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Congenital Heart Disease

CME

Comparison of Surgical, Stent, and Balloon Angioplasty Treatment of Native Coarctation of the Aorta

An Observational Study by the CCISC (Congenital Cardiovascular Interventional Study Consortium)

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Comparison of Surgical, Stent, and Balloon Angioplasty Treatment of Native Coarctation of the Aorta

An Observational Study by the CCISC (Congenital Cardiovascular Interventional Study Consortium)

Objectives The purpose of this study was to compare the safety and efficacy of surgical, stent, and balloon angioplasty (BA) treatment of native coarctation acutely and at follow-up.

Background Controversy surrounds the optimal treatment for native coarctation of the aorta. This is the first multicenter study evaluating acute and follow-up outcomes of these 3 treatment options in children weighing >10 kg.

Methods This is a multicenter observational study. Baseline, acute, short-term (3 to 18 months), and intermediate (>18 months) follow-up hemodynamic, imaging data, and complications were recorded.

Results Between June 2002 and July 2009, 350 patients from 36 institutions were enrolled: 217 underwent stent, 61 underwent BA, and 72 underwent surgery. All 3 arms showed significant improvement acutely and at follow-up in resting systolic blood pressure and upper to lower extremity systolic blood pressure gradient (ULG). Stent was superior to BA in achieving lower ULG acutely. Surgery and stent were superior to BA at short-term follow-up in achieving lower ULG. Stent patients had shorter hospitalization than surgical patients (2.4 vs. 6.4 days; $p < 0.001$) and fewer complications than surgical and BA patients (2.3%, 8.1%, and 9.8%; $p < 0.001$). The BA patients were more likely to encounter aortic wall injury, both acutely and at follow-up ($p < 0.001$).

Conclusions Stent patients had significantly lower acute complications compared with surgery patients or BA patients, although they were more likely to require a planned reintervention. At short-term and intermediate follow-up, stent and surgical patients achieved superior hemodynamic and integrated aortic arch imaging outcomes compared with BA patients. Because of the nonrandomized nature of this study, these results should be interpreted with caution. (J Am Coll Cardiol 2011;58:2664–74) © 2011 by the American College of Cardiology Foundation

The past 5 decades have seen many improvements in therapeutic options for treatment of native coarctation of the aorta in children and adults. The first surgery was performed in 1944 by Drs. Crawford and Nylin, with refinement of surgical technique being accomplished over the past 4 decades (1,2). The transcatheter approach to this lesion was first performed using balloon angioplasty (BA) in the 1980s (3), with intravascular stent treatment gaining wider acceptance in the 1990s (4). At many institutions, the transcatheter approach has become the treatment of choice for children and adults with native coarctation of the aorta (5). Unfortunately follow-up for all 3 types of treatment has been limited, making it difficult to draw any meaningful conclusions as to which treatment option is superior. The issue is further complicated by uncertainty as to what constitutes an acceptable upper to lower extremity systolic blood pressure gradient (ULG) after repair. Although data were collected for both recurrent and native coarctation of the aorta, the main controversy remains as to which treatment should be used for correction of native coarctation of the aorta, which is the focus of this paper. The primary objective of this study is to compare the safety and efficacy of surgical, stent, and BA treatment of native coarctation of the aorta acutely, at short-term and intermediate follow-up.

Methods

Study population and design. This prospective, multi-institutional, observational study included the participation of 36 centers from the Congenital Cardiovascular Interventional Study Consortium (CCISC). A complete listing of

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Abbreviations and Acronyms

BA = balloon angioplasty

BP = blood pressure

Coarct:Dao = ratio narrowest coarctation dimension to aorta dimension at level of diaphragm

CT = computed tomography

MRI = magnetic resonance imaging

OR = odds ratio

TAA = transverse aortic arch

ULG = upper to lower extremity systolic blood pressure gradient

participating centers can be found in the Online Appendix. Treatment options (surgical, stent, or BA) were based on institutional/interventionalist preference. Institutional review board approvals were obtained from each institution before participation in the study. Inclusion and exclusion criteria are summarized in Table 1. Case report forms for the initial intervention, reintervention, and short-term (3 to 18 months) and intermediate follow-up (18 to 60 months) were filled out under supervision of the participating physician and entered directly onto a secure CCISC database. Possible confounders of treatment options including institutional experience, patient age, weight, and coarctation anatomy were evaluated using logistic regression. Follow-up imaging by computed tomography (CT), magnetic resonance imaging (MRI), or catheterization was considered standard of care by participating institutions. All initial, follow-up, and reintervention imaging studies were reviewed by core laboratory physicians.

Data collection. PRE-INTERVENTION DATA. Patient demographics such as age, weight, sex, and associated diagnosis were recorded. Baseline clinical information included upper and lower extremity systolic/diastolic blood pressures (BP), current antihypertensive medications, pre-operative CT, MRI, or catheterization measurements of the long axis of the aorta, coarctation type (discrete vs. long segment), and location.

PROCEDURAL DATA. Type of surgical repair and catheterization pre- and post-intervention hemodynamics in stent patients and BA patients were obtained. If the systolic pressure gradient from ascending to descending aorta post-intervention, measured by direct pullback measurement, was >10 mm Hg, a distal transverse aortic arch BP measurement was recorded to assess potential obstruction at the level of the transverse aortic arch.

The narrowest vessel measurements were recorded in 2 separate projections in antero-posterior/left anterior oblique and lateral view at the transverse aortic arch, coarctation segment, and aorta at the level of the diaphragm. Biplane angiography was performed pre-intervention, and orthogonal views were obtained post-intervention to rule out aortic arch pathology.

DISCHARGE DATA. Discharge date, upper and lower extremity BP, complications, and antihypertensive medications were recorded. Determination for using antihypertensive medications was by institutional preference.

FOLLOW-UP DATA. Imaging studies (MRI, cardiac catheterization, or multislice CT) were performed at short-term and intermediate follow-up. Patient demographics, upper and lower extremity BP, and antihypertensive medications were recorded at time of imaging study.

REINTERVENTION DATA. Indications for reintervention and whether it was planned or unplanned were documented. Hemodynamic and angiographic parameters similar to those obtained during original intervention were recorded.

Definition of coarctation/transverse aortic arch anatomy. Proximal coarctation was defined as a coarctation segment located ≤10 mm from the origin of the left subclavian artery, with distal coarctation being defined as a coarctation segment located >10 mm from the origin of the left subclavian artery. Hypoplastic transverse aortic arch (TAA) was defined as TAA (mm) divided by descending aorta measured at the level of the diaphragm (mm [Dao]) ratio <0.6. Aneurysm was defined as a diameter >20% than the Dao (that is, not considered to be post-stenotic dilation of the aorta) or an abnormal localized enlargement of the aortic segment.

Outcome assessments. HEMODYNAMIC OUTCOME. Systolic BP gradient measured from upper to lower extremities (ULG) at time of discharge, follow-up, and reintervention were used as the primary hemodynamic outcomes. These outcomes were dichotomized using 10 and 15 mm Hg ULG as cut-offs. The systolic gradient measured at coarctation site directly by catheter (ascending to descending aorta) pre- and post-treatment for stent and BA patient groups was also recorded.

ANGIOGRAPHIC OUTCOME. The coarctation repair site dimension was compared to the aortic diameter at the level of the diaphragm (Coarct:Dao). Follow-up outcomes were assessed by MRI/CT or catheterization measurements of the coarctation repair site. For surgical outcome, it is assumed that the initial surgical diameter would be the same as the proximal vessel diameter.

Table 1 Inclusion and Exclusion Criteria

1. Inclusion criteria
a. Body weight ≥10 kg
b. Presence of significant native coarctation based on the following:
1. ULG >20 mm Hg
2. ULG ≥10 mm Hg with either decreased LV function (EF <30%) or moderate to severe aortic insufficiency
3. ULG ≥10 mm Hg plus significant collateral flow
2. Exclusion criteria
a. Body weight <10 kg
b. Refusal to sign consent
c. Requiring other surgical procedures that would entail correction of the coarctation segment in the same setting
d. Known or suspected arteritis
e. Recurrent coarctation of the aorta

EF = ejection fraction; LV = left ventricular; ULG = upper to lower extremity systolic blood pressure gradient.

SAFETY ENDPOINT. Safety endpoints were death, aortic wall injury, other procedural complications, and unanticipated reintervention acutely and at short-term and intermediate follow-up.

REOBSTRUCTION. A filling defect within a previously placed stent was considered neointimal proliferation. Reobstruction of the coarctation repair site was deemed mild (<10% narrowing of vessel/stent lumen), moderate (11% to 30% narrowing), or severe (>30% narrowing).

POST-OPERATIVE HYPERTENSION. Definition of severe post-operative/post-interventional hypertension was persistent systolic BP ≥95% for the patient's height and weight lasting >48 h after initial intervention and requiring intravenous medical therapy.

CORE LABORATORY ASSESSMENT. All imaging data were reviewed at 1 of 4 core laboratory centers: Nationwide Children's Hospital, Columbus, Ohio; National Children's Medical Center, Washington, DC; University of Texas Southwestern Medical Center, Dallas, Texas; and Penn State University, Hershey, Pennsylvania.

Statistical methods. To compare patient baseline characteristics among treatment groups, chi-square tests or analysis of variance along with Tukey's multiple comparison tests were used. Association between various patient characteristics and outcomes was assessed using chi-square or Fisher's exact tests and analysis of variance. Multinomial logistic regression was performed to identify factors affecting treatment choices to be used in multivariate adjustment when comparing outcomes between treatment arms. Logistic and linear regressions were performed to compare outcomes between treatment groups while adjusting for confounders. The log-rank test was used to compare time to unplanned reintervention among the 3 treatment groups. Subgroup analysis limiting patient age to between 6 and 12 years was conducted to confirm results obtained in larger samples. Any p value <0.05 was considered statistically significant, and SAS version 9.2 software (SAS Institute, Cary, North Carolina) was used for all analyses.

Results

In all, 350 patients were enrolled between June 1, 2002, and October 31, 2010, from 36 institutions; of those patients, 217 underwent stent, 61 underwent BA, and 72 underwent surgical repair of their native coarctation segment.

Procedural technique. Seventy-two patients underwent surgical repair of coarctation. Sixty-three percent underwent end-to-end anastomosis repair, 17% tube graft interposition, 14% patch angioplasty, and 6% subclavian flap repair. Two hundred seventeen patients underwent 236 stent procedures. Nineteen patients required a second stent, due to stent migration in 6 patients or to cover the entire coarctation segment in the remaining patients.

Baseline characteristics. Table 2 compares baseline patient characteristics among the 3 treatment groups. Patients undergoing stent treatment were significantly older and weighed more than those undergoing BA or surgical treatment (p < 0.001). Stent patients had a significantly smaller

Table 2 **Baseline Characteristics**

	Surgery (n = 72)	Balloon (n = 61)	Stent (n = 217)	p Value (2-Sided)
Age, yrs	10.0 ± 9.7	9.0 ± 8.0	16.6 ± 10.9	<0.001*
Age range, yrs	0.1/58.6	0.4/42.5	2.2/74.3	
Weight, kg	35 ± 24	30 ± 21	55 ± 24	<0.001*
Male	69%	64%	69%	0.750
Pre-intervention right-arm SBP, mm Hg	137 ± 19	138 ± 23	143 ± 21	0.061
Pre-intervention ULG	37 ± 21	43 ± 23	40 ± 24	0.399
Pre-intervention catheterization SBP gradient	NA	38.7	36.7	0.459
Pre-intervention coarctation measurement, mm/BSA	NA	5.8	4.3	0.001*
Coarctation location				0.212
Isthmus	86%	95%	90%	
Distal	56%	63%	71%	
Proximal	31%	32%	19%	
Transverse aorta	7%	2%	8%	
Complex	5%	2%	1%	
Abdominal/thoracic aorta	0%	2%	1%	
Bicuspid aortic valve	40%	46%	40%	0.708
Other CHD diagnosis	13%	5%	9%	0.308
Catheterization laboratory patient volume				0.090
Large	60%	67%	66%	
Medium	14%	23%	19%	
Small	26%	10%	15%	

Values are mean ± SD, min/max, and %. *p < 0.05.
BSA = body surface area; CHD = congenital heart disease; NA = not available; SBP = systolic blood pressure; ULG = upper to lower extremity systolic blood pressure gradient.

pre-intervention coarctation measurement to body surface area ratio than the BA patients ($p < 0.001$). No coarctation measurement was available for surgical patients. Catheterization laboratory patient volume had no correlation with treatment option. There were no other anatomic, clinical, or demographic differences among the 3 groups. In a multinomial logistic regression, age and weight were found to be the only 2 significant confounders ($p < 0.001$) of treatment choice. Pre-intervention coarctation measurement was not entered into the regression because it was not available for surgical patients.

Acute hemodynamic and angiographic outcomes. Hemodynamic outcomes were assessed by the pre-intervention and discharge ULG measured noninvasively. All 3 treatment modalities showed a significant decrease in the pre- versus post-intervention ULG. Table 3 depicts the mean ULG for the 3 groups, as well as ULG at cut-offs of 10 and 15 mm Hg. A significant difference was observed between stent and BA groups ($p = 0.032$). Using a cut-off gradient of 10 mm Hg, stent remained superior to BA ($p = 0.005$) and trended toward superiority to surgery in univariate analysis. When controlling for age and weight in multivariate analyses, the stent group remained superior to BA in achieving lower gradient ($p = 0.008$), with no differences observed between stent and surgery. The post-intervention catheterization systolic gradient from ascending to descending aorta was significantly higher in the BA group than in the stent group ($p < 0.001$), with multivariate analyses confirming the univariate results.

Comparing measurements of the coarctation segment, significant improvement was observed in both the BA group and the stent group after intervention. However, the percent improvement in measurement was significantly higher in the stent group in both univariate ($p = 0.008$) and multivariate analysis ($p = 0.01$).

Acute adverse events. No deaths occurred in any group. Complications associated with BA patients were primarily related to aortic wall injury. Both the surgical group and BA group had a greater likelihood of encountering complications than the stent group ($p < 0.001$) (Table 3). Surgical complications included spinal injury (n = 1), which was observed in an 8-year-old child with remaining deficits over 3 years out from the procedure, sustained post-operative atrial fibrillation (n = 2), severe post-operative hypertension (n = 2), prolonged pleural effusion (n = 3), vocal cord paralysis (n = 1), and left facial paresis with complete recovery noted 2 months later. In the stent group, 1 patient had a large femoral hematoma, and 3 patients experienced stent migration during the procedure. When comparing the risk of all complications between treatment arms while adjusting for confounders, stent was safer than BA (odds ratio [OR]: 5.72; 95% confidence interval: 1.59 to 20.52; $p = 0.008$) and surgery (OR: 11.23; 95% confidence interval: 3.66 to 34.51; $p < 0.001$). Lastly, surgical patients had a longer mean length of hospital stay as compared with stent patients.

Follow-up outcomes. The mean follow-up (using the latest follow-up time) was 1.9 years (range 0.1 to 5.8 years) in 68% of the stent patients, 2.1 years (range 0.07 to 9.09 years) in 77% of the BA patients, and 1.9 years (range 0.1 to 9.7 years) in 81% of the surgical patients. No deaths were reported. All patients described in this section underwent follow-up imaging per study protocol with no clinical concerns expressed by the attending cardiologist that prompted the imaging studies.

Table 3 Acute Outcomes

	Surgery (n = 72)	Balloon (n = 61)	Stent (n = 217)	p Value (2-Sided)
Post-intervention right-arm SBP, mm Hg	123 ± 13	118 ± 15	125 ± 15	0.002*
Discharge ULG	7.7 ± 18.2	10.3 ± 12.9	4.9 ± 13.2	0.032
Discharge ULG ≤10 mm Hg	64%	56%	76%	0.011*
Discharge ULG ≤15 mm Hg	73%	69%	81%	0.101
Post-intervention catheterization SBP gradient	NA	12.4 ± 12.2	4.8 ± 8.6	<0.001*
% Increase in coarctation measurement post-intervention	NA	125%	172%	0.008*
Any complications	18.1%†	9.8%	2.3%	<0.001*
Aortic wall injury	UK‡	9.8%	0.0%	<0.001*
Dissection/intimal tear	UK‡	9.8%	0.0%	
Aneurysm	UK‡	0.0%	0.0%	
Balloon rupture	NA	0.0%	0.5%	
Stent migration	NA	n/a	1.4%	
Femoral	UK‡	0.0%	0.5%	
Atrial fibrillation	3%	0%	0%	
Severe/prolonged hypertension	3%	0%	0%	
Length of stay, days	6.4/5.0	3.6/1.0	2.4/1.0	<0.001*

Values are mean ± SD, %, or mean/median. *$p < 0.05$. †Complications experienced by surgical patients are severe hypertension, atrial fibrillation, pleural effusion, neurological/spinal cord injury, chylothorax, and vocal cord paralysis. ‡Unknown (UK), as these types of complications are not routinely evaluated for surgical patients.

Abbreviations as in Table 2.

Table 4 Short-Term Follow-Up Outcomes

Outcomes	Surgery (n = 52)	Balloon (n = 37)	Stent (n = 125)	p Value (2-Sided)
Age at follow-up, yrs	12.1 ± 10.9	10.4 ± 9.2	17.2 ± 10.1	<0.001†
Weight at follow-up, kg	41.3 ± 30.6	34.4 ± 22.4	59.3 ± 21.9	<0.001†
Normal SBP*	84.6%	72.2%	87.2%	0.096
Antihypertensive medications	40%	16%	41%	0.019†
Right-arm SBP, mm Hg	114 ± 17	118 ± 14	121 ± 13	0.005†
ULG	1.2 ± 21.5	9.9 ± 16.8	0.9 ± 13.9	0.011†
ULG ≤10 mm Hg	89%	35%	75%	<0.001†
ULG ≤15 mm Hg	91%	65%	86%	0.004†

Values are mean ± SD or %. *Defined as <97.5 percentile SBP of normal subjects (age and sex adjusted). †p < 0.05.
Abbreviations as in Table 2.

Short-term follow-up. We defined short-term follow-up as any clinical evaluation and/or integrated imaging between 3 and 18 months from the initial procedure. A total of 125 stent, 37 BA, and 52 surgical patients underwent short-term follow-up evaluations; of these, 78%, 75%, and 50% underwent integrated imaging, respectively.

HEMODYNAMIC OUTCOMES. There were no significant differences in percent of patients with normalized BP at short-term follow-up among the 3 treatment groups, although the BA group showed a trend toward having the lowest percent of patients with normalized systolic BP (Table 4). Patients undergoing stent or surgical repair were more likely to be taking antihypertensive medications than BA patients ($p < 0.019$). Logistic regression adjusting for antihypertensive medications showed that BA patients continued to have the lowest percent with normal systolic BP. The adjusted difference was significant between BA patients and stent patients (OR: 0.292; $p = 0.011$), but not between BA and surgical patients (OR: 0.365; $p = 0.072$). Univariate and multivariate analysis showed a significant advantage of the surgical group and stent group over the BA group in achieving ULG ≤10 ($p < 0.001$) and ≤15 mm Hg ($p = 0.004$) (Table 4).

INTEGRATED IMAGING OUTCOMES. The mean Coarct:Dao ratio was significantly higher in the surgical patients versus the BA patients ($p = 0.015$), with no differences in achieving Coarct:Dao ratio >0.60 among the 3 groups (Table 4). Aortic wall injury was significantly greater in the BA group than in the stent group (21.4% vs. 3.1%; $p = 0.004$), primarily because of aneurysm formation (Table 5). In all BA patients, and in all but 1 stent case, the aneurysms were localized to the area of coarctation. In 1 stent case, the aneurysm was observed just proximal to the previously placed stent (Fig. 1A), with progression observed at follow-up, and was treated with a covered stent (Fig. 1B and 1C). All other aneurysms post-transcatheter intervention are small (<5 mm) and localized. Surgical aneurysms were observed with the subclavian flap and patch onlay techniques and tended to be more diffuse (Fig. 2A and 2B). Multivariate logistic regression indicated that the stent group was significantly less likely to encounter aortic wall injury than the BA group (OR: 0.08; 95% confidence interval: 0.02 to 0.39; $p = 0.002$), with no differences observed between the surgical group and stent groups.

Angiographic reobstruction was noted with equal frequency in all 3 treatment groups, with BA showing the greatest propensity toward developing reobstruction at short-term follow-up (Table 5). Mild stent restenoses were secondary to stent recoil (EV3 stents) in 2 and moderate restenosis secondary to stent fracture (Genesis XD stent) in 1 patient.

Intermediate follow-up. We defined intermediate follow-up as any clinical evaluation and/or integrated imaging between 18 and 60 months from the initial procedure. A total of 77 stent, 25 BA, and 23 surgical patients underwent intermediate follow-up evaluation. Of these, 73%, 64%, and 70% underwent integrated imaging studies, respectively.

HEMODYNAMIC OUTCOMES. There were no significant differences in resting hypertension among the 3 groups; however, the BA group trended toward having higher percent of hypertension than the stent and surgical groups (Table 6). Logistic regression adjusting for antihypertensive medications indicated that BA patients continued to have the lowest percent of normalized BP. The adjusted difference was significant between BA and surgical patients (OR:

Table 5 Short-Term Follow-Up Outcomes by Integrated Imaging

Outcomes	Surgery (n = 26)	Balloon (n = 28)	Stent (n = 97)	p Value (2-Sided)
Any complications*	23.1%	32.1%	8.3%	0.003‡
Aortic wall Injury	11.5%	21.4%	3.1%	0.004‡
Dissection/intimal tear	0.0%	7.1%	0.0%	0.062
Aneurysm	11.5%	14.3%	3.1%	0.040‡
Coarct:Dao ratio, mean	0.91	0.73	0.82	0.003‡
Coarct:Dao ≥0.6	87.0%	79.0%	90.0%	0.247
Any reobstruction	19.2%	32.1%	15.4%	0.057
Mild†	7.7%	17.9%	11.3%	
Moderate	7.7%	3.6%	4.1%	
Severe	3.9%	10.7%	0%	

*Defined as any moderate to severe reobstruction, aortic wall injury (aneurysm, dissection, intimal tear) or stent fracture. †Mild reobstruction was not considered as a complication in our analysis. ‡p < 0.05.
Coarct:Dao = narrowest coarctation dimension (mm)/the dimension of the descending aorta at the level of the diaphragm (mm).

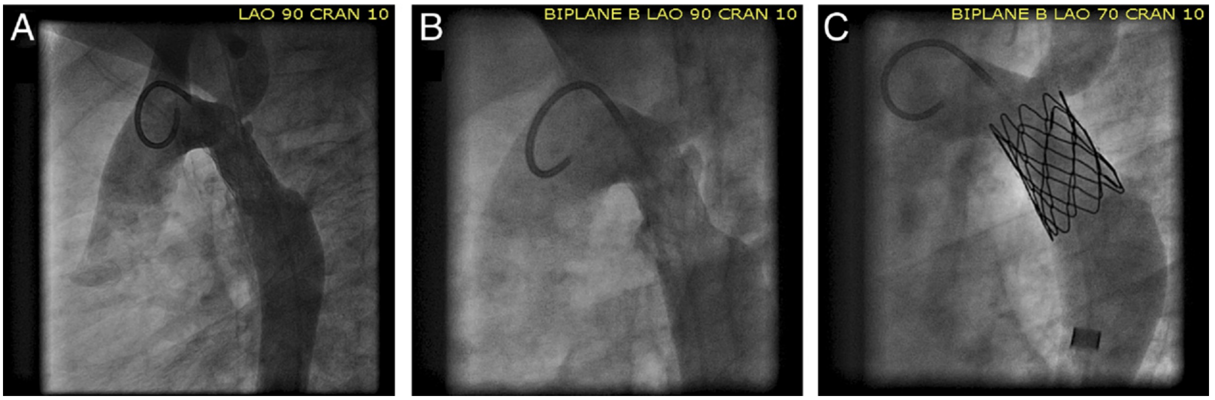

Figure 1 **Stent-Related Complication**

(A to C) Figure 1A depicts a small localized aneurysm in the proximal stent 4 years after initial stent placement. Progression was observed in aneurysm size depicted in Figure 1B at 8-year follow-up which required covered Cheatham-Platinum stent placement which is noted in Figure 1C.

0.117; $p = 0.05$), with no differences observed between BA and stent patients (OR: 0.581; $p = 0.309$). When comparing mean ULG among the 3 treatment groups, no significant differences were found, although when using a cut-off of 10 mm Hg, the surgical group showed an advantage over BA ($p = 0.030$).

INTEGRATED IMAGING OUTCOMES. The mean Coarct:Dao ratio in surgical patients was significantly higher than in the BA patients or stent patients ($p = 0.011$), with no differences in percent achieving Coarct:Dao ratio >0.60 among the 3 groups (Table 7). Aneurysms were more common in BA patients ($p < 0.001$), with no progression in aneurysm size observed in any patient at a mean follow-up of 24 months (range 18 to 64 months). Re-intervention due to aneurysm formation was required in 1 stent patient. A small aneurysm was observed 4 years out from the procedure, with an interval increase in aneurysm sized observed 8 years out from initial stent placement which required placement of a covered stent (Figs. 1A, 1B, and 1C).

Reintervention. Fifty-four patients had reinterventions performed at a mean of 1.7 years after the initial procedure. These were further divided into anticipated and unanticipated reinterventions (Table 8). Anticipated reinterventions were performed either because of a staged approach or secondary to patient somatic growth. Except for the stent aneurysm case noted above, unanticipated reinterventions were due exclusively to reobstruction, with no differences observed among the 3 groups. The primary reason for unanticipated reintervention in the stent group was secondary to neointimal proliferation in 6 patients and stent

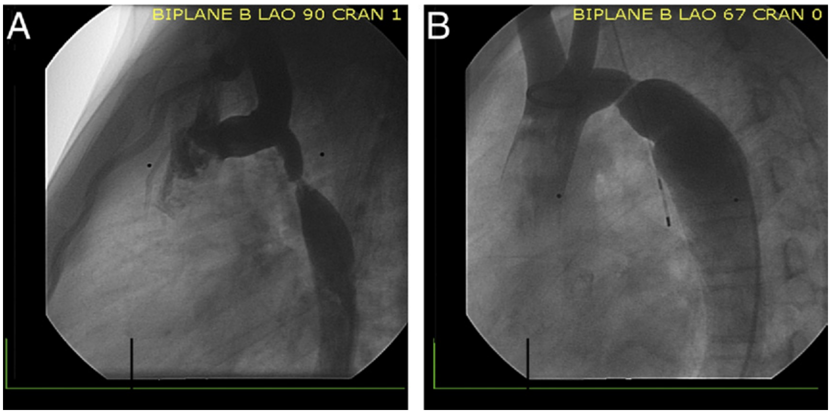

Figure 2 **Pre-Surgical Native Coarctation of the Aorta and Post-Surgical Aneurysm**

(A) Pre-surgical coarctation segment in a 3-year-old child is shown. Severe discrete coarctation with isthmus hypoplasia is observed. Numerous intercostal collaterals are present, with no post-stenotic dilation of the descending aorta observed. **(B)** Angiogram shows aneurysm formation 3.5 years out from the surgery, with the repair site measuring 2.7 cm, and the aorta at the level of the diaphragm measuring 1.8 cm. There was recoarctation at the distal transverse aorta, which was subsequently stented at this catheterization.

Table 6 Intermediate Follow-Up Outcomes

	Surgery (n = 23)	Balloon (n = 25)	Stent (n = 77)	p Value (2-Sided)
Age at follow-up	15.0 ± 11.2	12.9 ± 6.5	18.3 ± 9.8	0.035†
Weight at follow-up	57.4 ± 22.4	40.3 ± 16.2	60.8 ± 18.6	<0.001†
Normal SBP*	96%	72%	82%	0.092
Antihypertensive medications	13%	16%	31%	0.130
Right-arm SBP, mm Hg	115 ± 9	122 ± 13	123 ± 13	0.044†
ULG	−1.4 ± 13.9	5.5 ± 14.3	1.9 ± 13.7	0.118
ULG ≤10 mm Hg	90%	55%	75%	0.032†
ULG ≤15 mm Hg	95%	82%	85%	0.421

Values are mean ± SD or %. *Defined as <97.5 percentile SBP of normal subjects (age and sex adjusted). †$p < 0.05$.
Abbreviations as in Table 2.

fracture (Genesis XD stent) in 2 patients. The need for reintervention both in the BA group and the surgical group was secondary to recurrent scarring at the coarctation site, with the majority being treated with stent placement. Mean Coarct:Dao ratios were calculated for pre-intervention (0.25), immediate post-intervention (0.66), pre-reintervention (0.59), and post-reintervention (0.85). Analyses determining statistical differences between treatment groups were not performed because most of the reinterventions observed were planned and the number of unanticipated reintervention was extremely small.

Subgroup analysis. Subgroup analysis restricting patients' age to 6 to 12 years was conducted (Table 9). The ULG measured immediately after the procedure remained significantly lower in the stent and surgical patients when compared with BA patients ($p = 0.050$). The overall acute complication rate was significantly higher in BA and surgical patients ($p = 0.035$). When examining short-term follow-up outcomes, the surgical group remained superior in achieving a lower ULG compared with the BA group ($p = 0.004$). Stent and surgical repair continued to show a higher percentage of patients with normal BP when compared to BA patients. Short-term follow-up complication rates (both overall and aortic wall) remained lower in the stent group versus the BA group. No statistically significant differences in short-term follow-up complication rates were observed between the BA group versus surgical group or between the stent group versus surgical group, most likely because of the small sample size. There was no correlation between age and antihypertensive medication use observed in this subgroup analysis. Analysis describing intermediate-term follow-up outcomes are not presented here because of relatively small sample size.

Table 7 Intermediate Follow-up Outcomes by Integrated Imaging

	Surgery (n = 16)	Balloon (n = 16)	Stent (n = 56)	p Value (2-Sided)
Any complications*	25.0%	43.8%	12.5%	0.020‡
Aortic wall injury	12.5%	43.8%	7.1%	0.003‡
Dissection/intimal tear	0.0%	6.3%	1.8%	0.598
Aneurysm	12.5%	43.8%	5.4%	<0.001
Coarct:Dao ratio, mean	0.98	0.79	0.80	0.011‡
Coarct:Dao ratio ≥0.6	88%	93%	89%	1.000
Any reobstruction	18.8%	18.8%	14.3%	0.923
Mild†	6.3%	18.8%	12.5%	
Moderate	6.3%	0%	1.8%	
Severe	6.3%	0%	0%	

*Defined as any moderate to severe reobstruction, aortic wall injury (aneurysm, dissection, intimal tear) or stent fracture. †Mild reobstruction was not considered as a complication in our analysis. ‡$p < 0.05$.
Coarct:Dao = narrowest coarctation dimension (mm)/the dimension of the descending aorta at the level of the diaphragm (mm).

Discussion

Coarctation of the aorta comprises 4% to 5% of all congenital heart defects. Native coarctation has historically been treated by surgery. Recently, transcatheter approaches have been increasingly refined, in part because of increased operator experience, and also because of improved balloon and stent technology, which has translated to improved safety and success of these procedures. As a result, numerous institutions have reported success with transcatheter treatment of native coarctation (5–7). Controversy has surrounded the growing trend to treat native coarctation of the aorta by the transcatheter route. Analyzing prior studies to evaluate a superior treatment to this disease has been difficult due to the majority of series having low volumes and inconsistent follow-up. In our review of the literature, there were only 3 studies that directly compared surgery to BA (8–10), and none compared surgery to stent treatment of aortic coarctation. Cowley et al. (9) noted that at follow-up, the BA group showed a significantly greater propensity for aneurysm formation and need for reintervention in comparison to surgery, with our study supporting their contention regarding aneurysm formation but not the need for reintervention. The remaining comparative studies noted inconsistent follow-up. Ours is the first multi-institutional observational study that attempts to answer which treatment option for the treatment of native coarctation of the aorta in patients weighing >10 kg is optimal. In our study, surgical and BA patients were significantly younger and of lower weight than patients undergoing stent treatment, with no other anatomic, clinical, or demographic differences observed among the 3 groups.

Regarding the surgical group, it was surprising with regard to the number of patients who underwent tube graft

Table 8 Reintervention

	Surgery (n = 72)	Balloon (n = 61)	Stent (n = 217)
Patients with reintervention	4	6	44
Patients with planned procedures	0	2	35
Patients with unplanned procedures	4	4	9
Time to first planned reintervention, yrs	NA	1.43 ± 1.70	1.14 ± 1.15
Time to first unplanned reintervention, yrs	2.24 ± 2.23	1.28 ± 1.43	2.84 ± 1.43

Values are n or mean ± SD.
NA = not available.

interposition or patch angioplasty of the coarctation segment. Performing an end-to-end anastomosis with coarctation resection would seem to be the preferred procedure (11). In this experience, the requirement for tube graft interposition or onlay patch augmentation of the coarctation segment increased significantly as the child reached teenage years. That may be particularly true in circumstances where long segment coarctation (>5 mm) is present (12–14). Only 42% of the patients >8 years of age, 25% of patients >12 years of age, and none >16 years of age were able to undergo end-to-end repair of their coarctation segment.

Hemodynamic outcomes. Hemodynamic outcome parameters were the most difficult metric used to define success versus failure while developing the study. To date, no evidence-based criteria for ULG have been established to define a successful repair. Furthermore, the majority of studies use recorded gradients immediately after repair, measured intraoperatively or in the catheterization laboratory while under anesthesia, which can lead to underestimating the true gradient. Few people would disagree that an ULG ≤10 mm Hg is a success; however, past studies have arbitrarily defined success as ≤20 mm Hg systolic gradient across coarctation segment (8,10). The ultimate aim for any coarctation repair is the resolution of the ULG, as persistent hypertension can be observed in as many as 50% of patients even with a "perfect" repair, particularly if initial repair is performed after 1 year of age (15–17). To complicate matters further, exercise treadmill testing does not predict the severity of aortic arch reobstruction (16,17). In our study, stent and surgical groups appeared to have an advantage over the BA group in achieving lower BP gradients at acute and short-term follow-up, with these differences disappearing among the 3 groups at intermediate follow-up. The preferential use of antihypertensive medications in surgical patients may be in part related to the manipulation of the aorta and increased likelihood of surgical patients encountering post-operative hypertension as well as increased ULG, both of which resolved over time.

Angiographic outcomes. Review of the literature revealed no evidence to support the determination of successful treatment of coarctation of the aorta on the basis of angiographic outcomes alone. In normal patients, the aortic isthmus is 80% to 90% of transverse aortic diameter and similar to descending aortic diameter at level of the diaphragm by angiographic imaging (18). The CCISC experience, consistent with others (19,20), confirmed that the majority of patients requiring reintervention for recoarctation had a Coarct:Dao ratio of <0.60. In determining the definition of clinically significant TAA hypoplasia, we believe that a ratio of TAA:Dao <0.60, similar to our experience with Coarct:Dao ratio, would likely require future intervention and, therefore, should be addressed at time of coarctation repair.

Complications. The stent group was superior to both the surgical group and the BA group regarding the incidence of acute complications in all patients and in the subset of

Table 9 Subgroup Analysis, Age 6 to 12 Years

	Surgery	Balloon	Stent	p Value (2-Sided)
Acute outcome	n = 23	n = 23	n = 57	
Age, yrs	8.7 ± 2.1	8.6 ± 2.1	9.3 ± 1.8	0.301
Discharge ULG	2.3 ± 12.9	10.1 ± 14.3	2.9 ± 10.6	0.050†
Any complications	13.0%	13.0%	1.8%	0.035†
Aortic wall complications	NA	13.0%	0.0%	0.022†
Short-term follow-up outcome	n = 18	n = 14	n = 32	
Antihypertensive medications	44%	0%	28%	0.018†
Normal SBP*	89%	79%	84%	0.728
ULG	−4.9 ± 14.3	10.2 ± 16.5	2.0 ± 11.3	0.016†
Any complications	25%	38%	4%	0.010†
Aortic wall complications	13%	31%	0%	0.009†

Values are mean ± SD or %. *Defined as <97.5 percentile SBP of normal subjects (age and sex adjusted). †$p < 0.05$.
Abbreviations as in Table 2.

patients ages 6 to 12 years. For both BA group and stent group, acute complications were due almost exclusively to aortic wall injury. Acute dissections and aortic ruptures have been described in both procedures, with the majority occurring in older patients (12,21,22). Acute aortic dissection or rupture was not encountered in this study. One possible reason for this may be related to the increased approach to staging the procedure in patients with severe native coarctation of the aorta. The development of an acute dissection/aortic rupture after transcatheter treatment of the coarctation segment is equally prevalent in native versus recurrent coarctation and is not related to balloon/coarctation ratio (5,23).

In this experience, the likelihood of encountering aortic wall injury of any type at follow-up was significantly higher in the BA group than in the surgical group and stent group, a finding that is also consistent to what was observed in the literature (24). Hassan et al. (25) noted an aneurysm rate of 7.5%, all observed at 1-year angiographic evaluation, which is significantly less than what we observed. That may be due, in part, to their patient cohort being significantly older (25). In contrast to surgical patients, aneurysm formation in BA patients and stent patients typically occurs within the first year after the transcatheter procedure (25,26), with rare situations observed where progression of the aneurysm required covered stent or surgical treatment (26,27). We observed "late" aneurysm formation in only 3 patients—2 after BA and 1 after stent placement. The patients had normal MRI/CT scans ranging from 7 to 24 months after initial intervention, with small aneurysms noted between 3.2 and 4.0 years. We observed the lowest aneurysm rate in our stent group (Table 6). Prevention of an intimal tear has been advanced as to why initial stent implantation may protect against later aneurysm formation (28). There is evidence that exceeding a balloon:coarctation ratio of >4 and performance of pre-stent BA may increase the risk of encountering aneurysm formation at intermediate follow-up (26,29). Aneurysm formation in the surgical group (11.5% at short term and 12.5% at intermediate term) occurred exclusively in the subclavian flap and onlay patch techniques. The development of late aneurysms has been reported in all types of surgical repair. More recently, there appears to be improvement in avoidance of encountering surgical aneurysms, with 9% of patients overall having local aneurysms late after surgical repair (30,31). There were 2 patients, 1 in the stent group and 1 in the surgical group, who were noted to have aneurysm formation at short-term follow-up and had imaging at intermediate follow-up. No progression in aneurysm size was noted in either patient. In the stent patient who required covered stent placement for treatment of an aneurysm, the initial aneurysm was first observed at intermediate follow-up.

Reintervention. Planned repeat intervention was most likely in the stent group, at 16.1%. In the experience of CCISC, staged procedures were nearly exclusively observed among patients undergoing stent treatment for severe native coarctation of the aorta. The staged approach has been advocated to decrease the likelihood of encountering large aneurysms, which were encountered in our early experience. That appears to have been successful, as we have not encountered any large aneurysms in any of the stent patients at short-term or intermediate follow-up. In the Quebec Native Coarctation Study, at a mean of 38 months, 32% of the transcatheter patients required reintervention (32). In their stent patients, the study made no distinction between anticipated (staged) and unanticipated reintervention. Unfortunately, there are no strict criteria for performing a reintervention, which our data clearly indicated. Of the 17 patients undergoing unanticipated reintervention due to recurrent obstruction, 6 (35%) had a resting systolic BP <130 mm Hg and an upper to lower extremity resting systolic BP gradient <15 mm Hg prior to reintervention. The Coarct:Dao ratio of 0.60 appears to be an important ratio regarding the requirement for reintervention. Although there were others who underwent reintervention with a ratio of >0.60, the vast majority had a ratio <0.60.

Study limitations. This is a not a randomized study. Although we noted no treatment bias related to the catheterization volume of a particular institution, many centers supplied fewer than 10 subjects to the study. Therefore, because of low numbers, a potential treatment bias relating to catheterization volume could have been overlooked. We did observe a bias toward surgery and balloon angioplasty in the younger patient. It would also be logical to presume that not every participating institution enrolled every eligible patient into the study. Therefore, selection bias for entry into the study could not be ruled out. Finally, although compliance was reasonable in obtaining integrated follow-up imaging at the prescribed times, we still fell short of comprehensive evaluation of all subjects. One could not rule out the possibility of an upward bias in the estimation of aortic wall complications at follow-up by excluding patients from analysis who did not undergo integrated imaging at follow-up.

Conclusions

In this large multi-institutional observational study, we attempted to determine which of the 3 modalities for the treatment of native coarctation had better patient outcomes in terms of hemodynamic improvement, complications, and reintervention acutely and at short-term and intermediate follow-up. To adjust for age and size difference, we conducted multivariate analysis as well as a subgroup analysis limiting patient age to 6 to 12 years. Stent patients had significantly lower acute complications compared to surgery patients and BA patients. At short-term and intermediate follow-up, stent and surgical patients achieved superior hemodynamic and integrated aortic arch imaging outcomes compared to BA patients. Stent patients were more likely to require a planned reintervention, with no differences observed among the 3 groups regarding the need for performing unplanned reinterventions. End-to-end resection of the native coarctation segment was not able to be performed in the majority of surgical patients over the age of 8. Because of the nonrandomized nature of this study, these results should be interpreted with caution.

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Key Words: aortic coarctation ▪ balloon angioplasty ▪ stent ▪ surgical treatment.

APPENDIX

For a list of CCISC coarctation participating institutions, please see the online version of this article.

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