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PEDIATRIC AND CONGENITAL HEART DISEASE

Original Studies

Intermediate Follow-Up Following Intravascular Stenting for Treatment of Coarctation of the Aorta

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Background: We report a multiinstitutional study on intermediate-term outcome of intravascular stenting for treatment of coarctation of the aorta using integrated arch imaging (IAI) techniques. Methods and Results: Medical records of 578 patients from 17 institutions were reviewed. A total of 588 procedures were performed between May 1989 and Aug 2005. About 27% (160/588) procedures were followed up by further IAI of their aorta (MRI/CT/repeat cardiac catheterization) after initial stent procedures. Abnormal imaging studies included: the presence of dissection or aneurysm formation, stent fracture, or the presence of reobstruction within the stent (instent restenosis or significant intimal build-up within the stent). Forty-one abnormal imaging studies were reported in the intermediate follow-up at median 12 months (0.5–92 months). Smaller postintervention of the aorta (CoA) diameter and an increased persistent systolic pressure gradient were associated with encountering abnormal follow-up imaging studies. Aortic wall abnormalities included dissections (*n* = 5) and aneurysm (*n* = 13). The risk of encountering aortic wall abnormalities increased with larger percent increase in CoA diameter poststent implant, increasing balloon/coarc ratio, and performing prestent angioplasty. Stent restenosis was observed in 5/6 parts encountering stent fracture and neointimal buildup (*n* = 16). Small CoA diameter poststent implant and increased poststent residual pressure gradient increased the likelihood of encountering instent restenosis at intermediate follow-up.

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Conclusions: Abnormalities were observed at intermediate follow-up following IS placement for treatment of native and recurrent coarctation of the aorta. Not exceeding a balloon:coarctation ratio of 3.5 and avoidance of prestent angioplasty decreased the likelihood of encountering an abnormal follow-up imaging study in patients undergoing intravascular stent placement for the treatment of coarctation of the aorta. We recommend IAI for all patients undergoing IS placement for treatment of CoA.

Key words: coarctation; intravascular stent; intermediate complications

BACKGROUND

Over the past two decades, endovascular stent implantation has become an accepted modality for treatment of native and recurrent coarctation of the aorta (CoA) in older children and adults [1–17]. However, follow-up has primarily been limited to clinical blood pressure measurements, echocardiographic evaluation, and chest X-ray [3,10,12]. Sensitivity of either chest X-ray or echocardiography in detecting aneurysms or restenosis following stent placement has been questioned [11]. Integrated arch imaging (IAI) following stent placement by cardiac catheterization, CT scan, or magnetic resonance imaging (MRI) would offer optimal assessment of the aortic arch, but has been sparsely reported. We report a multiinstitutional study on the intermediate-term outcome of intravascular stenting for treatment of CoA using IAI techniques.

METHODS

A retrospective review of the medical record charts of all patients undergoing intravascular stent placement for the treatment of native and recurrent CoA was performed. At each institution, internal review board approval was obtained, with Health Information and Privacy Assurance Act guidelines being met. A total of 17 institutions contributed to this study. Patients undergoing further IAI (either MRI/CT/repeat cardiac catheterization) following initial stent procedure made up our cohort group for which further analysis was done. Imaging was evaluated by the investigator at each institution. Strict definitions were followed in classification of various lesions. Data forms were then sent to the coordinating center for further analysis. Fifteen patients undergoing IAI have been included in previously published reports [3,12–15]. Data of 16 procedures undergoing staged approach to stent dilation were noted, though were excluded from further analysis. Comparisons were made between those patients who were noted to have normal imaging studies (group A) and those having abnormal imaging studies (group B) at follow-up. Patients with abnormal follow-up imaging studies were further subdivided into: (1) vessel injury, including dissection and/or aneurysm, and (2) in-stent restenosis, including intimal hyperplasia, stent fracture, and/or stent recoil. Follow-up imaging findings were correlated with patient and procedural characteristics to determine if associations existed between the groups.

Demographic Information

Patient demographic information obtained at time of initial stent implantation included: patient age, weight, CoA type (native vs. recurrent), associated cardiac lesions, minimal CoA diameter, CoA length, CoA location (transverse arch, isthmus, or other), and prestent pressure gradient. Procedural information obtained at time of stent implantation included: performance of prestent angioplasty, balloon:CoA ratio, type of stent, the presence of complications (which were further broken down to the presence of aortic wall injury vs. the occurrence of a technical complication), minimal CoA diameter poststent implant, percent increase in CoA diameter poststent implant, poststent residual pressure gradient, and subclavian/carotid vessel overlap by stent. If a repeat catheterization was performed, measurements were obtained prior to reintervention.

Definitions

Aneurysm was defined as a >10% expansion of the aorta outside the stent or normal aorta that was not present prior to the intervention. Dissection was termed as an extravasation of contrast outside the vessel wall. Intimal flap was noted when a thin filling defect was observed within the vessel lumen. In-stent restenosis was noted when greater than 10% of the stent lumen was obstructed either due to intimal proliferation within the stent, stent fracture, or stent recoil.

Statistical Analysis

Abnormal follow-up imaging included the presence of dissection, aneurysm, or in-stent restenosis. After excluding the results from 16 procedures which underwent planned stage procedures, outcomes were divided into group A (normal follow-up imaging), and group B (abnormal follow-up imaging). We further subdivided group B into: aortic wall injury group and in-stent restenosis group. The mean and standard error were calculated for continuous parameters, such as age, weight, pre- and postintervention data. The frequency and percentage were calculated for parameters such as characteristics and location of coarctation, prestent angiography, presence of acute complication, and types of complications. Group comparisons were evaluated using *T*-test, χ^2, and Fish exact test. Statistical significance was set at $P \leq 0.05$. All analyses were performed with SAS version 8.2 statistical software (SAS Institute, Cary, NC) using default settings.

RESULTS

The medical charts and records from 17 medical institutions were included in the study. A total of 588 cardiac catheterization procedures were performed in 578 patients, with 650 stents being placed. The 160 patients available for follow-up have undergone IAI. About 50 patients had CT imaging, 20 patients had MRI, and rest of 90 patients had repeat cardiac catheterization. Sixteen patients (10%) underwent a planned stage procedure. No dissection or aneurysm formation was observed in this subgroup. Different criteria for final stent expansion were used for these parts in comparison with parts undergoing one stage treatment of their coarctation. Because of separate criteria being used at time of the initial procedure, we excluded these patients from further analysis. Though, if after having undergone the second stage, they underwent follow-up integrated imaging of their aortic arch, they were included in the study. Therefore, only patients undergoing final expansion of their stent underwent further analyses ($n = 144$).

Median follow-up interval in all patients was 12 months (range 0.5–92 months). Follow-up IAI studies were done as protocol at three institutions ($n = 63$). The majority of imaging studies were performed either due to concerns of reobstruction on clinical examination or development of an aortic aneurysm via follow-up CxR/echocardiographic examination. At follow-up, there were 103 (71.5%) patients noted to have normal imaging with 41 parts (28.5%) having abnormal follow-up imaging results. The abnormal findings included: 16 patients (11%) with neointimal hyperplasia, with 5 requiring repeat stent placement, 13 parts (9%) developed an aneurysm, 5 (3%) developed a dissection/intimal tear, and 6 parts (4.2%) developed stent fractures, 4 requiring repeat stent placement. The reintervention rate was 9/41 (22%) for the group with abnormal follow-up imaging. Comparisons were made between parts with normal (group A) vs. those with abnormal (group B) imaging at intermediate follow-up. In an attempt to identify the causalities, we performed subgroup analysis by comparing normal follow-up image group vs. both aortic wall injury and in-stent restenosis groups, respectively.

Group A (Normal Follow-Up)

One hundred and three patients (71.5%) had normal imaging at a median follow-up interval of 12 months (0.5–92 months) in the cohort study. In this group, the mean age was 18.6 ± 11 years and average weight was 59.4 ± 23.3 kg. Sixty-six patients (64%) were diagnosed as native coarctation, with 73 (70%) parts having their CoA located at the isthmus. Palmaz 8 and 10 series stents were used in majority of these procedures and half of these stents were delivered on a BIB balloon. Nine (8.7%) parts required two stents to cover the entire coarctation segment. Pre- and poststent implant minimal CoA diameters were 6.5 ± 3.2 and 14.4 ± 3.7 mm with mean percent change in CoA diameter poststent implant of 180% ± 20%. Balloon: CoA ratio was 3.0 ± 2.0. In these procedures, pre- and poststent coarctation systolic pressure gradients were 35.6 ± 19.5 and 2.8 ± 4.4 mm Hg, respectively.

Group B (Abnormal Follow-Up)

There were 41 patients with abnormal findings at follow-up imaging. Median follow-up period was 19.8 months (0.6 months, 84 months). The mean age was 16.0 ± 11 years and average weight 49.1 ± 22 kg. Fifty four percent of the studies ($n = 22$) were in native coarctation, with 21 (52.6%) located at the isthmus, 8 at the distal transverse arch, and 4 at the abdominal aorta. In this group, the Genesis, Palmaz 8, and P10 series stents were used most frequently, being delivered on BIB, Z med, or Cordis balloons in the majority of cases.

Group A vs. Group B

Group B parts had significantly smaller prestent CoA diameters (5.3 ± 2.5 mm vs. 6.6 ± 3.3 mm, $P = 0.02$) and poststent minimal CoA diameters (12.4 ± 4.0 mm vs. 14.4 ± 3.7 mm, $P = 0.008$) in comparison with group A parts. Percent (%) of increased CoA diameter after stent placing in group A was 183% vs. 241% in group B ($P < 0.001$). The poststent residual systolic pressure gradient was significantly higher in group B (mean 5.2 ± 7.3 mm Hg) vs. group A (mean 2.8 ± 4.4 mm Hg) ($P = 0.02$) parts. Patients in group B were more likely to be smaller ($P = 0.03$) and have the coarctation in a location other than the usual isthmic region ($P = 0.008$), such as distal transverse arch or abdominal aorta. Age, discrete vs. long segment coarctation, prestent gradient across the CoA, pre- and postcoarct:decending aorta ratio, balloon:coarctation ratio, nor stent type were not different between the two groups. Please see Tables I, II and III.

Normal (Group A) vs. Aortic Wall Injury Group

Our definition of aortic wall injuries included dissection and aneurysm. A total 18 parts with median follow-up interval 22.5 months (range 0.6 to 84 months), showed vessel wall injury. Follow-up timeframe was

TABLE I. Result of Normal Group vs. Abnormal Group

Char	Normal (n = 103)	Abnormal group (n = 41)	P value
Age (mean, SD)	18.6 (11.1)	16.0 (11.3)	
Weight (mean, SD)	59.4 (23.3)	49.2 (22.7.0)	0.032
N (%) recurrent coarctation	37 (36%)	18 (45%)	
Time to F/U (month)	12 (0.5–92)	19.75 (0.6–84)	
Median (range)			
Location			
N (%) isthmus	73 (71%)	21 (53%)	0.0085
N (%) other	11 (29%)	12 (47%)	
Precoarctation diameter	6.6 (3.3)	5.3 (2.5)	0.0283
Postdiameter	14.4 (3.7)	12.4 (4.0)	0.0082
Increase in Diameter (X precoarctation diameter)	1.8 (2.0)	2.4 (3.5)	
Balloon/coarctation ratio	3.0 (2.0)	3.7 (3.8)	
Pregradient	35.6 (19.5)	42.7 (21.5)	
Gradient post	2.8 (4.4)	5.2 (7.3)	0.0254

TABLE II. Result of Normal Group, Aortic Wall Injury Group, and Instent Restenosis

Char	Normal (n = 103)	Aortic wall Injury (n = 18)	Instent restenosis (n = 16)
Age (mean, SD)	18.6 (11.1)	20.4 (12.2)	9.8 (4.7)
Weight (mean, SD)	59.4 (23.3)	57.3 (19.7)	37.7 (21.3)
% Recurrent coarctation	37 (36%)	5 (27.9%)	11 (69%)
Time to F/U (Month)	12 (0.5–92)	22.5 (0.6–84)	14 (1.1–42.5)
Median (range)			
Location			
N (%) isthmus	73 (71%)	10 (56%)	6 (43%)
N (%) other	11 (29%)	3 (17%)	8 (57%)
Precoarctation diameter	6.6 (3.3)	5.4 (2.8)	5.2 (2.4)
Postdiameter	14.4 (3.7)	15.3 (3.1)	9.2 (2.5)
Increase in diameter (X precoarctation diameter)	1.8 (2.0)	3.5 (4.7)	1.6 (1.8)
Balloon/coarctation ratio	3.0 (2.0)	4.7 (4.9)	3.1 (2.9)
Pregradient	35.6 (19.5)	41.3 (18.2)	34.8 (16.6)
Gradient post	2.8 (4.4)	4.9 (9.1)	5.8 (5.4)
N (%) with prestent angioplasty	19 (18%)	8 (44%)	6 (38%)

TABLE III. List of Balloon Types and Stent

Balloon type	Normal group (N)	Abnormal group (N)
Z med	17	9
Cordis	14	5
BIB	42	11
XXL	5	3
Other	2	4
Stent type		
P8 series	26	11
P10 series	30	9
LD	1	1
EV3	1	0
Genesis	12	6
CP series	16	5
Cp covered	5	3
Other	3	3

not significantly different between the two groups. Eight of 18 patients (44%) underwent prestent angioplasty prior to stent placement, which was significantly higher than parts in group A 19/103 (18%) (P = 0.04). The percent increase in the prestent vs. poststent CoA diameter (3.5 ± 4.7% vs. 1.8 ± 2.0%), and the balloon: CoA ratio (4.7 ± 4.9 vs. 3.0 ± 2.0) was significantly higher in the aortic wall injury group in comparison with the normal group (P = 0.01). In reviewing the data, we noted that exceeding a balloon:coarc ratio >3.5 at the initial procedure significantly increased occurrence of aortic wall injuries at follow-up. Compared to patients with balloon:coarc <3.5, the odds ratio of observing aortic wall injury at follow-up imaging was 1.5 (confidence interval 0.5–4) in those

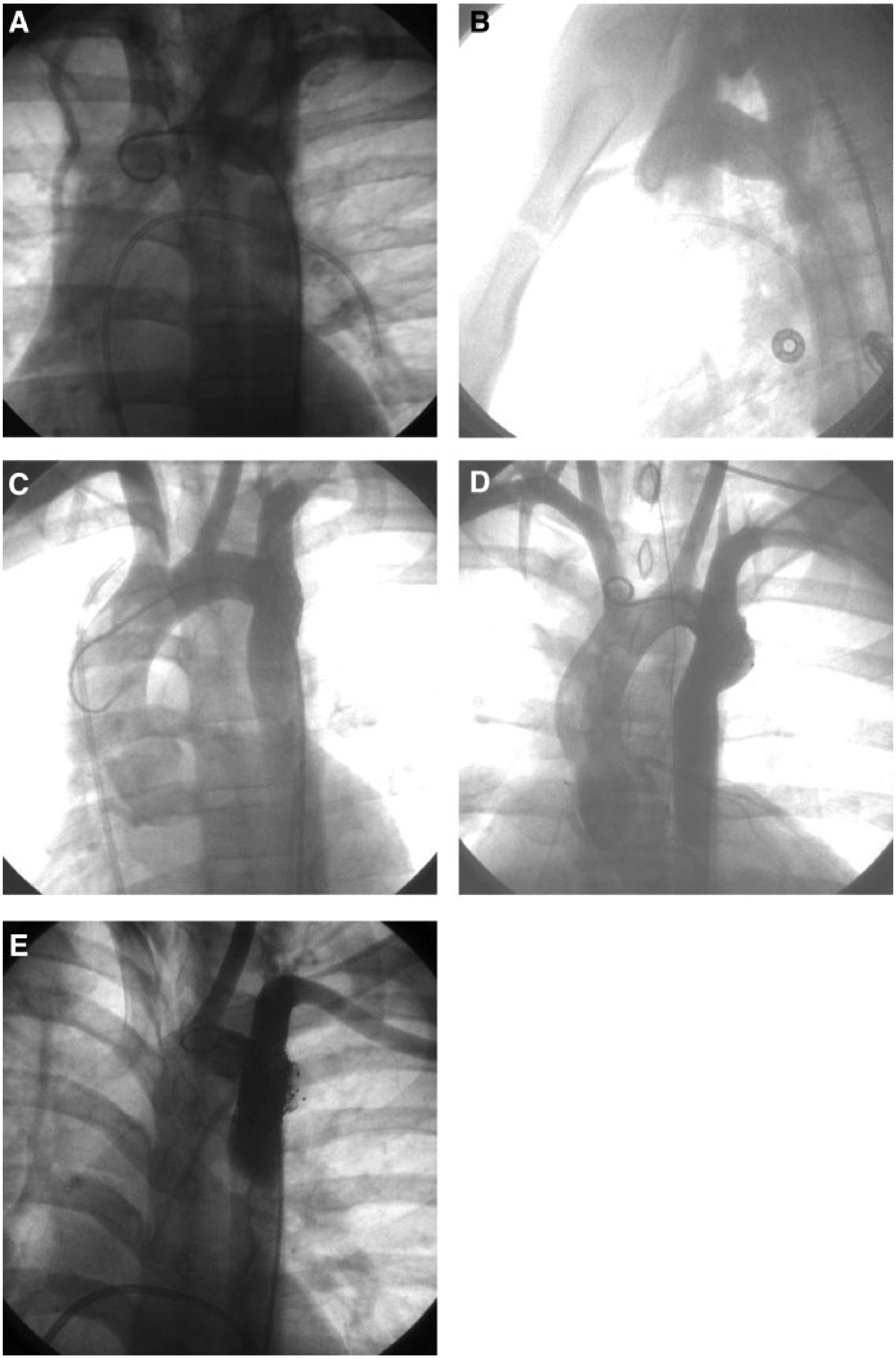

Fig. 1. (A,B) A-P and lateral views of a discrete, native CoA in the typical location in a 14-year-old girl. (C) S/p placement of a Genesis XD stent across coarctation segment. No residual obstruction observed. Neither dissection nor aneurysm formation noted. Balloon:coarct ratio of 2.2 was achieved. (D) Approximately 2 years following initial stent placement, development of a moderate sized aneurysm is noted. (E) S/p placement of a CP covered stent with complete exclusion of the coarctation aneurysm and no obstruction to flow observed (courtesy M. Ebeid).

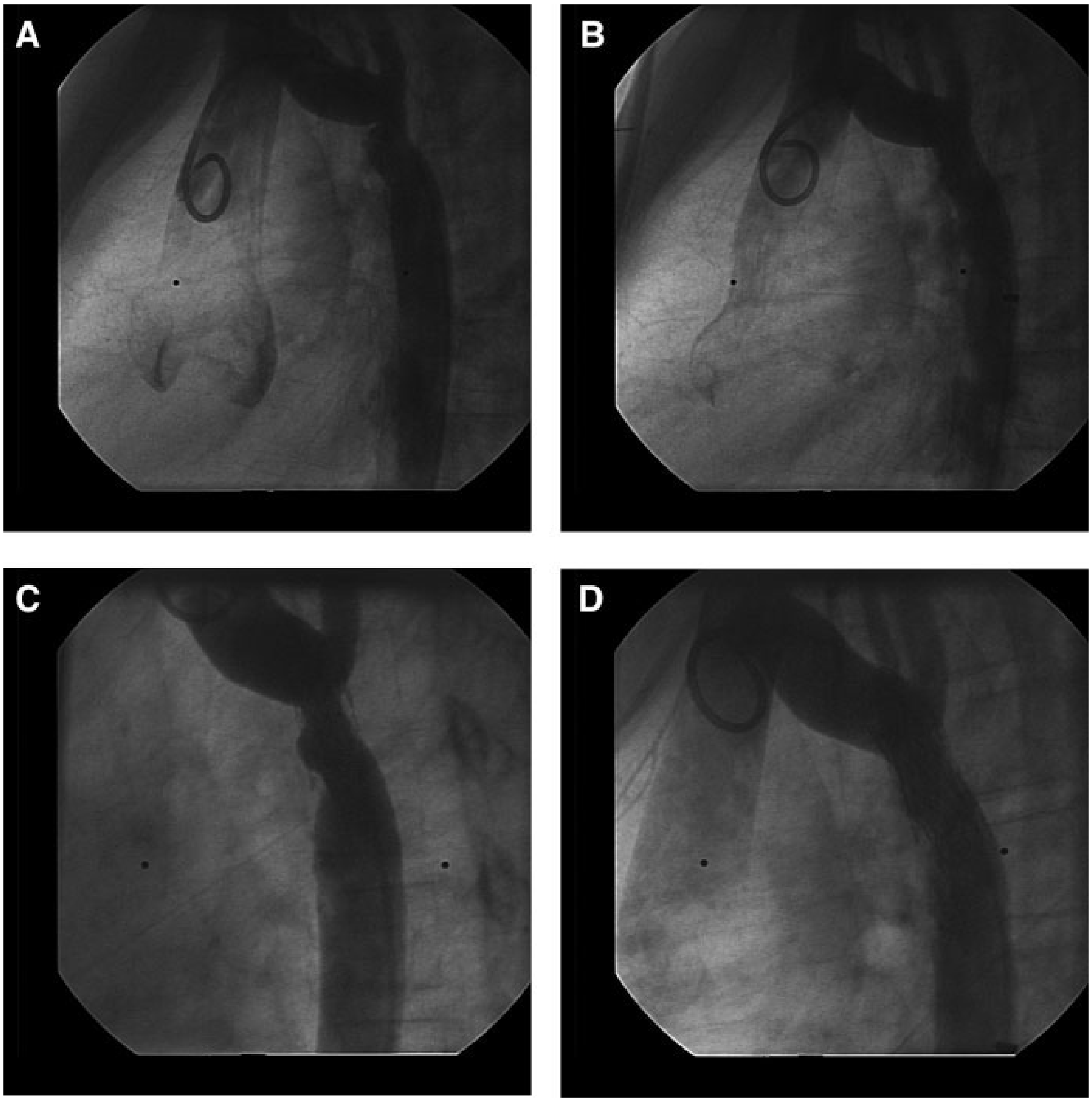

Fig. 2. (A) Recurrent CoA following surgical repair noted. Surgical repair was performed 8 years prior. (B) Placement of Genesis XD stent across coarctation segment. Stent is observed minimally crossing orgin of brachiocephalic vessel. No residual stenosis observed. (C) Development of significant neointimal build-up within the stent 2 years after initial stent deployment. (D) Placement of a second Genesis XD stent across previously placed stent, no residual obstruction present.

patients with balloon:coarc ratio ≥3.5. Age, weight, location, and type of coarctation, pre- and postintervention diameter of coarctation segment, encountering a complication at time of initial intervention, pre- and postintervention systolic pressure gradient were unrelated to encountering aortic wall abnormalities at intermediate follow-up. Please see Table II.

Aneurysm

In our 144 patients that underwent IAI, 13 (9%) developed an aneurysm. The time to follow-up after initial stent placement was a median of 35.7 months (8–84), which was significantly longer than group A patients (12 months; $P = 0.009$). The majority of aneurysms were small, being managed conservatively with observation. In four patients however, a significant aneurysm developed which required further intervention (Fig. 1A–E). Aneurysm formation occurred most commonly at the site associated with the narrowest segment of the coarctation, though in one patient, the aneurysm started proximal to the previously placed stent. Development of aneurysms was not

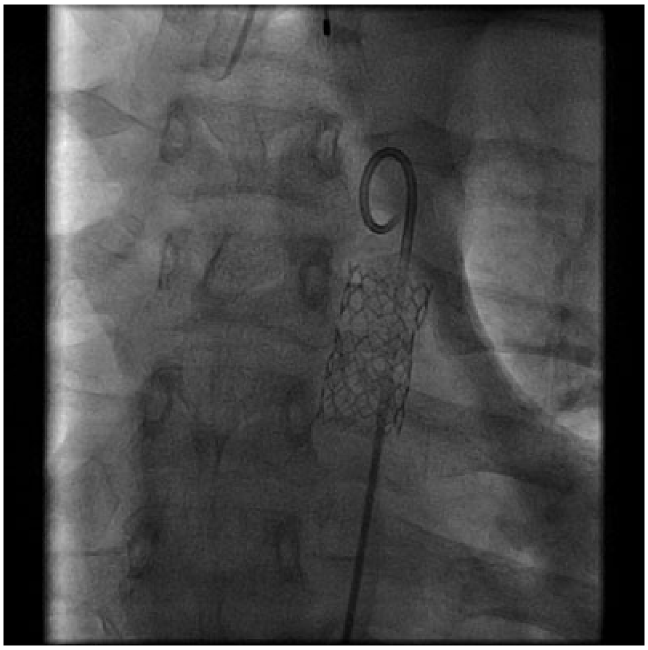

Fig. 3. Circumferential fracture of a Genesis stent in a native coarctation of the aorta, 2 years after intial implantation. This was treated with a second Genesis stent placed within previously placed stent without further incident.

related to patients' age, weight, initial diagnosis, recurrent vs. native coarctation, type of stent, encountering an acute complication at time of initial intervention, or balloon:coarct ratio.

Normal (Group A) vs. In-Stent Restenosis

We combined stent fracture ($n = 6$) and neointimal build up ($n = 16$) to form the in-stent restenosis group, though for further analysis, we excluded stent fracture, discussing this group separately in the following section. Please see Fig. 3. Comparisons between the two groups noted that younger age (9.8 $\pm$ 4.7 years vs. 18.6 $\pm$ 11.1 years) ($P = 0.02$) and lower weight at time of initial procedure (37.7 $\pm$ 21 kg vs. 59.4 $\pm$ 23.3 kg) ($P = 0.007$) was associated with the development of in-stent restenosis at intermediate follow-up. In addition, smaller poststent diameter (9.2 $\pm$ 2.5 mm vs. 14.4 $\pm$ 3.7 mm) ($P < 0.001$) and poststent systolic gradient (5.2 $\pm$ 5.4 mm Hg vs. 2.8 $\pm$ 4.4 mm Hg) ($P = 0.05$) were also associated with the development of in-stent restenosis at time of follow-up. Location and type of coarctation, postintervention diameter of coarctation segment, encountering a complication at time of initial intervention, presystolic pressure gradient were unrelated to encountering instent restenosis at intermediate follow-up.

One case of neoinitimal build-up occurred following stent fracture, and two occurred with stent recoil (both with the earlier version of the EV3 DS LD stent). Please see Figure 2(A–D).

Stent Fracture

Six patients reported stent fractures. All were encountered in native coarctation (please see Fig. 3). Among them, CP stent was implanted in four and the Genesis XD was placed in two procedures. There were no fractures observed in the Palmaz "8/10" series or the EV3 stents. Four parts required repeat stent placement and one redilation due to reobstruction. No distal fragments were observed, with the fractures either being circumferential (Genesis series), or localized to two to four neighboring cells (CP series).

The small number of stent fractures precluded any meaningful analysis.

DISCUSSION

A number of studies have reported excellent clinical results at intermediate follow-up in parts undergoing IS placement in the treatment of native and recurrent CoA [2–4,6,8,12,13,15,16]. However very few have reported on IAI of the aorta following IS placement in the treatment of CoA [3,14,17]. Though ultrasound imaging was routinely obtained in all of these patients, it may not reliable assess the severity of the gradient across the stent. Furthermore, aortic wall abnormalities may be missed due to artifact created by the stent. Integrated aortic arch imaging is the best method to assess aortic wall abnormalities and restenosis. To date, this is the largest report of follow-up in patients undergoing IAI following intravascular stent placement for treatment of native and recurrent CoA. In our experience, we observed a 25.6% incidence of aortic arch abnormalities following intravascular stent placement. The most common abnormalities encountered were the development of an aneurysm and intimal proliferation within the stent.

Development of aortic wall aneurysms following intravascular stent placement has been previously described in numerous reports [2,9,10,16,17] with the incidence of aneurysm formation ranging from 9 to 17%. The incidence in developing large aneurysms, requiring further treatment, ranges from 0 to 9% [2,3,9,17]. In Harrison's report, out of 18 parts undergoing repeat cardiac catheterization (mean 1.3-years follow-up time), three developed aneurysms. One was in a native coarctation, with a very large (>2 cm) aneurysm that required surgical removal of the stent and resection of the aneurysm [17]. The balloon:coarct ratio was five in this patient. The other two aneurysms were small and are currently being followed. In their report, neither dissection nor significant neointimal proliferation/restenosis was present. Ledesma et al. also reported a large aneurysm formation at intermediate follow-up in a native coarctation. In this patient, the balloon to coarct ratio was 7.5 [9]. Suarez et al. reported in 30 parts undergoing repeat cardiac catheterization (mean 25-months follow-up) with no aneurysm or dissections observed [2]. The cause and actual incidence of aneurysm formation at intermediate follow-up remain unknown. It is felt that overaggressive dilation of the native coarctation segment (balloon:coarct ratio >3.5) may contribute to aneurysm formation at intermediate follow-up. Our experience supports this contention, with a greater likelihood of encountering this complication when one exceeds balloon:coarct ratio >3.5. However, as depicted in Fig. 2, one can still encounter aneurysm formation even when one takes a conservative approach to stent dilation of the coarctation segment (balloon:coarct ratio 2.2). This is concerning and underlies the importance of developing a method to reliably assess aortic compliance prior to stent placement. This also stresses the importance of obtaining IAI of the aorta at reliable intervals following coarctation stenting. It has been implicated that native coarctation parts are more likely to encounter aneurysm formation than recurrent coarctation parts. We found no support for this, with an equal number of native and recurrent coarctation patients encountering aneurysm formation at follow-up. In our previous report on acute complications, we noted that age was associated with the development acute aortic of wall injury following stent placement. However at intermediate follow-up, we noted no age preferences for the development of aortic aneurysms.

Another factor, other than aortic wall compliance, that influenced the development of aortic wall injury at intermediate follow-up in our experience was performing prestent balloon angioplasty. In animal studies, Ohkubo et al. reported that when compared with conventional balloon angioplasty, primary stent implantation caused less vessel wall injury [18]. This contention was supported in a study by Magee et al., who felt that primary stent placement, rather than balloon angioplasty alone, supported the aortic wall, thus preserving medial integrity and thereby preventing extension of tears through the media into the adventitial layer [10]. Though the authors wanted to stress that preballoon angioplasty is not the same as assessing aortic wall compliance with balloon testing. Compliant balloon testing was not performed routinely by any of the authors during initial stent deployment and therefore was not evaluated in this study. Preballoon angioplasty, as we define it, related to an aggressive attempt to eliminate coarctation stenosis prior to initial stent deployment.

An equally common occurrence noted at intermediate follow-up was the development of neointimal proliferation within the stent. In our experience, the location of CoA and smaller poststent CoA diameter were the two most important prognostic factors determining the development of neointimal buildup within the stent. Conversely, Duke et al. noted that overdilating the stent at time of implantation contributed to neointimal build-up [19]. Furthermore, we noted that younger age, lower weight, and recurrent coarctation all had a higher incidence of neointimal build-up at intermediate follow-up. Similar results were obtained by Suarez de Lezo et al., where their incidence of neointimal build-up within the stent was 27% at a mean 23-months follow-up, [2]. This likely is directly related to vessel injury. Hunter et al. noted in an animal model of arterial injury, that vascular endothelial growth factor (VEGF) inhibited the formation of neointima following arterial injury by accelerated endothelial repair. In that same study, they noted that sequestration of exogenous and/or endogenous VEGF delayed reendothelialization, significantly increasing neointimal proliferation [20]. It may be that drug eluding stents will play a large role in preventing neointimal build-up within the stent, though this remains speculative at this time.

Limitations

This study is a retrospective review, with all the attendant limitations associated in performing such a study. Follow-up IAI studies were done as protocol in just three institutions. The majority of imaging studies were performed due to concerns of either reobstruction or the development of an aortic aneurysm. Therefore, over estimation of poststent aortic arch abnormalities is likely to have occurred in our cohort group.

CONCLUSION

Exceeding balloon:coarct ratios >3.5 and prestent angioplasty should be avoided in patients undergoing intravascular stent placement for CoA. The true incidence of abnormal findings on aortic arch imaging following IS treatment of CoA remains unknown, since only 27% of the parts underwent IAI following IS treatment of their aortic coarcation. We feel that routine IAI following intravascular stent treatment of aortic coarctation is imperative in this group of parts.

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