradient (20-30 or ≥30 mm Hg), a minimal CoA preprocedural diameter of <3 mm, BA compared with stenting, and lower annual volume of CoA procedures at the reporting center (<5 cases/y) (Table 4). After adjustment for age, weight, nonelective procedures, genetic syndrome, preprocedural CoA diameter and peak gradient, and annual center volume, stenting remained a strong predictor of achieving a postprocedural gradient of <10 mm Hg (odds ratio [OR], 12.8; 95% CI, 7.6-21.5; $P <$ .001) compared with BA.

Adverse events

The composite MAE occurred in 4.9% of patients after transcatheter intervention for native CoA, with 5 deaths (0.4%) on the day of or the day after the procedure among the 1187 patients (Table 3). There were 3 intraprocedural deaths (0.2%). The mortality rate during the index hospitalization was 1.7% overall but 11% in those aged ≤90 days and 7% in those aged 90 to 365 days (Table 3). Two patients had tamponade and 2 had embolic strokes during the procedure, both aged >18 years. The most common MAE was a vascular complication (1.9%; this did not include bleeding or the need for transfusion) in all the age groups except the age group of ≤90 days. In neonates, the majority of the procedures were performed as emergencies (likely to support hemodynamics as a bridge to another intervention), and in that age group, the most common MAE was cardiac arrest in the catheterization laboratory (occurring in 4.5% of cases). Bleeding episodes occurred more often with increasing age (up to 5.7% of adults). Despite the use of a larger sheath size for covered stent implantation, there were similar access and bleeding complications in the covered vs bare-metal stent groups (1.3% vs 2.3% and 2.6% vs 3.4%, respectively). Balloon rupture occurred in 3% of patients overall but occurred in 8% of those who underwent BA and stenting and 17% of those who underwent balloon compliance testing prior to stenting. In the compliance testing and stenting group, it is not known whether the balloon used for compliance testing was the one to rupture or a balloon used for stent postdilation; this group excluded patients who had primary BA, however. Three out of 559 patients (0.5%) who underwent bare-metal direct stenting had possible aortic injury, and 1 out of the 10 patients (10%) who underwent both bare-metal and covered stent implantation had aortic injury. For this patient, it is not known whether the aortic injury occurred because bare-metal and covered stent implantation was used as a rescue procedure or because of the covered stent itself. Of 41 patients who underwent compliance testing, 1 underwent an unplanned vascular surgery, and no other MAEs were reported. However, 2 out of 86 patients (2.3%) who underwent BA and stenting had a possible aortic complication.

Stenting, compared with BA alone, was associated with a lower incidence of MAEs (OR, 0.5; 95% CI, 0.28-0.88; $P = .016$). However, after adjustment for elective vs urgent/emergency procedure status, age (a higher risk of MAE in those aged <1 year and adults aged >18 years), and a minimal CoA diameter of <3 mm, stenting, compared with BA, was not a significant predictor of MAEs (Table 5).

Discussion

In this retrospective review of the largest national registry of transcatheter interventions for native CoA, successful intervention was safely achieved in the majority of patients aged >8 years, with >83% achieving a composite procedural optimal outcome, defined as a postintervention gradient of <10 mm Hg without MAEs, and >90% having procedural success, defined as no MAEs and a final gradient of <20 mm Hg. Procedural success was achieved in 70% to 80% of neonates and children aged <8 years, but an optimal outcome (<10 mm Hg) was less likely. Although these results certainly support the continued use of transcatheter interventions for native CoA in patients aged >8 years, these should not necessarily discourage the use of the technique in younger

Table 5. Predictors of major adverse events.

	Total cases $N = 1187$	Incidence of MAE $n = 58$ (4.9%)	*P* value	Multivariate OR (95% CI)	Multivariate *P* value
Demographic/clinical predictors					
Weight			<.001		
<10 kg	213	27 (12.6%)			
0-20 kg	128	3 (2.3%)			
>20 kg	846	28 (3.3%)			
Age group			<.001	<1 vs 1-17 y	
<1 y	205	29 (13.6%)		11.9 (4.8-29.4)	<.001
1-17 y	770	16 (2.1%)		≥18 vs 1-17 y	
≥18 y	212	13 (6.1%)		2.8 (1.3-6.0)	.008
Female sex	407	22 (5.4%)	.5		
Nonelective procedure	136	18 (13.2%)	<.001		
Genetic abnormality present	37	3 (8.1%)	.4		
Hemodynamic/anatomic predictors					
IMPACT-predicted risk			<.001		
Low: <7 points	847	26 (3.1%)			
Medium: 7-11 points	207	14 (6.7%)			
High: >11 points	133	18 (13.5%)			
Coarctation peak gradient at baseline			.14		
<20 mm Hg	218	16 (7.3%)			
20-30 mm Hg	427	17 (3.9%)			
>30 mm Hg	529	23 (4.3%)			
Minimum CoA diameter			.11	Diameter <3 vs ≥3 mm	.2
<3 mm	330	21 (6.3%)		0.7 (0.3-1.3)	
3-6 mm	485	25 (5.1%)			
6-12 mm	315	8 (2.5%)			
≥12 mm	39	3 (7.7%)			
Procedural predictors					
Type of procedure			.038	Stent vs balloon for angio	.2
Balloon angioplasty	289	22 (7.5%)		1.7 (0.7-3.9)	
Stent (bare or covered)	850	33 (3.9%)			
Center CoA volume (per y)			.5		
<5	51	1 (2.0%)			
5-10	227	13 (5.7%)			
>10	909	44 (4.8%)			

CoA, coarctation of the aorta; IMPACT, IMproving Pediatric and Adult Congenital Treatment; MAE, major adverse event; OR, odds ratio.

children. Sometimes, a residual peak gradient of 10 to 20 mm Hg is deemed superior to surgical repair, particularly with nonelective catheterization, which occurred in more than half of patients aged <1 year. In addition, postdilation after stent implantation for CoA is sometimes done in a staged fashion to decrease the risk of aortic injury, and an initial residual gradient of 10-20 mm Hg is expected. Our findings could not determine the number of patients aged <8 years who experienced these particular situations. It is important to note that stenting in neonates and infants is usually performed as a bridge to another procedure because the diameter of small stents (coronary stents in particular) cannot be expanded to diameters adequate for aortic size in adults. In this large cohort, balloon compliance testing prior to stenting as well as BA and stenting were quite rare (<7% each). This may have been because of the recognition of the risk of aortic injury with compliance testing[6] and the success of direct stenting techniques.

The indications for intervention in this cohort generally followed the guidelines, with systemic hypertension as the primary indication in up to 40% of adolescents and adults. Of note, fewer than half of these patients were treated with antihypertensives prior to the procedure. Vascular function has been shown to remain abnormal in patients born with CoA despite early correction.[5] Exercise hypertension is correlated with hypertension, as determined via ambulatory blood pressure monitoring.[25] In this cohort, patients in whom exercise hypertension was the primary procedural indication had a similarly high intraprocedural systolic blood pressure under anesthesia but a lower preprocedural peak CoA gradient than patients with resting hypertension. This suggests that vascular tone and reactivity make a greater contribution to the hypertensive response to exercise than anatomic narrowing at the CoA site, in addition to differences in the number, size, and vascular properties of collateral vessels.

In adults, nearly one-fifth had the CoA procedure performed under conscious sedation. In our experience, this can be safely performed under the supervision of a cardiac anesthesiologist, with deep sedation administered at the time of CoA dilation and stent implantation, and with the necessary equipment available for very rare cases in which a complication that requires general anesthesia arises. Conscious sedation for cardiac procedures is associated with shorter and easier recovery[26,27]; intubation and general anesthesia may be preferred if cases in which lateral angiographic view is required for the duration of the procedure (and thus, arms have to be positioned above the head for a longer period of time).

Gradient reduction

A large, recent series of BA as a first-line treatment for native CoA in 68 infants aged 91 to 365 days[4] demonstrated a slightly higher incidence of gradient improvement than our study (88% of their patients had a final gradient of ≤20 mm Hg compared with 74% in 116 patients in our study); in that series, there were 6 patients with identified intimal tears, of whom only 1 required intervention.

The acute gradient reduction reported in the current study is similar to the experience reported by the Congenital Cardiovascular Interventional Study Consortium[14] in 278 patients with native CoA aged 2.5 months to 75 years (mostly treated with bare-metal stents). Higher postprocedure gradients persisted in infants and children aged 1 to 7 years, which may have been because of BA being the procedure of choice in those groups and because a staged approach was chosen with a planned reintervention for the expansion of a stent. Over 85% of adults

who underwent stenting had a satisfactory immediate postprocedure gradient of <10 mm Hg (obtained while still under anesthesia in most cases). Overall, 96% of those who underwent stenting had a final gradient of <20 mm Hg, and 86% achieved a gradient of <10 mm Hg. This real-world experience is similar to single-center experiences.[22] In contrast, the Coarctation of the Aorta Stent Trial,[6] which included 60 patients aged >8 years with native CoA who underwent bare-metal stenting, found a gradient reduction of <10 mm Hg across the stented segment in all the patients, with 7% experiencing serious adverse events (aortic injury or bleeding). However, that series excluded patients with atretic or near-atretic CoA (a preprocedural diameter of <3 mm), which represented nearly one-third of our cohort overall and 12% of adults.

After adjustment for age, weight, preprocedural gradient and diameter, nonelective procedures, and center volume, stenting remained strongly associated with an optimal postprocedural gradient of <10 mm Hg. A recently published, single-center experience (39 patients) showed that stenting could be performed safely, with effective gradient reduction in patients weighing <20 kg with recurrent or native CoA.[10] In our registry analysis, which focused only on native CoA, 41 out of 213 patients (19%) weighing ≤10 kg and 57 out of 132 patients (43%) weighing 10 to 20 kg underwent stenting, potentially representing a shift in practice toward increased use of stenting in smaller patients.

Adverse events

The incidence of MAEs was low, except in the small number of patients aged <90 days and 90 to 365 days, who had high complexity and in whom the procedure was most likely to be urgent, emergent, or salvage. There were several phenotypes of patients across the age spectrum in this registry; most of the patients aged <1 year underwent the transcatheter intervention for CoA as an urgent, emergency, or salvage procedure and experienced high morbidity and mortality during their hospitalization. In contrast, adolescents and adults were most likely to undergo elective procedures, with a high degree of procedural success and a low incidence of MAEs.

However, bleeding events were more common in adults, likely related to more difficult hemostasis due to body habitus, bigger sheath size, and the potential for peripheral arterial disease, which can occur because of atherosclerotic disease and the sequelae of prior instrumentation. The broader availability and increasing use of ultrasound-guided access[28,29] to ensure first-stick, front-wall puncture above the bifurcation of the common femoral artery as well as vascular closure devices may reduce the incidence of bleeding complications,[30] especially in patients in whom stenting and the use of larger sheath sizes are planned. Vascular complications, excluding bleeding, were the most common MAE across the age groups. Despite the use of larger sheath sizes, we did not find evidence of more prevalent acute vascular complications with covered stent implantation, although the incidence of pulse loss and long-term complications, such as claudication or pseudoaneurysms, was not recorded in this registry. Preprocedural computed tomography imaging of peripheral vessels may help in the choice of access site—in particular, in adults who are more likely to have vascular calcification or tortuosity—and is recommended prior to large-bore vascular access for other structural interventions in adults.[31]

Although there were more complications in the bare-metal stent group than in the covered stent group—in particular, aortic wall injury requiring reintervention or surgery—they remained rare; unfortunately, data on anatomic complexity and the preprocedural assessment of the risk of aortic dissection or subclavian artery compromise are not available.

The incidence of MAEs was higher in those who underwent BA alone than in those who underwent stenting because of an increased risk of cardiac arrest and vascular complications. After adjustment for nonelective procedures and minimal baseline CoA diameter, younger age groups remained a significant predictor of MAE, whereas BA had a trend toward higher risk (OR, 1.7; 95% CI, 0.7-3.9; $P = .2$).

Center volume

Patients treated at a center with a higher annual volume of CoA procedures (at the 25th percentile and above), as reported to the IMPACT Registry, achieved a lower postprocedural CoA gradient, including after adjustment for age, elective procedures, genetic syndromes, preprocedural diameter and gradient, and procedure type. However, there were no statistically significant differences between the incidences of MAEs across the groups of annual volume of CoA procedures. This is different from prior reports obtained from the IMPACT Registry and pediatric and congenital heart surgeries recorded in the Society of Thoracic Surgeons database, which showed an association between higher center volume and lower MAEs.[32,33]

Limitations

Participation in the IMPACT Registry is voluntary and, therefore, may present a biased sample. However, based on patient and hospital characteristics, the registry contains a broad and representative set of patients, operators, and procedures. Because it is large, the data quality can vary and errors can have a large impact on rare populations. We chose a stringent definition of native CoA in order to have higher specificity and a homogeneous population for the comparison of angioplasty and stenting for the treatment of native CoA. This resulted in the exclusion of patients with more complex congenital heart disease from this analysis. The studied population was heterogeneous, including a variety of ages, weights, and anatomies, which impacted their procedural risk and characteristics. Anatomic details that are relevant to procedural planning (eg, distance to the subclavian artery and the length of CoA) were not recorded in the database. Only patients who had received a CoA intervention were included in the registry; thus, information on patients who were deemed not to be candidates for transcatheter interventions is not available. Only acute outcomes prior to discharge from the hospital were recorded in this registry. Therefore, the outcomes in patients who underwent other procedures or surgeries during the same admission cannot be attributed to the CoA procedure of interest with certainty, and there is no linkage of patients across repeat procedures or long-term hemodynamic follow-up data. The low incidence of MAEs limited our statistical power to detect associations in a multivariate model.

In conclusion, based on the large, diverse, contemporary registry, transcatheter interventions for native CoA can be performed safely, with a high degree of procedural success, particularly in patients beyond infancy and when stenting is used. Lower postprocedural gradients were achieved with stenting than with BA for native CoA. In this interventional cohort, the importance of acknowledging arterial vascular dysfunction contributing to hypertension in the older population with CoA was evident. The combined rate of MAEs was low, with complex neonatal anatomy demonstrating the highest risk and vascular complications driving adverse events overall.

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Declaration of competing interest

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Ethics statement

This study only involved deidentified patient data and did not require IRB approval.

Supplementary material

To access the supplementary material accompanying this article, visit the online version of the *Journal of the Society for Cardiovascular Angiography & Interventions* at 10.1016/j.jscai.2022.100393.

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