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Balloon-expandable stents for native coarctation of the aorta in children and adolescents

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Abstract

Although balloon-expandable stent implantation for native aortic coarctation is a preferred method in the adolescent age group, there are insufficient data about indications for and the efficacy of the procedure in a younger age group. The aim of this study was to compare and evaluate the data of young pediatric and adolescent patients who underwent balloon-expandable stent implantation because of native aortic coarctation. The retrospective analysis included the demographic characteristics and data related to the procedure and follow-up of patients who underwent stent implantation for native aortic coarctation between August 2010 and November 2017. Patients with re-coarctation were excluded from the study. The patients were separated into 2 groups as the adolescent group (Group I: 10–18 years) and the pediatric group (Group II: ≤ 9.9 years). Group-I comprised of 18 patients and Group-II, 32 patients. Covered stent was implanted to 32 (73%) patients and uncovered stent to 12 (27%) patients. The procedural success rate was 100%. Following stent implantation, peak systolic gradient decreased significantly in both groups ($P < .0001$) (Group-I: from 35.9 ± 16.6 mm Hg–2.2 ± 3.4 mm Hg, Group II: from 34 ± 13.3 mm Hg–3 ± 4.09 mm Hg). Complications developed in 3 patients, and all in Group I. Femoral hematoma developed in 1 patient, balloon rupture occurred during the procedure in 1 patient, and there was temporary loss of pulse in 1 patient. All the complications were treated successfully. All the patients were taking anti-hypertensive drugs before intervention and during the mean 23-month follow-up period (range, 2–84 months), hypertension recovered in 35 (80%) patients and drugs were terminated. Stent implantation for aortic coarctation in the pediatric age group may provide pleasing results, reducing the coarctation gradient, providing effective dilatation in the lesion area and eliminating hypertension.

Abbreviations: CoA = coarctation of the aorta, CP = Cheatham platinum.

Keywords: adolescents, children, native coarctation, stent implantation

1. Introduction

Coarctation of the aorta (CoA) has been reported in 0.04% of all live births and in 5 to 8% of all patients with congenital heart disease.[1,2] Surgical repair is the gold standard treatment for CoA in infants and young children.

Since 1982, when Singer et al[3] performed transcatheter balloon angioplasty to coarctation in a newborn, this intervention has become an alternative method for selected patients. For older children and adults with recently diagnosed (native) CoA, non-surgical balloon dilation[4,5] and stent enlargement[6–9] is often performed. Although transcatheter stent implantation for aortic coarctation (AoCo) is being increasingly used as a treatment option at a younger age, there is limited information about long-term results and follow-up in the pediatric population.[6,7]

The aim of this study was to follow the procedural results of stenting for aortic coarctation in young children and adolescents and evaluate the safety and effectiveness of this procedure for younger patients.

2. Materials and Methods

A retrospective evaluation of the data of patients aged < 18 years who underwent stenting for native aortic coarctation between August 2010 and November 2017 was made. Patients were excluded from the study if they had a complex cardiac pathology, transverse arch and long isthmus hypoplasia, or a history of surgical coarctation treatment or balloon angioplasty.

Clinical features as indications for treatment included upper body systolic hypertension, lower body hypotension, blood

Patient consent was waived due to retrospective study.

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The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board of Istanbul Saglik Bilimleri University Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Education and Research Hospital (date:2020, number:47).

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pressure gradient between the upper and lower extremities (>20 mm Hg indicates significant coarctation of the aorta) and radio-femoral pulse delay. Information related to the structure, and extent of coarctation of the aorta, left ventricular function and hypertrophy, associated cardiac abnormalities, and aortic and aortic arch diameters were obtained from echocardiographic examination.[8]

Patients were separated into 2 groups as Group I, comprising of patients between 10 to 18 years of age, and Group II including patients 4.3 to 9 years of age to compare the outcomes and to evaluate the safety and effectiveness of stent implantation,

Before the procedure, computed tomography was performed to all of the patients and lesion diameter, length, and the diameters of normal aortic tissue on the proximal and distal were measured.

For all patients included in the study, the following CT and angiographic details were recorded; characteristics of the pathology (discrete, subatretic, long-segment, or tortuous morphology), localization and diameter of the coarctation; other concomitant congenital heart diseases; pre-procedural and post-procedural blood pressure values and systolic gradients; and procedural data such as the dimensions, types and covers of the stents and balloons used.

Blood pressure values were measured from 4 extremities. Hypertension was diagnosed when the measured upper extremity systolic blood pressure was found to be more than 95% of the normal range. The use of anti-hypertensive drugs was recorded.

2.1. Catheterization technique

Catheterization protocol and technique was similar to the previously published articles.[10,11] In the younger patients, before the procedure, a femoral artery injection was made to assess the size of the femoral artery for the procedure.

Measurements of the diameter of the ascending aorta, isthmus, coarctation, and descending aorta, the length of the coarcted segment, and the distance to the brachiocephalic artery were recorded. Balloon size and stent type was chosen according to the published articles.[10–12]

The criteria defining the success of the procedure included no catheterization-related death, systolic gradient < 10 mm Hg on the stent, and no residual stenosis (dilatation of the narrowest segment by > 50%).[6,13] Complications that developed during the procedure or that required observation/treatment before discharge were classified as acute complications.

2.2. Post-procedure follow-up

Following the procedure, patients were hospitalized for at least 24 hours for observation of acute complications. Apart from the heparin infusion performed in the catheter room, no routine anticoagulation was given. Anti-hypertensive treatment was continued in cases with persistent hypertension after the procedure. Stent position was evaluated in all patients with telecardiography and gradient across the stent was evaluated via echocardiography on the next day after the procedure.

All patients, without any complication, were discharged after 24 hours. Follow-up visits were planned at 1 week, 1 month, 3 months and 6-month intervals thereafter. Echocardiographic imaging, electrocardiography, and blood pressure measurements from 4 extremities were evaluated routinely at the follow-up visits. Patients with hypertension were monitored with 24-hour Ambulatory Blood Pressure Monitoring. CT imaging was not performed routinely to all patients, but to those with an increase in echocardiographic gradient across the stent or those with hypertension or inadequate noninvasive imaging. Patients diagnosed as re-coarctation on CT, those with hypertension with a gradient of > 20 mm Hg between the upper and lower extremities, or those with an end-diastolic tail velocity with continuous Doppler across the stent on echocardiography during follow-up were evaluated with repeated angiocardiography.

Primary outcomes of the study were defined as immediate adverse events and late adverse events. Immediate adverse events included hospital mortality, thrombosis or injury of the femoral arteries, immediate stent migration, aortic dissection, and thrombosis of the arteries, whereas late adverse events included re-stenosis, stent fracture or aneurysm after re-dilatation, stent migration, aortic dissection, femoral artery stenosis, or occlusion.

2.3. Statistical analysis

Data obtained in the study were analyzed statistically using Statistical Package for the Social Sciences for Windows 17 software (SPSS Inc., Chicago, IL). Categorical variables were stated as number (n) and percentage (%), and continuous variables as mean ± standard deviation, median, minimum and maximum values. Categorical data were compared using the Chi-square test or Fisher's Exact test when expected frequencies were <5. In the comparisons of quantitative variables between the 2 groups, the Student's *t* test, -test for paired data and the Mann-Whitney *U*-test were used. A 2-tailed *P* value <0.05 was considered statistically significant.

3. Results

Evaluation was made of a total of 44 patients (34 male, 10 female) aged 4.3 to 18 years. Following femoral artery injection, in 3 patients who had been admitted for the procedure, the femoral artery size was determined to be too small for long sheath placement. Although a stent was applied later, these 3 patients were excluded from the study.

Patients separated into 2 groups as Group I (n:18, adolescent age group, 10–18 years) and Group II (n:26, young pediatric age group, ≤ 9.9 years).

On multi-slice CT, interrupted aortic coarctation was thought to be present in 4 patients, but during the cardiac catheterization, aortic interruption was seen in only 1 patient. Other patients were categorized as subatretic aortic coarctation.

Before the procedure, all the patients were taking anti-hypertensive medical treatment. After the invasive treatment, hypertension recovered in 35 (80%) patients. In 5/9 patients whom hypertension persisted treatment was continued with 2 anti-hypertensive drugs, and in 4/9 patients with a single anti-hypertensive drug. Of these 9 patients, 4 required re-dilatations of the stent, 3 of these patients were on 2 drugs and 1patient on a single drug for anti-hypertensive treatment. Following the stent re-dilatation procedure, all 4 patients continued with single drug treatment.

Cheatham platinum (CP) stents (NuMED®, Hopkinton, NY) were implanted in all the patients, as covered CP stent in 32 (73%) cases and bare CP stent in 12 (3 in group I and 9 in Group II) (27%) patients.

No mortality or stent fracture developed during or immediately after the procedure. Complications developed in 3 patients immediately after the procedure, all in the adolescent age group. One of these cases was a 14-years-old girl, in whom hematoma and bleeding developed in the femoral region following stent implantation. The bleeding and hematoma were brought under control with compression. In the second case, a 16-year-old girl, the femoral artery pulse was lost. After 24 hours of heparin infusion, the pulse was viewed on color Doppler USG, the heparin treatment was ceased, and the patient was discharged. The third complication was in an 18-year-old male, where balloon rupture occurred while balloon dilatation was being performed with a 16 × 40 mm balloon. The balloon was removed but the distal part was missing.

This remaining part was grasped and retrieved with a snare to the femoral region, but could not be drawn into and removed with the sheath, so a surgical incision was made to the femoral artery, the reptured balloon was removed, and the femoral artery was repaired via surgically.

Re-coarctation was observed in 1/18 (6%) patient in Group I and in 4/26 (15%) patients in Group II (P = .634). The invasive gradient of 40 mm Hg decreased to 6 mm Hg in 1 patient in Group I with re-dilatation at 70 months after the procedure. In Group II, the stent re-dilatation procedure was needed in 4 patients after a mean of 38.5 months (range, 8–66 months). The systolic arterial pressure gradient was decreased in all cases after the second procedure. No complications developed in anyof the patients after balloon re-dilatation.

Detailed information was given in the Table 1.

4. Discussion

Including the results of the current study, most stent implantations have been shown to be successful in the acute and mid-term. There was no procedure-related mortality, the invasive systolic blood pressure gradient fell below 10 mm Hg in all patients, a significant increase of the mean CoA diameter was achived after interventions and a decrease in the number of hypertensive patients after the procedure, all of which can be stated as markers of the treatment efficacy and reliability.

Although surgical intervention is the gold standard for the treatment of native aortic coarctation, in selected patients transcatheter approach has become an alternative treatment in several centers. Besides, there is an increasing tendency to adopt this approach for low body weight patients, recently.[6,7,9,10]

While stent implantation was 1st used after aortic coarctation surgery or in strictures developing after balloon aortic angioplasty (re-coarctation/residual coarctation), now it is started to be used in the treatment of native aortic coarctation.[9,10] The evident advantages of the transcatheter approach are no thoracotomy scar, diminished psychological effect, shorter hospital stay, decreased use of intensive care and a more rapid return to normal daily activities.[9,14] However, the major disadvantages are; a need for re-dilatation due to the body growth, insufficient femoral artery size in pediatric patients, and high cost of the stent. Nevertheless, with increasing experience, and the improvement of equipment and catheters, many studies showed that stent implantation alone is superior to balloon angioplasty, and it is a comparable alternative treatment to surgery for coarctation of the aorta.[6,9,10]

In an evaluation of a meta-analysis for stent implantation in aortic coarctation, which included 17 studies and 561 patients, only 3 of the studies were comprised of pediatric patients.[9] These 3 studies had a total of 62 patients with a mean age of 11.1 years (range, 4–19 years) and the procedure was unsuccessful in only 1 of these 62 patients, which was due to a long segment aortic coarctation, who underwent elective surgery afterwards. Also, Gendera et al,[6] reported aortic coarctation stent procedures in 34 infants (<3 years of age, <16 kg body weight) which resulted in success in all cases without any mortality. The peak systolic pressure gradient decreased after stenting, and the lesion diameter dilated by > 50% in that study.

Table 1

Patient demographics and procedural data.

Variables	Total n = 44	Group I n = 18	Group II n = 26	*P*
Age at procedure (yrs) Median (range)	10.4(4.3–18)	14.7(12–18)	9(4.3–11)	
Weight (kg) Median (range)	37(16–84)	52.5(37–84)	28.8(16–54)	
Height (cm) Median (range)	139(107–175)	160(143–175)	125(107–162)	
Gender (male, n %)	44 (77.2%)	14 (77%)	20(77%)	.71
Pre-stent noninvasive systolic pressure	134.4 ± 14.6	141.8 ± 16.9	136 ± 12.6	.223
Invasive systolic pressure	121 ± 17.2	121 ± 20.2	121.3 ± 15.3	.957
noninvasive gradient (mm Hg)				
Pre-stent	65.7 ± 14.1	67.9 ± 16.8	63.7 ± 12.4	.35
Post-stent	26 ± 8.1	26.8 ± 7.3	24.1 ± 8.9	.38
Invasive gradient (mm Hg)				
Pre-stent	34.8 ± 14.6	35.9 ± 16.6	34 ± 13.3	.689
Post-stent	2.6 ± 3.8	2.2 ± 3.4	3 ± 4.09	.497
Pre stent lesion diameter (mm)				
Angiographic measurement	5.19 ± 1.94	5.4 ± 2.3	5.05 ± 1.69	.583
Computed tomography	4.28 ± 2.17	3.79 ± 2.46	4.63 ± 1.91	.141
Post-stent lesion diameter (mm)	11.5(9.5–13.4)	12.2(10.5–13.4)	10.8(9.5–11.3)	.405
Balloon size (mm)	**12.6 ± 2.2**	**14.1 ± 1.3**	**11.6 ± 2.1**	**≤.001**
Hypertension [n (%)]				.128
Pre-stent	44/44(100%)	18/18(100%)	26/26(100%)	
Post-stent	9/44(20.4%)	6/18(33%)	3/26 (11.5%)	
Anti-hypertension drug usage [n (%)]				.128
Pre-stent	44/44(100%)	18/18(100%)	26/26(100%)	
Post-stent	9/44(20.4%)	6/18(33%)	3/26 (11.5%)	
Complications (n,%)	**3/44(6.8%)**	**3/18(16.8%)**	**-**	**≤.001**
Follow-up duration (month)	23(2–84)	20(2–80)	25.5(2–84)	.968
Stent re-dilatation [n (%)]	5/44(11.3%)	1/18(5.5%)	4/26(15.3%)	.634
Covered CP stent, (%)	32 (72.8%)	15(34%)	17 (38.6%)	.303
Bare CP stent, (%)	12 (27.2%)	3(6.8%)	9(20.4%)	.303

CP = Cheatham platinum.

As seen in surgical repair and balloon angioplasty studies, a significant proportion of patients still require anti-hypertensive drugs after the intervention.[15,16] As long-term persistent aortic arch obstruction is a known risk factor for permanent systemic hypertension in an adult population, this may cause some confusion. However, Weber[12] showed that after successful stenting of native CoA in young patients, systemic blood pressure associated with rest and exercise could be normalized approximately within 3 years after the intervention, without any need for anti-hypertensive drugs. Other studies also suggest that antihypertensive treatment can be ceased up to 75% within 3 years.[6,17] In the present study antihypertensive treatment ceased in 80% of the cases. However, 9 patients still have hypertension, but as it is reported that hypertension mostly recovered 3 years after stent implantation for native CoA by Weber et al,[12] this suggests that some of the cases in the current study who are still receiving treatment may be able to terminate the medical treatment in the future.

Many different procedure-related complications might develop in the early period after the implantation of aortic coarctation stent and the most common complication at the young age group (4–19 years), was reported to be problems related to the femoral artery.[9] Complications rate was reported between 9% to 30% in different series.[6,9,17,18] In the current study, complications developed during or immediately after the procedure in 3 (6.8%) patients, all in the adolescent group. No complications developed during or immediately after the procedure in the younger group. These results show that there is a lower risk of procedure-related complications in pediatric age group.

Before the catheterization procedure, femoral artery diameter was measured with contrast injection, especially in the younger age group patients to evaluate whether the femoral artery diameter was sufficient for the procedure. Patients diagnosed with small artery diameter after the injection, stent implantation was canceled with an aim to reduce the complication risk. As no complications developed during or immediately after the procedure in any of the 26 cases in the younger group (Group II), this demonstrates that the procedure is just as effective and safe in young children as in adolescents. However, as sustained body growth is much more prolonged in this group than in adolescents, the re-dilatation rate associated with re-coarctation was higher.

Yang et al reported in their meta-analysis; the most common complication as re-coarctation, in 32 (6.85%) patients among all reported cases and among 3 pediatric studies, and conventional balloon angioplasty was performed in 3 patients.[9] Bondanza et al, reported a total of 5/34 (11.3%) cases who underwent balloon re-dilatation (4 in 3–11 years group and 1 in 12–18-year group).

5. Conclusions

The results of this study show that transcatheter stent implantation for the treatment of native CoA is a procedure which can be preferred for suitable patients, with high success rates and acceptable complication rates although current stent technology, which requires a larger sheath, raises concerns in the very young age group. Further long-term studies of younger age groups, possibly including newborns, will be important in this respect to determine the safety of serial stent dilatation.

Author contributions

All authors have read and agreed to the published version of the manuscript.

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Formal analysis: E.-O., M.-S.
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Supervision: T.-K., M.-S., A.-G.
Validation: E.-O.
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