

Stenting Coarctation of the Aorta

Indications, techniques, and outcomes in treating native and recurrent CoA.

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Coarctation of the aorta (CoA) accounts for approximately 5% of all congenital heart disease and is found in approximately one out of 1,500 patients.¹ The first published case describing coarctation was from a 1791 postmortem study performed in Paris;² it was not until 1928 that Abbott published the findings of 200 postmortem cases in patients presenting over the age of 2 years.³ Reifstein et al documented another subsequent series dating from 1928 to 1947, including 104 additional cases of late presentation of CoA.⁴

In 1970, Campbell published the first natural history of CoA with subsequent outcomes, making use of these previously published series.⁵ In his report, he noted the median age for death in all 304 cases was 31 years, with nearly 73% attributed to complications of CoA. Heart failure accounted for 26% of the deaths, spontaneous aortic rupture in 21%, bacterial endocarditis in 18%, and intracranial hemorrhage occurred in just over 10% of patients at a median age of 25 to 29 years in adults.

Campbell also reviewed data from three of the four presurgical case series published between 1933 and 1956. He observed 22 deaths in this patient group, corresponding to a mortality rate of 1.6% per year for the first 2 decades of life, increasing to 6% to 7% for the sixth and subsequent decades. Similar to his previous observations, heart failure was the most common cause of death, followed by bacterial endocarditis and intracranial hemorrhage.

Heart failure secondary to CoA is likely to be caused by left ventricular dysfunction associated with long-standing high afterload. Therapeutic options for CoA include surgery, balloon angioplasty, and stent placement. The data comparing the efficacy and safety between these treatments have been scarce. Therefore, the Congenital Cardiovascular Interventional Study Consortium (CCISC), which is a prospective interventional registry, has made collaborative efforts to gather

these data.⁶ The CCISC has collected the efficacy and follow-up data of three different treatments for CoA and has published several relevant articles on the largest number of patients with CoA.⁷⁻¹⁰

DIAGNOSIS

Systemic arterial hypertension and discrepant upper and lower extremity pulses may trigger the suspicion for the presence of CoA, especially in adults. In patients with systemic arterial hypertension, simultaneous palpation of the brachial and femoral pulses is recommended to search for brachial-femoral pulse delay.¹¹

The blood pressure gradient between upper and lower extremities is critical information to assess the severity of CoA. However, the blood pressure gradient may not accurately reflect the degree of CoA in the presence of sizable collaterals. In patients suspected to have CoA, transthoracic echocardiography is the best choice for initial imaging, although in many cases, echocardiography falls short in accurately delineating coarctation anatomy.

Magnetic resonance imaging and angiography or CT angiography with three-dimensional reconstruction is recommended to delineate the precise location and anatomy of the coarctation segment.¹¹ Cardiac catheterization is considered only if catheter-based intervention is indicated.

INDICATIONS FOR TREATMENT

Indications for treatment typically relate to hypertension, although in many children younger than 12 years of age, CoA is first discovered during workup of a heart murmur. In our experience, patients older than 35 years who present for treatment of CoA have been on antihypertensive medications for an average of 6 years, leading to the eventual discovery of their coarctation. In the vast majority of cases, indication for both discovery and eventual treatment of the coarctation

TABLE 1. AMERICAN HEART ASSOCIATION RECOMMENDATIONS FOR STENT PLACEMENT IN NATIVE AND RECURRENT CoA

Class	Indications
Class I	1. Recurrent CoA with gradient > 20 mm Hg, in which the stent can be expanded to an adult size
Class IIa	1. Native or recurrent CoA, with (a) Gradient > 20 mm Hg (b) Gradient < 20 mm Hg but with systemic hypertension (c) A long-segment CoA with gradient > 20 mm Hg 2. Native or recurrent CoA with failed balloon angioplasty
Class IIb	1. Complex aortic arch obstruction that persists despite surgical or catheter-based therapy, when further surgery is considered as high risk, in neonates and infants 2. Native or recurrent CoA, with (a) Gradient < 20 mm Hg but with elevated left ventricular end-diastolic pressure (b) Gradient < 20 mm Hg with significant aortic collaterals, resulting in an underestimation of CoA

lesion relates to upper extremity hypertension. Other indications for treatment include leg claudication, fatigue, and headaches that are more frequently associated with exercise or activity. Leg claudication occurs in approximately 2% to 5% of patients, especially in patients older than 40 years of age.^{7,8}

A recent American Heart Association scientific statement defined the indication for stent placement in native and recurrent CoA (Table 1).¹² The decision as to which method should be utilized for treatment of coarctation, out of the options of surgical, balloon angioplasty, and stent placement, remains controversial. In the experience of the CCISC, the vast majority would favor either balloon angioplasty or surgical treatment of the coarctation segment in patients weighing less than 25 kg for late-onset CoA (ie, older than 4 years of age).⁹ Once the patient is over 25 kg, opinions are equally divided between balloon angioplasty and transcatheter stent treatment of the coarctation segment, with primary surgical treatment becoming less frequent.

In a recently published study that compared coarctation stenting, surgery, and balloon angioplasty, surgical treatment utilizing resection and end-to-end anastomoses significantly decreased in children older than 8 years of age, becoming < 50% at 12 years of age, with no patient older than 16 years undergoing the classic end-to-end resection of the coarctation segment.⁹ As the patient reaches young adulthood, the aorta becomes less compliant and mobile, and stent therapy becomes the treatment of choice.

TECHNICAL CONSIDERATIONS

This section will primarily discuss the experience of the 44 centers currently participating in the CCISC

and in discussions regarding technical details on stent treatment of CoA over the past 4 years on the CCISC listserv, which includes 205 interventionists from 103 sites. Four hundred seventy-eight stents have been placed—63% for the treatment of native CoA and 37% for recurrent CoA.

We will break this section down into general technical principles and information on how to avoid specific acute complications associated with stent treatment of CoA. This section will mainly discuss stenting native CoA, although the technique in stenting of recurrent coarctation is similar. Furthermore, complications are significantly less in stent treatment of recurrent CoA than what is observed in native coarctation patients.¹⁰

General Principles

Nearly 85% of institutions participating in the CCISC registry place patients under general anesthesia for the procedure, with a threefold increase in the likelihood of encountering an adverse event (primarily stent migration or vascular injury requiring further observation or treatment) in patients undergoing moderate sedation versus general anesthesia for stent treatment of CoA ($P = .055$). Patients are anticoagulated, maintaining an activated clotting time > 250 seconds. Wire placement in the majority of patients is in the ascending aorta or the right subclavian/right common carotid artery.

Balloon types used depend on the initial nominal diameter of the balloon delivery catheter. If the stent was delivered on a < 16-mm-diameter balloon, Z-Med II or BIB balloons (BIB dilatation catheter; NuMed, Inc., Hopkinton, NY) were most commonly used. At diameters > 16 mm, BIB balloons were used nearly exclusively. There have been no differences between balloon types in

TABLE 2. CHARACTERISTICS OF THE MOST COMMONLY USED STENTS IN THE UNITED STATES

	Palmaz P188/308 (Cordis Corporation)	Palmaz 3010/4010 (Cordis Corporation)	Genesis 19/29/39 (Cordis Corporation)	IntraStent LD DoubleStrut (Covidien) 16/26	IntraStent LD Mega (Covidien) 16/26/36	IntraStent LD Max (Covidien) 16/26/36
Nominal expansion sizes	7–18 mm	12–26 mm	5–20 mm	7–20 mm	7–20 mm	9–25 mm
Final wall thickness	0.0055 inch	0.0103 inch	0.0095 inch	0.0076 inch	0.0093 inch	0.0105 inch
Minimal crimp ID	0.093 inch	N/A	0.066 inch	N/A	N/A	N/A
Delivery sheath (5–8 mm)	8 F	10 F	6 F	8 F	9 F	9 F
Delivery sheath (9–12 mm)	9 F	10 F	7 F	9 F	9 F	10 F
Delivery sheath (14–16 mm)	10 F	11 F	8 F	10 F	10 F	11 F
Cell	Closed	Closed	Closed	Open	Open	Open
Predelivery flexibility	None	None	Yes	Yes	Yes	Yes

encountering an adverse event (balloon rupture or stent embolization).

The most commonly used stents are the Genesis XD (Cordis Corporation, Bridgewater, NJ), which made up 40% of the total stents used, followed by the IntraStent LD Mega and IntraStent LD Max (Covidien, Mansfield, MA) at 20%. The advantage of using the Genesis XD stent is its hoop strength (Figure 1) and low profile (Table 2); however, a persistent problem with the Genesis stent has been fracture, with a consistent 4%

to 6% stent fracture rate observed in the treatment of native CoA (Figure 2). Twenty percent of the observed stent fractures required a second stent to be placed, due to reobstruction.⁹

Avoidance of Adverse Events During Stent Implantation

Stent malposition. For the CCISC, stent malposition was defined as misplacement of a stent that required a second stent or separate intervention to be required to completely treat the coarctation segment.

This would include minor stent malposition that required a second stent, or a completely embolized stent that required either a second stent be placed or surgical treatment of the coarctation site. In 2004, the CCISC noted stent malposition in 8% of cases, but over the past 4 years, there has been a notable decrease in stent migration (3.1% per year).⁷⁻¹⁰

In the experience of the CCISC, there are three main scenarios that lead to stent malposition. The primary cause of stent malposition is improper assessment of the coarctation segment. The discrete fold rather than true stenosis was believed to be the cause in more than 70% of stent malposition cases.⁸ We believe that improved angiography and increased use of balloon sizing for suspicious lesions have played the greatest role in decreasing this complication. Others have strongly advocated pacing during

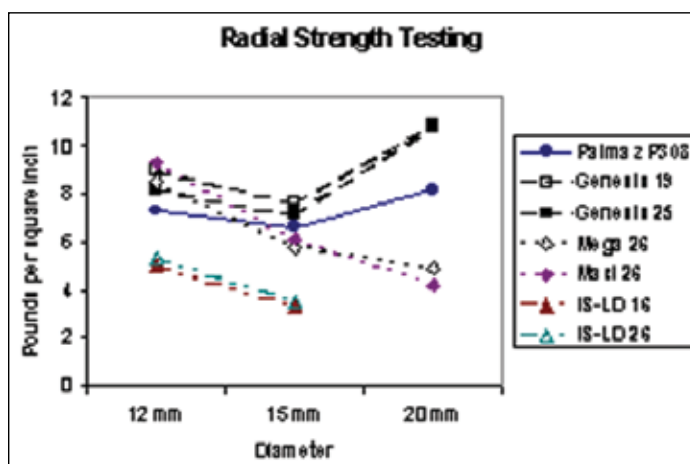


Figure 1. Hoop strength testing of the most commonly used stents for treatment of CoA. Of note, the original IntraStent LD DoubleStrut stents showed in-stent restenosis at 15-mm diameter. We believe that 4 psi (pounds per square inch) of radial force is necessary to maintain complete expansion.

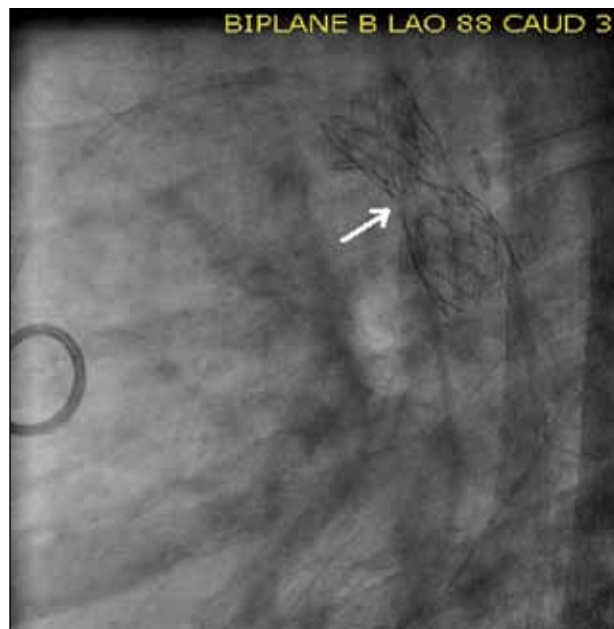


Figure 2. Circumferential stent fracture (arrow) in a Genesis XD stent.

stent deployment. The goal is to decrease the blood pressure by half during pacing. The CCISC has observed no differences regarding stent embolization between institutions that regularly pace and those that do not. The second most common scenario for encountering stent malposition during deployment is balloon catheter migration during inflation distal to the coarctation segment into the midthoracic aorta. The final cause of stent malposition is inadvertent balloon rupture. Although inadvertent balloon rupture was a problem in the 1990s, this has decreased considerably since 2002,⁸ primarily due to improved balloon technology and the rounding of the edges of the second-generation stents that are currently in use.

Finally, as previously mentioned, improved balloon technology has undoubtedly played an important role in the decrease of inadvertent stent malpositioning in treatment of CoA. Controlled deployment of the stent is key to accurately positioning the stent across the coarctation segment. The technique of rapidly inflating the stent across the coarctation segment should be avoided. The BIB balloon allows for controlled stent deployment.

Another method that we use is the delayed sheath retraction technique. In this scenario, the delivery sheath covers up the proximal balloon catheter, causing the distal stent to gradually expand (Figure 3). Once the distal stent is fully expanded, the sheath is pulled off of the balloon catheter, and the remainder of the

balloon catheter is inflated, completely deploying the stent across the coarctation segment.

The delayed sheath retraction technique works well with all bare-metal stents and the covered Cheatham-Platinum stent (NuMed, Inc.); however, the authors and other interventionists have experienced that the Advanta V12 covered stent (Atrium Medical Corporation, Hudson, NH) can slip proximally off the balloon catheter over the delivery sheath with this maneuver. It is also important to attempt to match the balloon catheter length with stent length. We will frequently mount a 26-mm IntraStent LD Max or 29-mm Genesis XD on a balloon catheter that is 2 cm in length.

Acute aortic dissection or rupture. Acute aortic dissection or rupture is exceedingly rare, occurring in 0.4% of stent cases.⁷⁻¹⁰ Aortic compliance plays a role, and so it is the older patient who is at increased risk for encountering acute aortic dissections (Figure 4) and catastrophic aortic rupture.

Determination of aortic wall compliance remains a difficult proposition. Some institutions have advocated performance of balloon compliance testing, which was part of the protocol for the COAST I trial; the national Primary Investigator was Richard Ringel, MD, of Johns Hopkins University.¹³

The development of the staging technique (Figure 5) has helped decrease aneurysm formation at early follow-up (ie, within 6–12 months after stent implantation). Maintaining a balloon:coarctation ratio of < 4 , we believe, decreases the likelihood of encountering aneurysm formation at early and intermediate follow-up, although this remains somewhat conjectural, with further studies being required.

Navigation of Complex Aortic Arch Anatomy

The CCISC's experience, which has been consistent with other single institutions' experience, has been that if the ratio of the transverse aortic arch diameter to the diameter of the descending aortic at the level of the diaphragm is < 0.60 , the transverse aortic arch will need to be addressed at that time. Although certainly not preferred, overlapping of brachiocephalic vessels can be undertaken with minimal risk. The CCISC's experience of more than 100 patients with observed stent overlap of a brachiocephalic vessel is that, in just under 400 patient years of follow-up, neither acute nor intermediate follow-up complications have been observed. There are two case reports that have noted peripheral emboli, stroke events that were believed to have been caused by a stent overlapping a brachiocephalic vessel. In one case, the neurologic event occurred during redilation of the previously placed stent.¹⁴

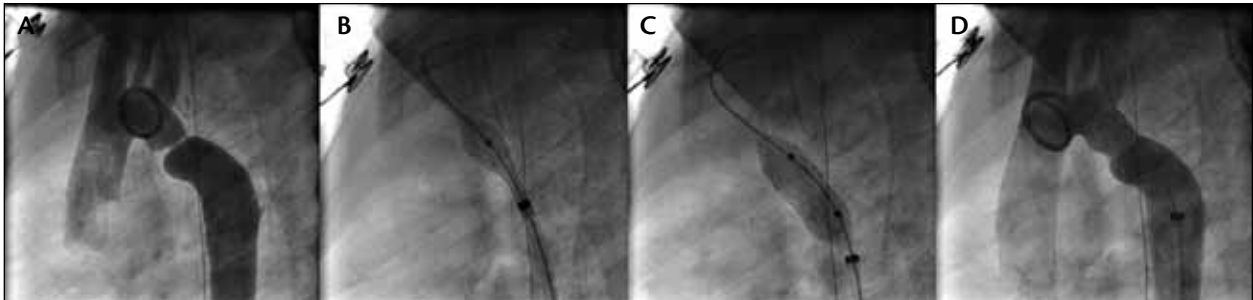


Figure 3. Delayed sheath retraction technique. Discrete coarctation of the aorta is noted distal to the origin of the left subclavian artery (A). The delivery sheath covers up the proximal balloon catheter, causing the distal stent to gradually expand (B). Once the distal stent is fully expanded, the sheath is pulled off of the balloon catheter, and the remainder of the balloon catheter is inflated, completely deploying the stent across the coarctation segment (C). The final angiogram (D).

In situations in which the coarctation segment is directly adjacent to the origin of the left subclavian artery (LSA), Lampropoulos and Gewillig devised an innovative dual-wire technique to ensure that the origin of the LSA would not be compromised during placement of a covered stent.¹⁵ The covered stent is placed on the balloon catheter along with a catheter and wire that overlaps the balloon and stent catheter (Figure 6). Lampropoulos and Gewillig were able to advance a 16-mm balloon with catheter and wire enclosed within a Cheatham-Platinum stent via a 14-F sheath across the coarctation segment. The wire via the 4-F sheath is then guided up into the LSA, with the other wire placed across the aortic arch. After initial dilation of the covered stent, a second balloon catheter is advanced over the second wire into the LSA, and simultaneous dilation of the covered stent is performed, thereby preventing any obstruction to flow into the LSA.¹⁵ This technique is not necessary with a bare-metal stent. In the case of a bare-metal stent extending across a brachiocephalic vessel, some interventionists have advocated using the open-cell IntraStent LD Mega and IntraStent LD Max and performing balloon angioplasty of the overlapped brachiocephalic vessel, thereby dilating the cell of the stent and preventing overlapping of cell strut across the vessel orifice.

OUTCOMES

Although stenting of CoA has been performed over the past 2 decades, few studies directly compare the three treatment modalities of surgery, stenting, and balloon angioplasty. Cochrane Peripheral Vascular Diseases Group performed a systematic review of the literature, attempting to compare surgery versus stent placement for the treatment of CoA.¹⁶ Out of 743 studies, none met their criteria for analysis, concluding that there is insufficient evidence to prove which is the best

treatment and suggesting a need for a prospective, randomized controlled clinical trial.¹⁶ However, a prospective, randomized controlled trial is all but impossible to achieve in the current treatment era. The CCISC has attempted to address this issue through a prospective, nonrandomized clinical trial and has recently come up with some data that we hope will answer the question regarding the safety and effectiveness of stent treatment of CoA.

Holzer et al recently published data from the CCISC regarding acute, intermediate (< 18 months) and long-term (> 18 months) follow-up in patients with recurrent and native CoA.¹⁰ Procedural success has been defined by the CCISC as resting systolic blood pressure and upper to lower extremity blood pressure gradient less than 20 mm Hg, lack of significant recurrent obstruction, and freedom from unplanned repeat intervention. In 302 patients treated with stent placement for CoA, acute, intermediate, and long-term procedural success was 96%, 86%, and 77%, respectively. Acutely, the ratio of smallest CoA diameter to the diameter of the aorta at the diaphragm significantly increased from 0.44 to 0.85 ($P < .0001$), and the systolic blood pressure gradient significantly decreased from 26 mm Hg to 2 mm Hg ($P < .0001$). Recurrent obstruction was seen in 20% of the patients at either short-term or intermediate follow-up imaging, with 12% requiring repeat intervention (elective staged [8%] vs unplanned [4%]). The incidence of acute complications was 5%, including aortic wall complications (1%; dissection [0.5%] and aneurysm [0.5%]), stent malposition (3%), balloon rupture (0.3%), and femoral injury/pulse loss (1%). The incidence of late complications was 3%, including aortic aneurysm (2%) and stent fractures (2%). The incidence of resting hypertension decreased from 77% (pre-stent) to 42% at short-term and 23% at intermediate follow-up. The need for antihypertensive medication decreased from

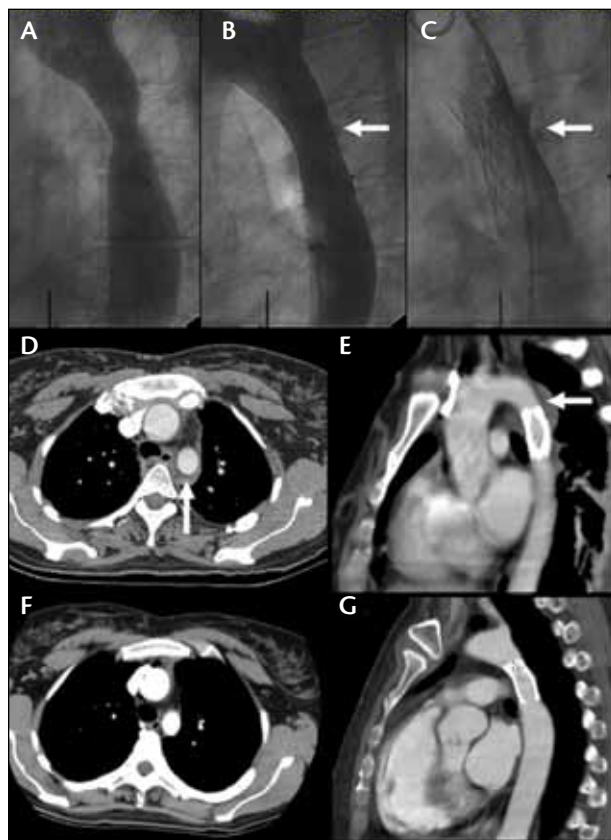


Figure 4. Aortic dissection after stent placement in a 42-year-old woman with native CoA. Angiography (A-C), computed tomography of the chest with contrast (D-G). Prestent angiography (A). The narrowest segment measures 7 mm, with diameter at the diaphragm measuring 15 mm. Poststent angiography (B, C). There is extravasation (A) noted outside the stented aortic wall. The narrowest portion of the stent measures 11 mm. CT of the chest at 24 hours after stent placement (D, E). There is a soft tissue density (arrow) that is circumferential around the stent and extends from the origin of the LSA down to 8 mm below the distal part of the stent, suggesting periaortic wall hematoma. No further intervention was performed, with close observation. CT of the chest at 3 months after stent placement (F). Note resolution of periaortic wall hematoma. CT of the chest at 8 years after stent placement (G). There is no evidence of aneurysm formation.

75% prestent to 32% at intermediate follow-up.¹⁰ The most recent update of 478 patients undergoing stent treatment of their native or recurrent coarctation noted that 38% of patients required antihypertensive medications at intermediate follow-up.

One of the most important findings from Holzer's study is that stent treatment of CoA continues to evolve as a procedure. As mentioned previously, the

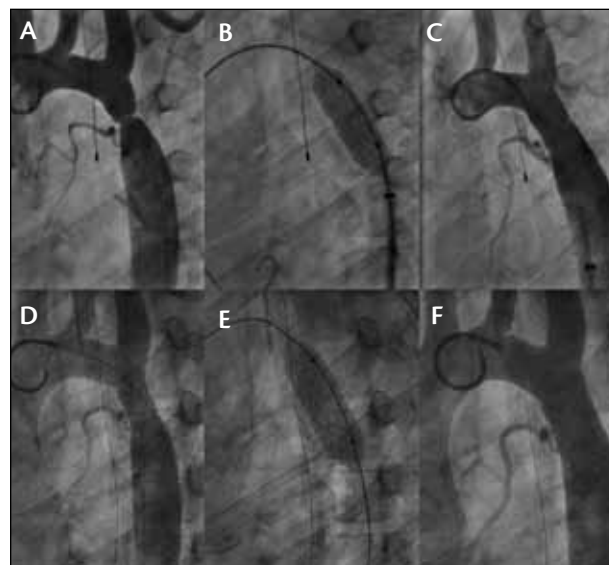


Figure 5. Staging approach. Initial stent placement on coarctation of the aorta at 5 years of age (A-C). Discrete coarctation is noted distal to the origin of the LSA (A). A Genesis XD 25-mm stent was dilated on a 10-mm balloon catheter, resulting in no residual gradient (B, C). Stent dilation at 12 years of age (D, E). Stented coarctation lesion is narrow compared to the transverse arch and descending aorta with somatic growth (D). The stent was dilated on a 14-mm balloon catheter, resulting in no residual gradient (E, F).

acute complication rate was 5% (15/302) in the most recent era (2000–2009).¹⁰ In contrast, the acute complication rate in the previous era (1989–2005) was much higher at 14.3% (81/565).⁷ The main improvement was observed in stent positioning and decreased balloon ruptures. Aortic wall injury, such as dissection, aneurysm formation, and intimal tears, remained consistent between the two studies at 4%.^{7,10}

Due to the persistent 4% intermediate follow-up aneurysm rates observed with stent treatment of CoA,⁸ some interventionists have advocated primary placement of a covered stent.^{17,18} At this time, there are no approved covered stents available in the United States, although the COAST II trial is currently underway to test the safety and efficacy of the covered Cheatham-Platinum stent for the treatment of CoA.¹⁹ Furthermore, the Advanta V12 covered stent trial will hopefully be underway in the United States within the next year.

The safety and efficacy of stent treatment of CoA cannot be fully addressed without considering the other two treatment options, surgery and balloon angioplasty. In December 2011, the CCISC reported the first prospective observational study to compare

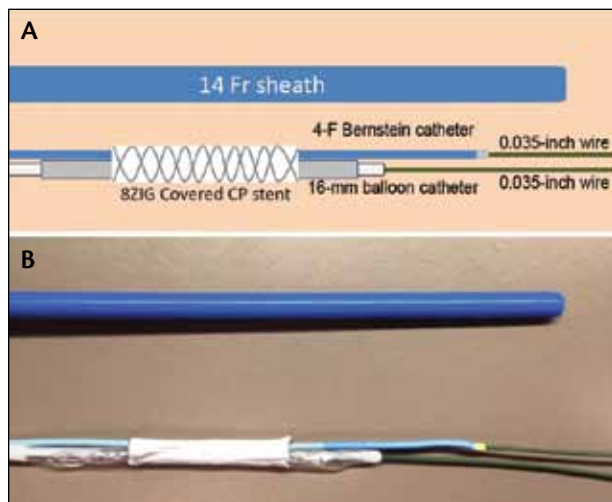


Figure 6. A schematic drawing of a double-wire stent complex (A) and a covered Cheatham-Platinum stent on a 16-mm BIB balloon (9 F plus a 4-F catheter) (B). This complex fits within a 14-F sheath.

the safety and efficacy of surgical, stent, and balloon angioplasty treatment of native CoA acutely and at follow-up.⁹ Between 2002 and 2009, 217 patients underwent stent placement, 61 underwent balloon angioplasty, and 72 underwent surgery. Although all three groups showed significant improvement acutely and at short-term and intermediate follow-up in upper to lower-extremity blood pressure gradient, stent treatment had the lowest acute complication rates between the three treatment modalities (2.3% for stenting, 8.1% for surgery, and 9.8% balloon angioplasty; $P < .001$). Furthermore, stent and surgical therapy achieved better hemodynamic and integrated aortic arch imaging outcomes than balloon angioplasty at short-term and intermediate follow-up. The stent group required planned reinterventions (20%), with no differences among the three groups regarding the need for unplanned reinterventions. In the most recent follow-up of the 478 patients, the aneurysm rate remained at 2.8% and 4.4% at short- and intermediate-term follow-up, respectively. This is similar to our surgical colleagues and significantly less than the balloon angioplasty cohort.

CONCLUSION

Stent treatment of CoA remains an evolving procedure, with significant improvements being observed over the past 2 decades with regard to encountering acute complications. Controversy remains in stenting younger patients (< 25 kg), who will likely require

a planned reintervention within 10 years after stent placement, due to patient somatic growth. Further study is required to determine which patients are at higher risk for aneurysm development at intermediate follow-up. ■

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