

Original Studies

Procedural Results and Acute Complications in Stenting Native and Recurrent Coarctation of the Aorta in Patients Over 4 Years of Age: A Multi-Institutional Study

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Background: We report a multi-institutional experience with intravascular stenting (IS) for treatment of coarctation of the aorta. **Methods and Results:** Data was collected retrospectively by review of medical records from 17 institutions. The data was broken down to prior to 2002 and after 2002 for further analysis. A total of 565 procedures were performed with a median age of 15 years (mean = 18.1 years). Successful reduction in the post stent gradient (<20 mm Hg) or increase in post stent coarctation to descending aorta (DAo) ratio of >0.8 was achieved in 97.9% of procedures. There was significant improvement ($P < 0.01$) in pre versus post stent coarctation dimensions (7.4 mm \pm 3.0 mm vs. 14.3 \pm 3.2mm), systolic gradient (31.6 mm Hg \pm 16.0 mm Hg vs. 2.7 mm Hg \pm 4.2 mm Hg) and ratio of the coarctation segment to the DAo (0.43 \pm 0.17 vs. 0.85 \pm 0.15). Acute complications were encountered in 81/565 (14.3%) procedures. There were two procedure related deaths. Aortic wall complications included: aneurysm formation ($n = 6$), intimal tears ($n = 8$), and dissections ($n = 9$). The risk of aortic dissection increased significantly in patients over the age of 40 years. Technical complications included stent migration ($n = 28$), and balloon rupture ($n = 13$). Peripheral

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vascular complications included cerebral vascular accidents (CVA) ($n = 4$), peripheral emboli ($n = 1$), and significant access arterial injury ($n = 13$). Older age was significantly associated with occurrence of CVAs. A significant decrease in the technical complication rate from 16.3% to 6.1% ($P < 0.001$) was observed in procedures performed after January 2002. **Conclusions:** Stent placement for coarctation of aorta is an effective treatment option, though it remains a technically challenging procedure. Technical and aortic complications have decreased over the past 3 years due to, in part, improvement in balloon and stent design. Improvement in our ability to assess aortic wall compliance is essential prior to placement of ISs in older patients with coarctation of the aorta. © 2007 Wiley-Liss, Inc.

Key words: coarctation; intravascular stent, complications

INTRODUCTION

Coarctation of the aorta affects 5–8% of patients with congenital heart disease. The initial treatment option was surgical resection with end-to-end anastomosis, first described by Crafoord in 1945 [1]. Over the past 15 years, balloon expandable intravascular stent (IS) placement for treatment of both native and recurrent coarctation of the aorta has gained acceptance in older children and adults [2–14]. Placement of ISs can be technically challenging and has been associated with serious complications. We report a multi-institutional experience in placement of ISs for the treatment of native and recurrent coarctation of the aorta. The primary focus of this study was to evaluate the efficacy of the procedure, determine risk factors for encountering acute complications, and relate consequences of the complications.

METHODS

Patients

All consecutive patients who underwent stenting at the 17 participating institutions were included. Decision to undergo IS versus balloon angioplasty or surgery was dependent upon the interventionalist, with no criteria being set as to who received which procedure.

Patients under 4 years of age were excluded from the study. The patient's (or guardian's) consent and the institution's Institutional Review Board approval were obtained. This was a retrospective study, and the data collection method was by way of extensive chart review. Data sheets were sent to each participating center, with the staff physician or research assistant performing data entry. To ensure patient confidentiality, no patient identifying information was shared between participating institutions.

Definitions

Coarctation of the aorta was defined as “the presence of systemic hypertension with an upper to lower limb systolic blood pressure difference ≥ 20 mm Hg or an upper to lower extremity blood pressure differential < 20 mm Hg in the presence of systemic hypertension

or left ventricular hypertrophy, and confirmation of the coarctation by computerized tomography (CT) scan, magnetic resonance imaging, or echocardiographic assessment.” In some patients, the obstruction occurred at the level of the transverse aortic arch. In these cases, the ratio of diameter of the narrowed segment to the diameter of the descending aorta (DAo) at the level of the diaphragm of less than 0.6 was used to define coarctation [15,16] in the presence of clinical evidence of coarctation. Discrete coarctation was defined as a coarctation segment measuring ≤ 5 mm, with long segment coarctation measuring > 5 mm. *Successful outcome* was defined as a “peak residual systolic catheterization gradient of less than 20 mm Hg following stent implantation and the absence of serious complications (death, requirement of surgery, permanent disability). Post stent peak gradients of ≤ 10 mm Hg were also calculated for comparisons with our definition, with further assessment regarding transverse arch anatomy being obtained to discern what role transverse arch hypoplasia played in residual coarctation gradient. *Acute complications* were defined as complications requiring additional procedures during the intervention, or additional observation/therapy prior to discharge from the hospital. They were categorized into aortic wall complications, technical complications, or peripheral vascular complications. *Aortic wall complications* included intimal tears, dissection (including aortic wall rupture), or the development of an aneurysm. Aneurysm was defined as an expansion of the aortic wall $> 10\%$ from the adjoining native lumen that was absent prior to the intervention. Dissection was defined as extravasation of contrast outside the vessel lumen, and intimal tear was defined as a filling defect observed within the vessel lumen with no evidence of extravasation outside the vessel lumen (either proximal or distal to previously placed stent. Aortic rupture was listed as dissection in our analysis. *Technical complications* included balloon rupture or migration of the stent off the balloon during deployment or immediately following deployment. *Peripheral vascular complications* included cerebral vascular accident (CVA), peripheral emboli, or significant vascular entry injury

requiring observation, surgical repair or anticoagulant therapy. Peripheral vascular complications were grouped under technical complications in our analysis. Overlapping the origin of a brachiocephalic vessel by the stent was not considered a complication, though will be discussed as a separate observation.

Study Data

Data collected included patient demographics; characterization of coarctation (discrete vs. long segment), coarctation location, other associated diagnosis, angiographic dimensions pre and post stenting, diameter of the coarctation; pre and post intervention systolic gradient, pre and post intervention coarctation:DAo and balloon: coarctation ratios. Technical data collected included: the use of general anesthesia, guide wire position, type and size of balloon used, sheath size, and type of stent used. The presence of complications was noted, as well as maneuvers performed to correct the complication.

Statistical Analysis

Descriptive statistics such as mean, median, SD, and frequency were calculated for each demographic and clinical characteristic whenever appropriate. Comparisons for continuous pre and post intervention data end points were performed using the paired *t* tests. Chi-square tests, two-sample *t* tests, and Pearson correlation were used to assess the degree of association between various patient characteristics. Logistic regression analyses were performed to assess the role of patient age, time of procedure, coarctation anatomy, balloon size, etc, in relation with the development of complications. The odds-ratio (OR) of any significant patient factors (*P*-value < 0.05) from the logistic regression analyses are reported along with their *P*-values. All statistical analyses were performed using SAS software version 8.2.

RESULTS

Patient Characteristics

Seventeen institutions (Table I) participated in this study (14 within the United States, 2 in Europe, and 1 in Brazil). The earliest procedure was performed in May 1989 and the most recent in August 2005. Five hundred and sixty-five intravascular stent procedures were performed, with a total of 627 stents being placed in 555 patients for treatment of native or recurrent coarctation of the aorta. The results of 139 procedures have been previously reported [2,10,12–14]. Pertinent patient demographics, including age and procedures performed prior to 2002 and after 2002, are tabulated in Table II.

Characteristics of the coarctation. Native coarctation was present in 52.3% and located at the isthmus

TABLE I. Volumes by Institutions (n = 565)

| Institution | Number of procedures | Number of complications | Number of procedures after January 1, 2002 |
|-------------|----------------------|-------------------------|--|
| 1 | 50 | 4 (8) ^a | 36 |
| 2 | 9 | 4 (44.4) | 4 |
| 3 | 98 | 8 (8.2) | 42 |
| 4 | 57 | 11 (19.3) | 28 |
| 5 | 23 | 2 (8.7) | 14 |
| 6 | 23 | 2 (8.7) | 11 |
| 7 | 42 | 13 (31) | 2 |
| 8 | 11 | 1 (9.1) | 8 |
| 9 | 8 | 2 (25) | 8 |
| 10 | 33 | 6 (18.2) | 9 |
| 11 | 48 | 5 (10.4) | 14 |
| 12 | 14 | 5 (35.7) | 5 |
| 13 | 7 | 1 (14.3) | 5 |
| 14 | 10 | 0 (0) | 5 |
| 15 | 55 | 8 (14.6) | 25 |
| 16 | 8 | 0 (0) | 0 |
| 17 | 69 | 8 (11.6) | 48 |

^aValues in parentheses indicate percentages.

TABLE II. Patient Characteristics

| | |
|---|---------------------------------|
| Age distribution | |
| 4–9 yrs old (<i>n</i>) | 74 (13.1) ^a |
| 10–19 yrs old (<i>n</i>) | 24 (57.4) |
| 20–29 yrs old (<i>n</i>) | 88 (15.6) |
| 30–39 yrs old (<i>n</i>) | 37 (6.6) |
| 40 + yrs (<i>n</i>) | 42 (7.4) |
| Median of age | 15 yrs [4–4.9 yrs] ^b |
| Median of patient weight | 56.4 kg [3.8–145 kg] |
| Patient diagnoses | |
| Isolated coarctation (<i>n</i>) | 242 (42.8) |
| Bicuspid aortic valve or Shone's complex (<i>n</i>) | 148 (26.2) |
| Vasculitis (<i>n</i>) | 8 (1.4) |
| Other (<i>n</i>) | 121 (21.4) |
| Missing (<i>n</i>) | 46 (8.1) |
| Procedures prior to January 1, 2002 (<i>n</i>) | 301 (53.3) |
| Procedures after January 1, 2002 (<i>n</i>) | 264 (46.7) |

^aValues in parentheses indicate percentages.

^bValues in square brackets indicate ranges.

in 81.4% of the procedures. Further details are provided in Table III.

Technical characteristics. As shown in Table IV, pre-stent angioplasty was performed in 17.6% of procedures where records were available. The mean balloon dimension was 15.2 mm ± 3.6 mm. The median balloon: coarctation ratio was 2 (range 1.1–18). Over 89% of stents were delivered either on Z-Med (Braun, Bethlehem, Penn), Balloon in balloon (BIB) (NuMED, Hopkinton, NY), or Cordis (Warren, NJ) balloons. Palmaz “8” and “10” series and the Genesis XD stent (Cordis) series were used in over 83.8% of the stent procedures, with the Genesis XD and Palmaz “10” series being the most widely used stents since 2001. The DS/Mega/Maxi stents (EV3, Bloomington, MN) and

TABLE III. Characteristics of Coarctation^a

| Characteristics | N |
|--------------------------|-------------------------|
| Type of coarctation | |
| Native | 296 (52.4) ^b |
| Recurrent surgical | 228 (40.4) |
| Recurrent interventional | |
| Post balloon angioplasty | 21 (3.7) |
| Post stent | 20 (3.5) |
| Location of coarctation | |
| Isthmus | 341 (81.4) |
| Distal transverse arch | 55 (13.1) |
| Other | 23 (5.5) |
| Extent of coarctation | |
| Discrete | 325 (74.7) |
| Long segment | 110 (25.3) |

^aMissing data accounts for the missing percentage in each characteristic.

^bValues in parentheses indicate percentages.

TABLE IV. Technical Characteristics

| Characteristics | |
|---|-------------------------|
| General anesthesia used in: <i>n</i> = 366 pts | 259 (70.8) ^a |
| Median of sheath size in Fr | 11 [6–16] ^b |
| Balloon type: <i>n</i> = 423 pts ^c | |
| Z-med | 118 (27.9) |
| Cordis | 71 (16.8) |
| Balloon in balloon | 188 (44.4) |
| XXL | 19 (4.5) |
| Other | 27 (6.4) |
| Pre-stent angioplasty: <i>n</i> = 449 pts | 79 (17.6) |
| Balloon dimension: <i>n</i> = 565 pts Mean ± S.D. | 15.2 ± 3.6 mm |
| Median balloon:Coarctation ratio | 2 [1.1–18] |
| Initial stent type: <i>n</i> = 511 pts | |
| P 8 series/P10 series | 170/154 |
| LD | 14 |
| EV3 | 16 |
| Genesis | 104 |
| Cheatham-Platinum series | 33 |
| Covered stent | 14 |
| Others | 6 |
| Number of stents used per procedure: <i>n</i> = 565 | |
| 1 stent | 517 |
| 2 stents | 40 |
| 3 stents | 5 |
| 4–5 stents | 3 |

^aValues in parentheses indicate percentages.

^bValues in square brackets indicate ranges.

^cMissing data accounts for the missing percentage.

Cheatham-Platinum, covered and uncovered (NuMED, Hopkinton, NY) made up the remainder of the stents used.

Success of Procedure

A successful treatment outcome was achieved in 553/565 (97.9%) procedures. In the successful group, the peak systolic ascending to descending aortic gradient decreased from a mean 31.6 ± 16.0 mm Hg to 2.7 ± 4.2 mm Hg ($P < 0.001$). The mean diameter of the

coarctation segment significantly increased from 7.4 ± 3.0 mm to 14.3 ± 3.2 mm ($P < 0.001$), and the mean coarctation: descending aortic ratio significantly increased from 0.43 ± 0.17 to 0.85 ± 0.15 ($P < 0.001$). Twelve procedures were unsuccessful as defined previously. Though the low number of unsuccessful procedures precluded any meaningful analysis, certain observations were noted. In two patients who underwent stent placement of their ascending to descending aortic conduit, both were unsuccessful, with one having acute rupture of his aorta and subsequently expiring. Six each had native and recurrent coarctation of the aorta. Five of the 12 had a gradient of more than 60 mm Hg across the coarctation prior to stenting. Two patients (one previously mentioned earlier) had dissection with subsequent aortic rupture post stent placement leading to termination of the procedure and emergent surgery. Success, when defined as a post stent coarctation systolic gradient ≤ 10 mm Hg, was noted in 92.2% (521/565) patients, with failures being observed in 7.8% (44/565) patients. The increase in unsuccessful procedures was felt to be due to planned staged procedure ($n = 10$) and transverse arch hypoplasia. ($n = 22$), as in each of these cases the post stent coarctation:descending aortic ratio was ≥ 0.80 . In using < 10 mm Hg post stent gradient as our criteria for success, we performed further sub analysis of the data. Success was increased in treatment of discrete versus long segment coarctation (94.6 vs 84.5%; $P < 0.001$), increased preprocedure coarctation diameter (7.4 vs 5.4 mm; SD 2.7, $P = 0.03$), and lower pre-stent systolic gradient 29.5 versus 38.1 mmHg; SD 16.9, $P < 0.001$). Patients' age, weight, location of coarctation, native versus recurrent coarctation, and balloon:coarctation ratio were not associated with successful outcome.

Complications

Complications were encountered in 81/565 (14.3%) procedures. The complication rate significantly decreased in procedures performed after January 2002 (Fig. 1). Complications were further broken down into Aortic wall and Technical complications for the following analyses. Encountering complications, either in total or divided into aortic wall and technical was not related to center volume.

Aortic wall complications. Acute aortic wall complications were encountered in 22/565 (3.9%) procedures. Intimal tears were noted in eight procedures, aortic wall dissection/rupture was encountered in nine procedures, and aortic aneurysm was noted in six procedures. Performing pre-stent balloon angioplasty, (11.4% vs. 3%; OR = 4.18; $P = 0.001$), location of the coarctation in the abdominal aorta versus the isthmus/transverse aortic arch (17.4% vs. 3.5%; OR = 5.74;

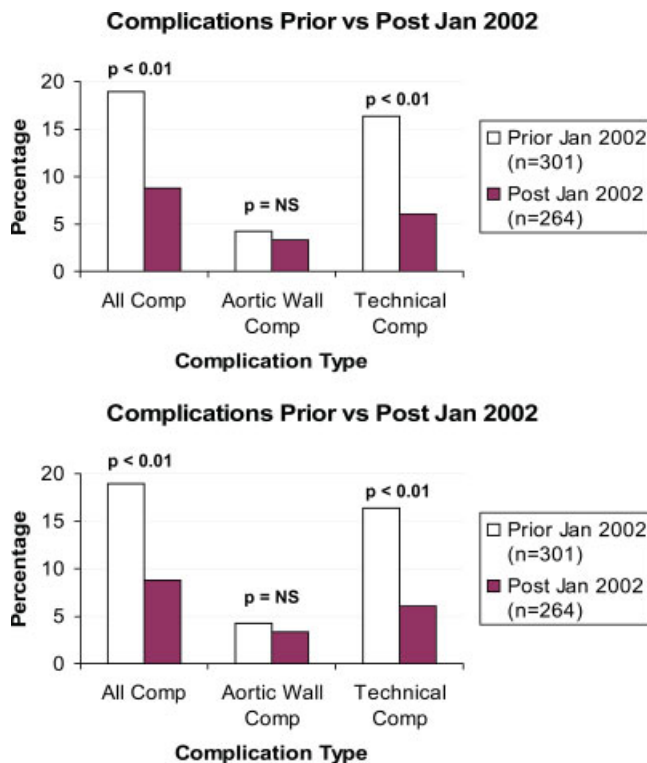


Fig. 1. Comparisons of complications, further broken down into aortic wall and technical complications prior to and following January 1, 2002.

$P < 0.01$), and age over 40 (9.5% vs. 3.4%; OR = 2.95; $P = 0.05$) were all significantly related to encountering an aortic wall complication (Table V). IS treatment of long segment coarctation (7.3% vs. 3.1%; OR = 2.47; $P = 0.06$) trended towards encountering acute aortic wall complications.

Intimal tear. Intimal tears were encountered in 8/565 (1.4%) of the procedures. In 5/8 procedures, the intimal tear occurred just proximal to the stent. In one patient with recurrent post surgical coarctation, an intimal tear was preceded by balloon rupture and stent migration. A second stent was successfully implanted at the coarctation site during the same procedure. All other intimal tears occurring during IS placement were not preceded by a technical complication, with none requiring any immediate reintervention.

Aortic dissection. Nine out of 565 procedures (4.6%) encountered dissection of the aorta/interposition

graft during initial stent placement. In one patient the development of a dissection was preceded by stent migration. In the other eight patients, no technical complications were encountered during stent deployment. Three patients (two aortic stents, one interposition graft stent patient) were sent emergently to surgery, including the one preceded by stent migration. Two of the three patients suffered severe neurological injuries, with one expiring the following day (interposition graft stent) and the other 6 months later (aortic stent). Three patients underwent successful placement of one, two, and three covered stents, respectively. The three remaining patients were managed medically with close ICU monitoring and aggressive regimen of antihypertensive medications. Resolution of the aortic dissection was observed at follow-up one month later in one patient (Fig. 2a–d).

Technical complications. Technical complications were encountered in 59/565 (10.4%) procedures. Five procedures had more than one complication, making a total of 64 technical complications. Technical complications included: stent migration ($n = 28$), balloon rupture ($n = 13$), and encountering a CVA or peripheral embolic event ($n = 5$). Vascular site hematoma ($n = 13$) is discussed separately though was also counted as a technical complication. The majority of technical complications (90%) encountered were resolved without any clinical sequelae, with seven (10%) procedures being associated with aortic wall injury, CVA, or peripheral vascular complications. The risk of encountering a technical complication increased in patients over the age of 40 years, (23.8% vs. 10.5%; OR = 2.65; $P = 0.01$), decreased with the use of anesthesia (5.8% vs. 19.8%; OR = 0.25; $P < 0.001$), and decreased with a procedure date after January 1, 2002 (6.1% vs. 16.3%; OR = 0.33; $P < 0.001$) (Fig. 1). The risk of encountering a technical complication, either prior to January 2002 or after January 2002, was not associated with weight, type, or location of coarctation, initial coarctation diameter, balloon:coarctation ratio, mean balloon diameter, the presence of other associated diagnosis, prestent angioplasty, use of the BIB balloon, stent type, or institution at which procedure was performed. Cardiac rate controlling measures were not used in any of the patient's undergoing stent placement. Furthermore, in institutions where >40 IS

TABLE V. Complications Split up by Age Group

| Age group (yrs) | 4–9 | 10–19 | 20–29 | 30–39 | >40 | Total |
|--------------------------|----------|-----------|-----------|----------|-----------|-----------|
| Number of patients | 74 | 324 | 88 | 37 | 42 | 565 |
| All complications | 6 (8.1) | 44 (13.6) | 11 (12.5) | 6 (16.2) | 13 (31) | 81 (14.3) |
| Aortic wall complication | 1 (1) | 11 (3.4) | 4 (4.6) | 2 (5.4) | 4 (9.5) | 22 (3.7) |
| Technical complication | 9 (10.7) | 36 (11.1) | 9 (10.3) | 6 (16.2) | 10 (23.8) | 71 (12.1) |

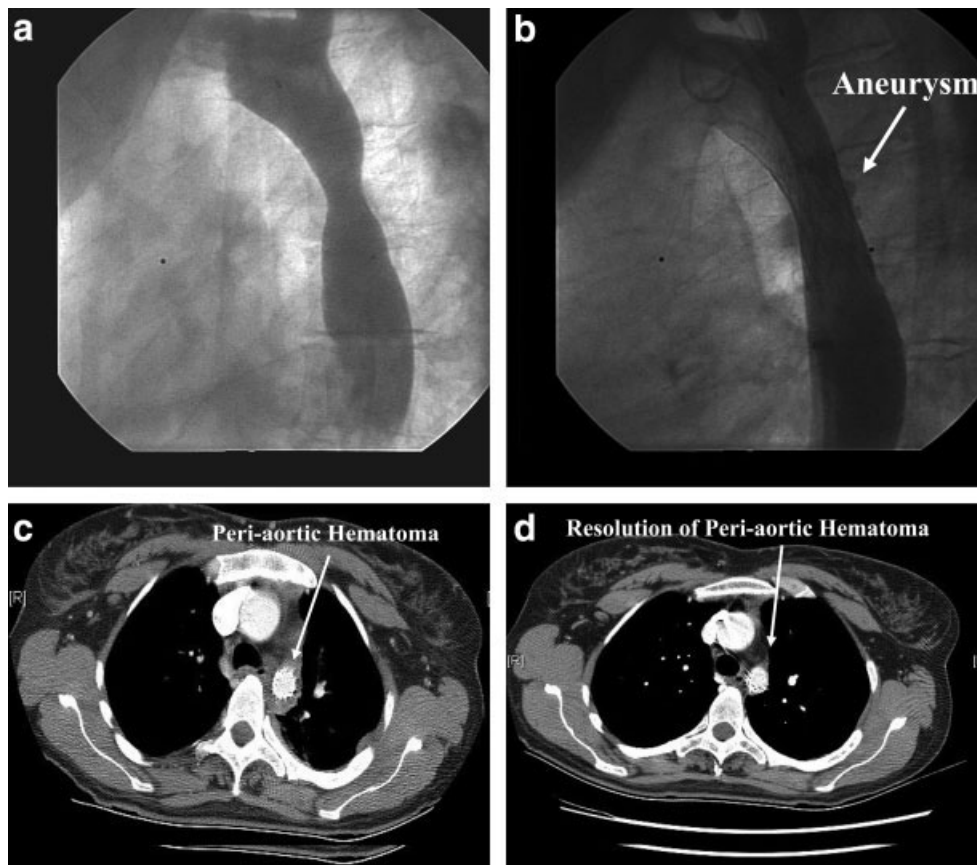


Fig. 2. (a–d) Imaging performed in a 42-year-old lady who underwent stent placement of her native coarctation of the aorta. (a) Injection in the aorta prior to stent placement. The narrowed segment measured 7 mm with the native vessel measuring 15 mm diameter. (b) Injection performed immediately following stent placement, extravasation of contrast is noted outside the Genesis stent (arrow). The narrowed section

of the stent measured 11 mm diameter (Ball:Coarct ratio 1:6). (c) CT scan of the aorta 24 hours after the intervention, with near transection of the aorta noted at the level of the stent (arrow). Circumferential periaortic wall hematoma is observed. (d) CT scan 30 days after the intervention, noting complete resolution of the aortic wall hematoma. No evidence of aneurysm nor dissection observed.

placement procedures have been performed, no difference in encountering technical complications were noted in comparing early (initial 25 stent procedures) versus late experience at each respective institution.

Stent migration. Stent migration was the most frequently encountered technical complication, occurring in 28/565 (5%) procedures. The major cause for stent migration was delivery of the stent on a balloon catheter that was larger than the aorta proximal to the coarctation site (>2 mm). This was observed in 14 out of the 28 procedures. The second most common cause of stent migration ($n = 9$) related to deployment of the stent on an undersized balloon where the coarctation site was not a true stenosis, but more of a fold in the aortic arch (pseudocoarctation). Balloon rupture was implicated in five stent migrations. Stent migration trended towards occurring on larger balloon sizes, with 18/28 (64%) stents migrating when the delivery bal-

loon diameter was greater than or equal to 15 mm. Thirteen of 28 migrated stents were successfully repositioned and did not require any further intervention. Eight of 28 procedures had placement of the malpositioned stent in a suboptimal location, requiring a second ($n = 7$), or third ($n = 1$) stent, culminating in a successful outcome. Six patients encountered aortic ($n = 2$) or peripheral vascular complications ($n = 4$) associated with stent migration.

Balloon rupture. Balloon rupture during initial stent deployment was encountered in 2.3% (13/565) of all procedures. In 9/13 (69%) instances, balloon rupture was associated with the use of Palmaz (P8) stents ($P = 0.01$). Initial balloon size did not correlate with balloon rupture. Balloon rupture was implicated in five stent migrations and as the possible etiology of a procedure associated CVA. In one case, a balloon fragment embolized to the left axillary artery requiring surgical removal.

Cerebral vascular accident. A cerebral vascular accident (CVA) occurred in 4/565 (0.7%) of procedures. In all but one case, complete recovery occurred, with the fourth case having near complete return to preintervention neurological status. Of note, two patients who encountered rupture of their aorta during the procedure, noted previously in the aortic dissection section, and suffered severe neurologic injuries because of volume loss, were not included in this analysis. The etiology of the CVA remains speculative but was associated with technical complications in 3/4 procedures (two stent migrations and one balloon rupture). The location of the strokes in two patients was related to wire positioning within the associated vessel. All patients were heparinized for the catheterization procedure, maintaining ACTs > 250 sec.

Injury to access vessels. Hemostasis was achieved almost exclusively in our patients via pressure dressing with immediate sheath removal following the procedure. Though a couple of patients underwent device closure, the low number prevented any reasonable analysis. Significant femoral arterial injury was observed in 13 procedures (2.3%). The majority were conservatively managed with observation (10/13) with one patient developing a retroperitoneal hematoma due to high puncture point that required surgical evacuation, and two others requiring heparin therapy. Access vessel injury was not associated with other complications, sheath size, or era in performing the catheterization procedure.

Stent overlap of brachiocephalic vessels. This observation was treated separately as the clinical relevance of this occurrence may be minimal. Out of 343 procedures where specific mention was made about stent overlap of brachiocephalic vessels, 61 (17.8%) had either partial or complete overlap of one of the brachiocephalic vessels. No acute complications were encountered, nor was there any noticeable obstruction to flow into the involved vessel following the procedure for 60/61 cases of overlap. One patient had a covered stent placed over a stented coarctation site that overlapped the left subclavian artery resulting in diminished flow to it. Another patient had coarctation involving the origin of the left subclavian artery. After successful stent implantation, balloon angioplasty of the origin was carried out through the struts of the stent. At a mean follow-up of 3.1 years with a 186 patient year follow-up, no CVAs or peripheral embolic events have been encountered through the affected vessels.

DISCUSSION

IS placement remains a technically demanding procedure with a high incidence of encountering compli-

cations for treatment of coarctation or the aorta. This study is the first multi-institutional study assessing the efficacy and safety of performing this procedure in children and adults, specifically addressing acute complications associated with the procedure. In this study, we separated complications into aortic wall and technical complications. Our experience suggests that treatment of native and recurrent coarctation of the aorta with ISs, even in patients with complex congenital anomalies, was frequently a successful procedure. Our results are supported by other studies, with acute success rates approaching 100% [2,7–14]. Though we didn't specifically evaluate balloon angioplasty in this article, reintervention following balloon angioplasty was low in our experience, suggesting that primarily performing this procedure, especially in younger children, is a reasonable option. Our experience has confirmed what others have experienced. This procedure is technically very demanding and can be associated with serious, albeit rare, complications [2,7–14]. The 14.2% incidence of acute complications reported in our study is high. The observed 31% incidence of complications in patients ≥ 40 years of age, makes this a high risk group.

Aortic Wall Complications

Acute aortic wall complications though rare, have been associated with both balloon angioplasty [15–19] and IS placement [9,10,20,21]. In our study, the performance of aggressive pre-stent angioplasty significantly increased the likelihood of encountering aortic wall complications. Though speculative, this may be due to disruption of the endothelium during the initial balloon angioplasty procedure, with further sheath and wire maneuvers, causing additional trauma to the vessel wall. Our experience would indicate that aggressive preballoon angioplasty should not be performed, at least in the same setting prior to stent placement. Though, the use of low atmosphere (<2 ATMs) for assessment of an aortic fold (pseudocoarctation) is routinely performed by the authors, formal aortic wall balloon compliance testing is not routinely performed. Surprisingly, balloon:coarctation ratios were not associated with the development of acute aortic wall complications of any type. In our experience, older age significantly increased the likelihood of encountering aortic wall complications. This is also consistent with what has been reported in the literature. Four case reports of aortic dissection shortly after stenting have been described; [20,21,22,23]. In two patients the aortic wall may have been weakened by other diseases (irradiation in a 44-year-old woman [20] and mucopolysaccharide infiltration shown on autopsy in a 65-year-old) [21]. We feel this is due to decreased

aortic wall compliance observed in this group. Studies of aortic wall compliance in humans [24] indicate that compliance decreases as patients reach adulthood [24–27]. Structural changes are believed to play a major role in age-associated decline in arterial compliance. The most important changes are thought to be: [1] increased fragmentation and decreased density of elastin in the arterial wall; [2] increased collagen content mediated by increased synthesis and decreased turnover; and [3] increased cross linking of collagen molecules associated with increased advanced glycation end-products [26,27]. In all likelihood, the adult aorta may be less resilient to expansion than a child/adolescent aorta. The difficulty lies in accurately and reliably assessing aortic wall compliance before performing transcatheter intervention. Pedra et al. advocated the use of intravascular ultrasound in high risk patients, in the hopes of identifying diseased segments of the aorta (ie cystic medial necrosis, calcific nodules), which may change one's approach to the procedure [14]. In older patients, it may be more prudent to aim for hemodynamic success rather than angiographic resolution of the stenosis. Unfortunately, at this time, in the United States, there are no bailout covered stents that would assist the interventionalist in the treatment of significant arterial injury if it should occur during initial IS placement. Regarding development of intimal tears immediately following IS placement, no reports have been observed in the literature, which differs from the experience in performing balloon angioplasty alone for treatment of coarctation of the aorta [15,16].

Technical Complications

The most frequent technical complication encountered in our study was stent migration. Stent migration has been described in other studies, with occurrence ranging from 0 to 6.1% in smaller reports [2,6,7,9]. In one report, late asymptomatic stent migration was noted in a patient three weeks following the procedure [8]. In review of the literature, the most common causes for stent migration were either balloon rupture during stent deployment or deployment of the stent on an undersized balloon catheter (with respect to diameter of the proximal aorta). In our experience, using an undersized balloon delivery catheter was the second most common cause of stent migration, only occurring in patients with a fold (not a true coarctation) in their aorta. In contrast, nearly 50% of stent migrations in our study occurred due to delivery of the stent on a balloon catheter that was larger (oversized) than the proximal transverse aortic diameter. The combination of traversing the aortic arch with a straight balloon catheter, occlusion of the majority of the cardiac output, and the use of larger balloon delivery catheters,

may increase the likelihood of encountering stent/balloon catheter migration during deployment. Use of BIB catheters, with a more controlled inflation, may decrease the likelihood of encountering stent migration. However, in our early experience in deployment of stents on BIB catheters, there was no notable decrease in encountering stent migrations (8/28 stent migrations used BIB). Use of cardiac output controlling measures (right ventricular pacing, adenosine infusion) or placement of a wire in a brachiocephalic vessel may also decrease the likelihood of encountering this complication. These methods were not formally evaluated in our study.

The second most common technical complication encountered was balloon rupture during initial stent deployment. Previous reports suggest that balloon rupture incidence during stent deployment ranged from 0 to 4% [2,6,7,9]. Complications associated with balloon rupture included the need for surgical removal of the embolized balloon catheter [2] and occurrence of a myocardial infarction during attempted retrieval of an embolized balloon catheter [8]. In our study, balloon rupture was more likely to be encountered with the Palmaz “8” series stents. This may be due to the sharp edges present in this stent, though could also be related to the older balloon technology used with these stents. The introduction of new balloon technology, combined with the more recent series stents having rounded edges, encountering balloon rupture during initial stent deployment appears to be decreasing.

The significant decrease observed in technical complications in procedures performed after January 2002 is encouraging. The reason for this could be multifactorial, with the introduction of newer stents and balloon catheters over this period, the interventionalist had greater options in performing the procedure, though one could not exclude a “learning curve” phenomenon with this procedure.

Peripheral Vascular Complications

In our experience, older age was associated with the occurrence of a CVA during stent deployment. Older patients, especially hypertensive patients, may have early vascular disease and atheromatous changes in the vessel wall. This should be kept in mind while manipulating a wire or catheter in a brachiocephalic vessel in these patients. Certain centers preferred to position the delivery wire in the left subclavian artery rather than the ascending aorta if there was a reasonable distance (>10 mm) between the coarctation segment and takeoff of the left subclavian artery, allowing the balloon catheter to remain straight during stent deployment. The recent addition of flexible stents, improvement in balloon technology, and the use of cardiac

output controlling measures, will likely decrease the concerns of positioning the wire across the aortic arch into the ascending aorta.

Stent overlap of brachiocephalic vessels is technically unavoidable in certain cases of transverse arch or proximal isthmic obstruction. This occurrence has been previously described [7]. Although, there appear to be no acute or intermediate follow-up implications of this, further long-term follow-up is warranted. There may also be a theoretical issue of causing distal emboli on performing a reintervention in a stent overlapping a brachiocephalic vessel.

Though this article did not specifically examine postoperative care of patient's undergoing stent placement for treatment of coarctation of the aorta, there were trends observed in the contributing authors. All felt that one should aggressively treat post stenting hypertension (systolic > 160 mm Hg and/or diastolic > 110 mm Hg) with IV antihypertensive medications to get the systolic pressures < 150 mm Hg and diastolic pressures < 90 mm Hg. At time of discharge, the majority felt that if the patient was on antihypertensive medications prior to the procedure, they would continue them ranging from 1 to 4 months post stent implant, discontinuing the medications once normal blood pressures was recorded in the clinic. If the patient was not taking any antihypertensive medications prior to the catheterization, a slim majority would still start antihypertensive medications for one month, even if the patient remained normotensive at time of discharge. The majority of author's would restrict the patient from competitive sports or strenuous exercise for 1–4 months after the procedure. All authors felt that integrated imaging of the aortic arch should be performed between 3 and 18 months after the catheterization procedure.

Limitations

This is a retrospective study dependant on accurate reporting by participating centers. All efforts were made to obtain complete records of each case. Adequate integrated imaging follow-up remained low in the majority of aortic wall complications that were encountered at time of initial stent deployment. The number of serious complications (aortic dissection, CVA) encountered was low, making an attempt to accurately ascertain a possible etiology of the particular complication difficult.

CONCLUSION

Use of intravascular stenting is highly successful in the treatment of native and recurrent coarctation of the

aorta. This procedure remains technically demanding, with a relatively high complication rate. Though, with recent improvements in catheter and stent technology, encountering technical complications significantly decreased after January 2002. Continued improvement in balloon technology and a better understanding of transverse aortic arch anatomy, may further help decrease complications associated with the procedure. Improved assessment of aortic wall compliance in older patients is necessary for the treatment of native or recurrent coarctation of the aorta in this subgroup. Prophylactic use of covered stents may play a role in the treatment of native or recurrent coarctation of the aorta in the older patient, or the patient with a non-compliant aorta. We speculate that the availability of covered stents would be an invaluable tool to have as a "bailout" procedure where aortic wall dissection/rupture has occurred, and may have a role as a primary stent in higher risk, older patients.

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