

## Original Article

# Endovascular stent implantation for aortic coarctation: parameters affecting clinical outcomes

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**Abstract:** Objective: To evaluate safety and efficacy of endovascular stenting for aortic coarctation (AC) and to explore the effect of clinical parameters and stent characteristics on outcomes. Material and methods: Clinical data of all patients with AC who had attempted transcatheter stenting between 2004 and 2019 were retrospectively reviewed. Eligible patients had native or recurrent AC with systemic arterial hypertension and resting arm-leg pressure gradient > 20 mmHg. Exclusions included distance between takeoff of cervical arteries and stenotic aortic lesion < 10 mm, contraindication to antithrombotic therapy, bodyweight < 25 kg, and secondary hypertension. Results: A total of 20 patients (75.0% with native lesions) were included with a mean age of 18.4 years and a mean bodyweight of 59.2 kg. Procedure was successful in 90.0% of cases with an immediate drop in the invasive pressure gradient across lesions. On a median follow-up of 12 months (range, 8 to 144.9 months), coarctation reoccurred in five patients, but four of them required intervention after a median of 104.4 months with successful outcomes. Cheatham Platinum stents were significantly associated with lower rates of recoarctations and reinterventions. At the latest follow-up, three out of six patients with persistent hypertension had no recoarctation. Analysis showed that the need for antihypertensive therapy was not influenced by clinical parameters, aortic arch geometry, or stent characteristics. Conclusion: Treating AC with stent implantation is a safe and successful procedure. Using Cheatham Platinum stents appears to be associated with better outcomes. The persistence of arterial hypertension despite successful stenting remains a complex and challenging phenomenon.

**Keywords:** Congenital heart disease, aortic coarctation, stent, outcomes, hypertension

## Introduction

Aortic coarctation (AC) is a relatively common congenital heart disease with male predominance [1]. It can occur as an isolated lesion but is often associated with other heart lesions. The AC is defined as a localized narrowing of aortic lumen commonly located opposite to PDA insertion. Infrequently, it can exist in the transverse aortic arch or be part of a long segment arch hypoplasia. The symptoms of AC depend on the severity of the condition. In some cases, the condition might not be detected until adulthood with hypertension being the usual presentation. The first-line treatment of native or recurrent symptomatic presentations was based on surgery since 1944 [2]. With the

improvements in transcatheter approach, balloon angioplasty, and more recently stent technology, endovascular stenting appears as an attractive less invasive alternative, especially for adolescents and adult patients [3]. Several authors reported that procedural success and long-term outcomes following stent therapy can be influenced by different parameters, yet with many controversial results [4-6]. More recent studies showed that balloon-expandable stents [7], lower body mass index, longer stent length, and Gothic arch geometry [8] were associated with worse procedure outcomes. Therefore, we aim to evaluate our local experience in AC stenting and to explore the clinical and stent characteristics affecting our mid-term outcomes.

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**Figure 1.** 30° Left anterior oblique projection aortography in a 21-year-old patient using a marked pigtail catheter. A. Before stent implantation: normal aortic arch anatomy followed by severely stenotic segment distant from the left subclavian artery. Note the JR catheter positioned in the left pulmonary artery and serving as a benchmark for accurate stent placement. B. A satisfactory anatomical result with no residual stenotic lesion and no parietal complication following implantation of a covered 39 mm long CP stent.

### Methods

#### *Study design and patients selection*

All patients with AC and scheduled for attempted stent implantation at our institution between 2004 and April 2019 were retrospectively reviewed. Collected data included patient demographics, clinical and stent characteristics, and all procedure outcomes until the latest available follow-up. Patients eligible for stent implantation had native or recurrent AC associated with systemic arterial hypertension (highest of 4 limbs non-invasive arterial pressure > 130/80) and a resting non-invasive pressure gradient > 20 mmHg between upper and lower limbs [9]. Excluded patients had one of the following: (1) distance between the takeoff of cervical arteries and stenotic aortic lesion < 10 mm; (2) contraindication to antiplatelet or anticoagulation therapy; (3) body weight < 25 kg; and (4) other etiology of secondary hypertension. Study protocol was reviewed and approved by the institutional research ethics committee on human clinical research. Informed consent was signed by the patients or their legal guardians to perform the procedure after they were provided with a comprehensive explanation about the procedural details, the advantages, and possible complications.

#### *Pre-stenting imaging*

Before the intervention, transthoracic echocardiography (TTE) was performed on all patients

by the same experienced operator. A CT-scan angiogram was performed to assess the geometry of the aortic arch, the site and the degree of the obstruction, and its relationship with the great vessels. Complex anatomy was defined by the presence of one or more of the following criteria: (1) tortuous and/or quasi-atretic AC; (2) close lesion to the cervical arteries; (3) aortic aneurysm; and/or (4) sharply angulated (quasi-perpendicular) aortic arch. Blood pressure was recorded at all limbs and hypertension was defined according to standard recommendations [10, 11].

#### *Catheterization technique*

All interventions were performed by the same experienced operator in the catheterization laboratory under general anesthesia and fluoroscopic control. Prophylactic antibiotic therapy was given. One femoral arterial line was obtained for all patients using a 7-Fr short introducer. A radial artery approach was anticipated in challenging anatomies to cross the lesion from above and for the establishment of radial-femoral arterial rail to control stent deployment. One femoral venous line was obtained to place a Judkins right (JR) catheter (Cordis Corp., USA) in the left pulmonary artery and was used as a benchmark to the site of the coarctation in left anterior oblique projection (**Figure 1A**). After heparinization, a 5-Fr or 6-Fr JR catheter was transarterially introduced to measure the pressure gradient across the coarctation. The

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**Table 1.** Patients' clinical characteristics, n=20

Variable	N (%)
Age groups at procedure	
Pediatric (< 16 years old)	9 (45.0)
Adult (≥ 16 years old)	11 (55.0)
Associated congenital heart defects*	10 (50.0)
ASD	1 (5.0)
VSD	2 (10.0)
BAV	8 (40.0)
Native coarctation	15 (75.0)
Coarctation geometry	
Romanesque	16 (80.0)
Gothic	4 (20.0)
Anatomical case	
Classical	15 (75.0)
Complex	5 (25.0)
Previous surgical repair	3 (15.0)
Previous balloon dilatation	3 (15.0)

\*More than once choice applied. BSA: Body surface area; ASD: atrial septal defect, VSD: ventricular septal defect; BAV: bicuspid aortic valve.

JR catheter was exchanged for a 5F marked (pigtail or Multitrack) angiographic catheter over a 0.035-inch super Stiff J-curved Amplatz guidewire (Boston Scientific Corp., USA). Selective aortographies were adjusted in different projections for optimal measurement of the following structures: (1) diameter of the transverse aortic arch distal to the brachiocephalic artery; (2) diameter of the aorta directly above and below the lesion; (3) length and diameter of the coarctation; (4) distance between the coarctation and the cervical arteries; and (5) diameter of the descending aorta at the level of the diaphragm. The size of the balloon was chosen equal to that of the distal arch just after the origin of the subclavian artery. The stent length was chosen to adequately cover the lesion and if needed to treat isthmus hypoplasia. We preferred bare-metal stents as they are smaller in size (for the same balloon diameter) and to avoid jailing the cervical arteries. Covered stents were reserved for severe coarctation (especially when the selected balloon diameter was 3 times bigger than the narrowest aortic segment) and for aortic aneurysms. Assisted surgical vascular access was needed when 14-Fr was used or 12-Fr in younger patients. Over the wire, the balloon catheter with the stent mounted on it was advanced and positioned across the stenotic segment. The bal-

loon was manually inflated to deploy the stent and eliminate the waist on the balloon catheter. Pressure pullback tracings along with aortography were done to evaluate the results and to rule out aortic wall complications (**Figure 1B**). Procedure was declared successful when residual transaortic gradient was less than 10 mmHg [3]. After achieving femoral hemostasis by manual compression or surgical repair, adequate heparinization was administered for 24 hours. All patients were discharged after an overnight observation except in cases of failed procedures or severe complications. Oral aspirin was prescribed for 6 months. The next day, all patients underwent clinical examination with blood pressure measurement at all limbs, a blood test, and a chest X-ray to detect early complications. A twelve-lead electrocardiogram was done to ensure the sinus rhythm. A TTE was also performed to detect transaortic peak pressure gradient and any other early complication.

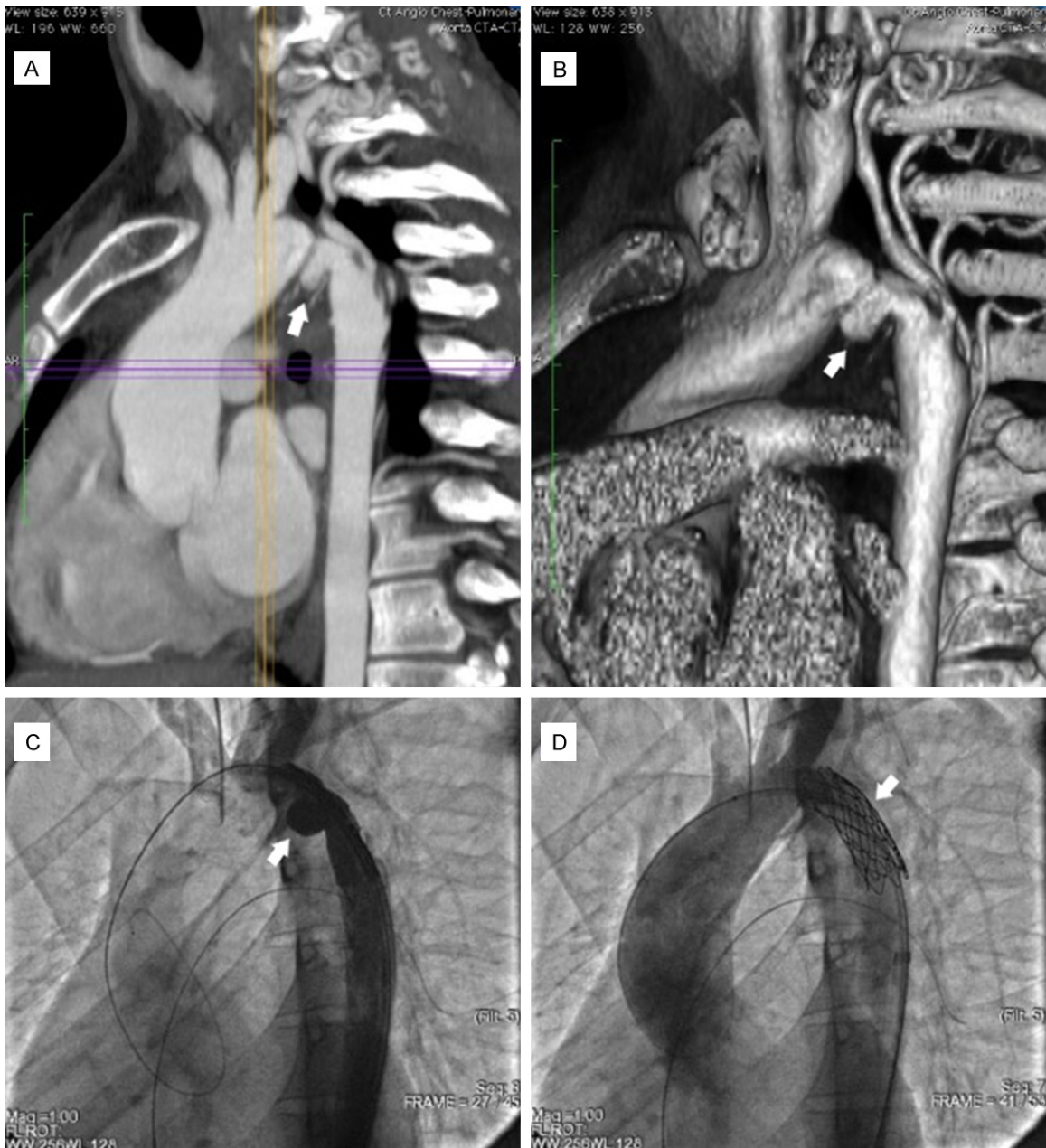
### Follow-up protocol

Routine outpatient follow-ups were scheduled for 1 week then 1, 3, 6, and 12 months post-procedure and thereafter annually. A TTE was performed to detect residual or recurrent coarctation. A CT-scan angiogram was performed in failed or complicated procedures and when a recurrent coarctation was suspected. Blood pressure was assessed before any adjustment or discontinuation of antihypertensive therapy and was measured at all four limbs.

### Statistical analysis

Statistical analyses were performed using the Statistical Package for the Social Sciences Statistics, version 22 for Macintosh (IBM, Armonk, NY, United States). Categorical variables were reported as frequency and percentage. Continuous variables are represented as mean with standard deviation or median with the range depending on the normality of distribution. The normality of measurements was assessed using skewness and kurtosis values and supported by the Shapiro-Wilk test. Statistical analysis for continuous variables was conducted using t-test or ANOVA test and Mann-Whitney U as appropriate and by Fisher's exact test for categorical variables. A *p*-value < 0.05 was considered statistically significant. All reported *p* values are two-sided.

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**Figure 2.** Complex aortic coarctation with very tortuous isthmus. A. Computerized tomography chest scan angiogram. B. Multiplanar reconstruction. C. Injection through the sheath to adjust a stent position upon deployment (30° left anterior oblique projection). D. Aortography after stent implantation with excellent results. Note the absence of parietal complication.

### Results

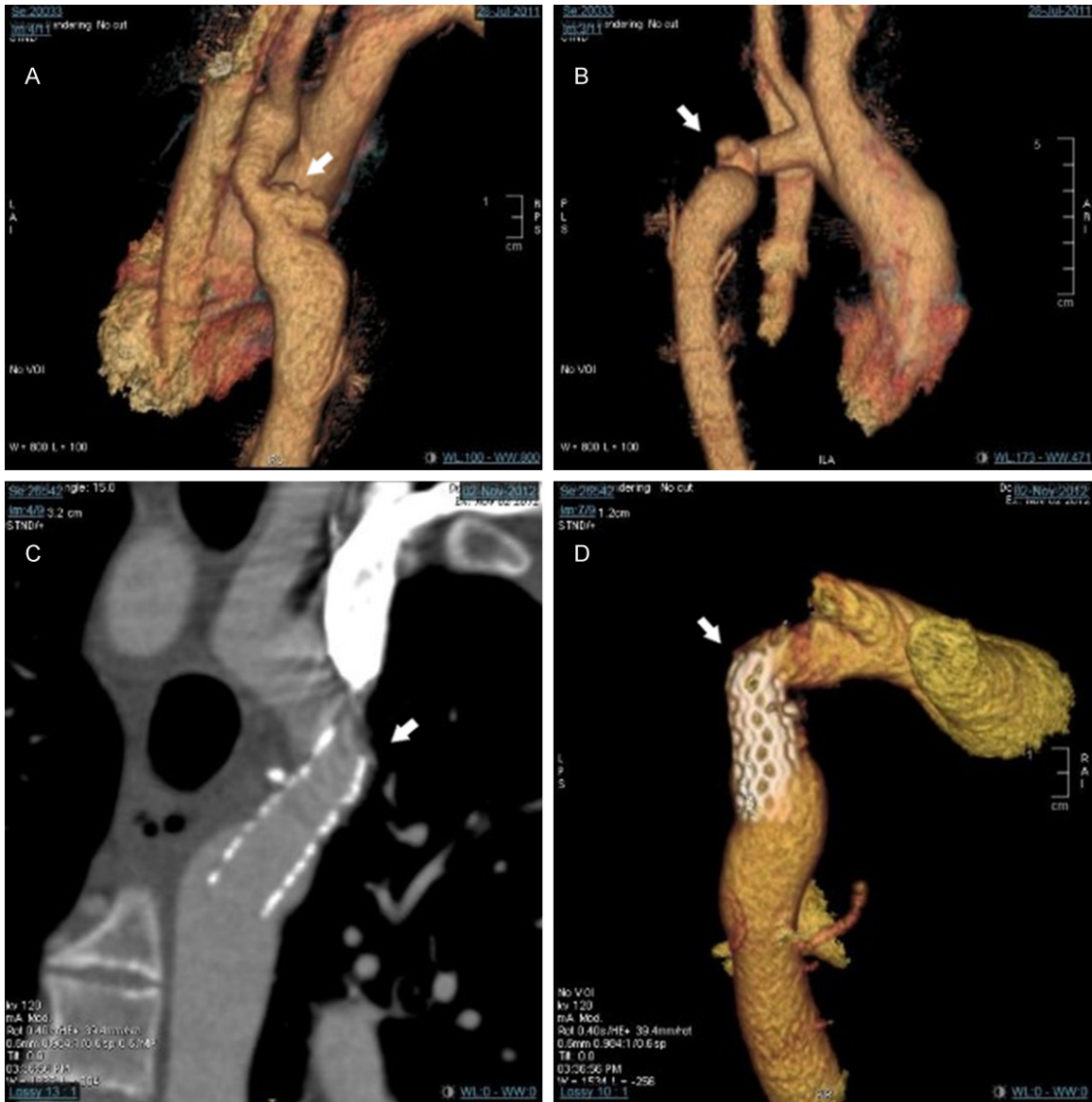
#### *Patients characteristics*

A total of 20 patients (75.0% of males) were identified and included in the study. Demographics and clinical characteristics of the participants are summarized in **Table 1**. At the time of the intervention, patients' mean age was  $18.4 \pm 9.5$  years (range, 3 to 38.9 ye-

ars) and the mean body weight was  $59.2 \pm 19.5$  kg (range, 18 to 100 kg). Five patients presented with complex anatomical cases including a sharply angulated (quasi-perpendicular) aortic arch (n=1), an aortic aneurysm (n=1), a close lesion to the cervical arteries (n=1), and a tortuous and/or quasi-atretic AC (n=2) (**Figure 2**). The procedure was successful in 90.0% of patients and the success rate was higher in



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**Figure 3.** Computerized tomography chest scan angiogram with multiplanar reconstruction. A, B. Severe and short recoarctation with isthmic aneurysm of the posterior wall following surgical repair in a 17-year-old patient and repetitive ballooning. C, D. Same patient. Implantation of a 41 mm long Atrium covered stent premounted on a 14 mm balloon. Note stent displacement in the aortic arch leading to an iatrogenic coarctation.

patients with native AC and classical anatomical presentations. Failure occurred in two patients treated surgically twice before undergoing stent implantation. The first patient was a 17-year-old male who presented with a residual isthmic aneurysm of the aorta's posterior wall (**Figure 3A, 3B**). He was successfully treated using a covered stent but the procedure was complicated with an iatrogenic narrowing at the junction of the aortic arch and the descending aorta (**Figure 3C, 3D**). He underwent surgical

aortic by-pass and remained under anti-hypertensive therapy at the latest follow-up. The second patient was a highly symptomatic six-year-old boy with a 10 mm long quasi-atretic AC. The decision to treat this patient percutaneously was made when a third surgical repair was considered very risky. Although his procedure was declared unsuccessful, the invasive pressure gradient across the lesion dropped from 60 mmHg to 18 mmHg, and the patient became asymptomatic.

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**Table 2.** Procedure-related data, n=20

Variable	N (%) or M ± SD (range)
Assisted (Cutdown) Vascular access	5 (25.0)
Radial artery approach	2 (10.0)
Primary ballooning	1 (5.0)
Stent characteristics	
CP	13 (65.0)
BMS	14 (70.0)
Premounted	5 (25.0)
Stent length (mm)	33.4 ± 7 (20-45)
Stent length indexed to height (mm/m)	20.7 ± 2.9 (14.4-25.7)
Stent length indexed to BSA (mm/m <sup>2</sup> )	21.4 ± 4.4 (13-29.6)
Stent diameter (mm)	14.1 ± 2.8 (8-20)
Total procedural time, sheath in-out (min)	90 ± 24.2 (60-145)
Fluoroscopy time (min), median (range)	11.4 (7.5-31.6)

M ± SD: Mean ± Standard deviation; CP: Cheatham platinum; BMS: bare-metal stent; BSA: Body surface area.

**Table 3.** Procedure outcomes

Variable	N (%) or median (range)
Peripheral artery complication	1 (5.0)
Procedural success	18 (90.0)
Follow-up duration (months)	12 (8-144.9)
Persistent hypertension without coarctation, n=18	3 (15.0)
Recoarctation, n=18	5 (27.8)
Time to re-intervention (months)	104.4 (65-144.6)
Reinterventions, n=18	4 (22.2)
Stent redilatation	4 (22.2)
Re-stenting	--
Surgery	--
Mortality	0 (0)

### Procedure outcomes

Procedure data and outcomes are summarized in **Tables 2** and **3**. An immediate reduction in the median invasive pressure gradient across the coarctation from 50 mmHg (range, 25-70 mmHg) to no gradient (range, 0-30 mmHg) was recorded after stent implantation. In total, 14 stents were bare-metal: 10 Cheatham Platinum (CP) (NuMED Inc., USA), 3 Genesis Cordis (Cordis Corp., USA), and one Cook Formula (Cook Medical, USA). Six stents were covered: 3 CP and 3 Advanta V12 (Atrium Medical Corp, USA). One pseudo-aneurysm formation of the left femoral artery was detected in a 23-year-old patient and was surgically treated without sequelae. On a median follow-up of 12 months,

mild re-coarctation occurred in five patients, but only four of them required intervention and were successfully treated with stent redilatation after a median of 104.4 months. Procedure outcomes and the need for reinterventions were assessed according to the clinical parameters as well as stent characteristics (**Figure 4**). All CP stents were successfully implanted and were significantly associated with lower rates of recoarctations and reinterventions. Before the procedure, all patients had arterial hypertension and seven among them were under anti-hypertensive drugs. This rate progressively decreased after aortic stenting so that only 6/20 (30.0%) patients were still hypertensive at the latest follow-up (**Figure 5**). Among those hypertensive patients, three subjects treated with CP, (bare-metal and hand-mounted) stents did not present any clinical sign of recoarctation. The analysis also showed that the need for antihypertensive therapy was not influenced by clinical parameters or by stent characteristics.

### Discussion

Aortic coarctation is one of the most common congenital heart defects associated with high rates

of morbidity and mortality if left untreated, mainly mediated by uncontrolled hypertension [9]. Percutaneous stent placement had widely replaced traditional open surgery as the first-line treatment of native or recurrent coarctation of the aorta. Yet, many factors that may influence the rates of post-stenting residual hypertension, complications, and morbidity need to be elucidated [3].

In our present study, the implantation procedure was successful in 90.0% of patients. This success rate seems to be similar to the one reported by Bassiri [12] but slightly lower than the one stated by the Congenital Cardiovascular Interventional Study Consortium [13]. A mortality rate of 0.7% was reported in the Valvulo-

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	Procedural success n=20	P	Procedure outcome, n=18			P	Reintervention n=18	P
			RC	HTN without RC	No HTN or RC			
<b>Age groups</b>								
Pediatric patients	8 (88.9)	1.000 <sup>a</sup>	3 (60.0)	1 (33.3)	4 (40.0)	0.827 <sup>a</sup>	3 (37.5)	0.275 <sup>a</sup>
Adults	10 (90.9)		2 (40.0)	2 (66.7)	6 (60.0)		1 (10.0)	
<b>Coarctation type</b>								
Native	15 (100.0)	0.053 <sup>a</sup>	5 (100.0)	2 (66.7)	8 (80.0)	0.540 <sup>a</sup>	4 (26.7)	1.000 <sup>a</sup>
Post-surgical	3 (60.0)		--	1 (33.3)	2 (20.0)		--	
<b>Aortic cross geometry</b>								
Roman	13 (81.3)	1.000 <sup>a</sup>	4 (80.0)	3 (100.0)	7 (70.0)	0.779 <sup>a</sup>	3 (21.4)	1.000 <sup>a</sup>
Gothic	4 (100.0)		1 (20.0)	--	3 (30.0)		1 (25.0)	
<b>Anatomical case</b>								
Classical	15 (100.0)	0.053 <sup>a</sup>	5 (100.0)	3 (100.0)	7 (70.0)	0.375 <sup>a</sup>	4 (26.7)	1.000 <sup>a</sup>
Complex	3 (60.0)		--	--	3 (30.0)		--	
<b>Stent model</b>								
CP	13 (100.0)	0.111 <sup>a</sup>	1 (20.0)	3 (100.0)	9 (90.0)	<b>0.023<sup>a</sup></b>	--	<b>0.002<sup>a</sup></b>
Non-CP	5 (71.4)		4 (80.0)	--	1 (10.0)		4 (80.0)	
<b>Stent type (1)</b>								
Covered	5 (83.3)	0.521 <sup>a</sup>	1 (20.0)	--	4 (40.0)	0.492 <sup>a</sup>	1 (20.0)	1.000 <sup>a</sup>
BMS	13 (92.9)		4 (80.0)	3 (100.0)	6 (60.0)		3 (23.1)	
<b>Stent type (2)</b>								
Premounted	3 (60.0)	0.053 <sup>a</sup>	1 (20.0)	--	2 (20.0)	1.000 <sup>a</sup>	1 (33.3)	1.000 <sup>a</sup>
Hand-mounted	15 (100.0)		4 (80.0)	3 (100.0)	8 (80.0)		3 (20.0)	

CP: Cheatham platinum; BMS: bare-metal stent; HTN: Hypertension; RC: Recoarctation.

<sup>a</sup>: Fisher exact test

Bold values are significant P-values

Figure 4. Distribution of primary outcomes according to the different clinical parameters and stent characteristics.

	Pre-stenting	At discharge	At the latest follow-up
<b>Anti-hypertensive therapy, N (%)<sup>*</sup></b>	7 (35.0)	6 (30.0)	4 (20.0)
Diuretics	1 (5.0)	1 (5.0)	--
CCB	4 (20.0)	3 (15.0)	1 (5.0)
ACEI	2 (10.0)	3 (15.0)	3 (15.0)
ARB	1 (5.0)	1 (5.0)	--
BB	3 (15.0)	4 (20.0)	2 (10.0)
<b>Hypertension, N (%)</b>	20 (100.0)	9 (45.0)	6 (30.0)
<b>Non-invasive SBP (mmHg), median (range)</b>	143 (120 – 200)	130 (103 – 165)	120 (100 – 170)
<b>Non-invasive DBP (mmHg), median (range)</b>	82 (60 – 120)	79 (50 – 100)	60 (50 – 120)
<b>TAG on CUS (mmHg), mean ± SD (range)</b>	64 ± 14 (46 – 98)	24 ± 18 (0 – 74)	22.4 ± 16.8 (0 – 64)

CCB: calcium channel blockers; ACEI: angiotensin-converting enzyme inhibitor; ARB: Angiotensin II receptor blockers; BB: Beta-blockers; SBP: systolic blood pressure; DBP: diastolic blood pressure; TAG: trans-aortic gradient

Figure 5. Evolution of the transaortic gradient, hypertension, and treatment across follow-up.

plasty and Angioplasty of Congenital Anomalies registry and was attributed to patients' comorbidities rather than stenting procedure [14]. Our results were consistent with these findings, indicating that stent implantation is a safe procedure. Several authors reported that aortic stenting success rate could be affected by the aorta's anatomical characteristics [8] and by stenting techniques [7, 15, 16]. Our results showed that all patients with native lesions, and in whom hand-mounted or CP stents were used, experienced successful procedures (Figure 4). Although these findings did not reach statistical significance, we believe that proper patient selection with native and focal coarctation as well as proper stent type could lead to better procedural outcomes [5, 7, 15, 16].

Unsurprisingly, 45.0% of our patients had residual arterial hypertension at discharge date, which is comparable to the rate of residual hypertension in the COAST study [17]. However, on a median follow-up of 12 months, this rate progressively decreased to 30.0% which is quite similar to the one following AC surgical repair [18]. Therefore, we can conclude that following aortic stenting, normal blood pressure status may be achieved during medium-term follow-up [19] since arterial baroreceptors need several months to adapt to the new hemodynamic status achieved after eliminating aortic stenosis [8].

After a successful procedure, recoarctation occurred in five patients (27.8%) and four of them were treated percutaneously with excellent outcomes. We noticed that 80% of this

phenomenon occurred in patients treated with exclusively non-CP bare-metal stents ( $P=0.023$ ). Some studies showed a similar recoarctation rate [20, 21], however, in other ones where covered CP stents were exclusively used, lower rates were reported [15, 22]. The CP stents with the 8-zig conformation are designed to minimize aortic wall injury which makes them the optimal choice for implantation in narrowed segments [15, 23-25]. Additionally, recoarctation occurred more frequently in younger patients and could be related to arterial growth, yet no statistical significance was identified. The median time to reintervention in our population was 104.4 months, similar to other studies [3, 26], indicating that procedure outcomes are sustainable over time, especially in patients treated with CP stents ( $P=0.023$ ) (**Figure 4**). When compared to premounted stents, treating AC using hand-mounted stents significantly decreases post-procedural transaortic invasive gradient from a median of 10 mmHg to no gradient ( $P=0.015$ ). This finding is consistent with the results reported by other studies [27, 28].

Finally, the mean trans-aortic gradient at the last follow-up was  $22.4 \pm 16.8$  mmHg, which is similar to what was found in other studies [23, 29]. On follow-up, we also witnessed that the non-invasive trans-aortic gradient tends to be lower in native lesions, and when CP stents were used. Yet, despite the normalization of the gradient, arterial hypertension was still present in four patients without any sign of clinical recoarctation. This may be explained by the fact that AC is not a focal disease consisting of aortic arch narrowing [14, 30] and could be associated with other aortic and vascular intrinsic factors leading to persistent arterial hypertension even after appropriate treatment [8].

### *Study limitations*

This is a single-center retrospective study with a relatively limited number of patients. Multivariate analysis was not possible and this could be related to unbalanced group sizes.

### **Conclusion**

Stent implantation is a feasible, and safe procedure for relieving aortic narrowing and improving clinical outcomes, with few morbidities. The persistence of hypertension after success-

ful stenting remains the challenge with complex underlying physiopathology and motivates a lifetime monitoring.

### **Disclosure of conflict of interest**

None.

### **Author contributions**

RH designed the study, performed all statistical calculations, analyzed and critically interpreted the results. RH took the lead with IH in writing the manuscript. All authors discussed the results, read and approved the final manuscript.

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