Original Article

# Complications of Aortic Stenting in Patients below 20 Years Old: Immediate and Intermediate Follow-Up

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#### Abstract

**Background:** Optimal timing and mode of treatment for patients with coarctation of the aorta (COA) remain controversial, particularly in children. Surgery, balloon dilatation, and stent implantation have all proven effective in the treatment of moderate or severe obstruction. The aim of this study was to investigate the complications of COA stenting angioplasty in pediatric patients.

**Methods:** This retrospective, descriptive study was conducted on patients less than 20 years of age who underwent aortic stenting angioplasty because of congenital COA in the pediatric catheterization laboratory of Rajaie cardiovascular, medical and research Center, Tehran between 2005 and 2010.

**Results:** A total of 26 patients (18 [65.4%] males and 9 [34.6%] females) with congenital COA who had undergone aortic stenting angioplasty were recruited. Nineteen (73.1%) of these patients had native COA and 7 (26.9%) had recurrent COA. Most of the early complications were minor and temporary; only one patient developed early major complications. During the follow-up, whereas none of the native group patients developed late complications, in the re-COA group 28.57% of the patients had re-stenosis and 14.28% had chronic systemic hypertension, requiring drug therapy.

**Conclusion:** Our investigation into post-stenting complications in patients with native COA and re-COA showed that endovascular stenting could be an effective and safe method, even in young patients with native COA.

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#### Introduction

Coarctation of the aorta (COA) occurs in about 6% to 8% of patients with congenital heart disease. If left untreated, COA is likely to have a poor natural history. Campbell's natural history data for untreated COA documented a mean age at death of 34 years (median = 31 years); 75% of the patients died by 46 years of age. The most common

causes of death were congestive heart failure (26%), aortic rupture (21%), bacterial endocarditis (18%), and intracranial hemorrhage (12%). Given such a poor prognosis, it is clear that intervention is indicated in almost all patients with COA.<sup>2,3</sup>

Crafoord and Nylin in 1944 performed the first surgical repair of COA.4 Surgical repair remains the conventional treatment for most children with COA. Various surgical

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techniques have been used to repair COA, each with its own advantages and disadvantages. In addition to mortality, surgical techniques are potentially associated with morbidity such as postoperative paradoxical hypertension, spinal cord ischemia and paralysis, recurrent laryngeal or phrenic nerve injury, chylothorax, bleeding, and infection.<sup>5</sup>

Balloon angioplasty has been utilized for COA since 1982. However, angioplasty of native COA has yet to gain wide acceptance because of concerns over residual or recurrent stenosis and aneurysm formation at the dilation site. <sup>6-8</sup> The acute effects of balloon angioplasty for recurrent postoperative coarctation are similar to those reported for native coarctation. As with native coarctation, re-stenosis and aneurysm formation do occur after the angioplasty of postoperative recurrent coarctation (re-COA). <sup>9-12</sup>

Balloon-expandable stents offer an effective therapy for patients with COA. Stents decrease coarctation restenosis, created by vessel recoil, and may also diminish the late incidence of aneurysm formation. Several clinical series have documented the effectiveness of coarctation stenting for native COA or re-COA.<sup>13, 14</sup> Nevertheless, this procedure can be associated with complications of balloon angioplasty and stent implantation, namely femoral artery injury and thrombosis, aortic injury, hemorrhage, stent fracture, aneurysm formation, endarteritis, endocarditis, restenosis, and death.

The present study sought to assess the immediate and intermediate complications of the aortic stenting angioplasty of native COA and re-COA in patients below 20 years old.

#### Methods

This retrospective, descriptive study was performed on patients younger than 20 years old who underwent aortic stenting angioplasty because of congenital COA between 2005 and 2010 in the pediatric catheterization laboratory of Rajaie cardiovascular, medical and research center, Tehran.

According to the patients' files, patient selection for aortic angioplasty was carried out after a thorough echocardiographic evaluation using General Electric Vivid-3 Machine with a 3-MHZ probe and subsequently angiography. The patients underwent angioplasty via the balloon stenting method. All patients who had ≥ 20 mmHg peak-to-peak pressure gradient (PG) across the coarctation site were included in this study, and those with < 20 mmHg PG or those who required heart surgery for other lesion or lesions were excluded. All the patients were followed up until May 2010 and were subjected to clinical and echocardiographic evaluations using GE Vivid-3 Machine. Additionally, 64-slice computed tomographic angiography was performed for all the patients with re-COA at follow-up.

Complications were divided into two categories: early (first 48 hours) and mid-term (up to the end of the follow-

up period). The early complications were divided into two categories of minor and major. Early minor complications consisted of transient arrhythmia, nausea and vomiting, transient abdominal pain, transient pulse weakening of the lower limbs, urinary retention, and mild bleeding of the vascular access site without need for transfusion. Early major complications were comprised of breathing disorder accompanied by bradycardia, leading to endotracheal intubation, and severe bleeding of the vascular access site, resulting in blood transfusion. The mid-term complications comprised re-stenosis, chronic systemic hypertension, aneurysm formation at the angioplasty region, and aortic dissection.

The demographic data of the patients, including age, sex, weight, type of coarctation (native COA versus re-COA), type and size of the stent and balloon used, procedure duration, type of anticoagulant and the duration of antiplatelet consumption therapy, follow-up duration, and early and mid-term complications of this procedure, were registered. The data are described as mean ± standard deviation (SD) for the interval variables and count (%) for the categorical variables. The One Sample Kolmogorov-Smirnov test was used to explore the fitness of the interval variables to normal distribution. The chi-square test or the Fisher exact test and the Mann Whitney U test were employed to compare the data between the two groups. SPSS 15 for Windows (SPSS Inc., Chicago, Illinois) was used to conduct the statistical analyses.

#### Results

The study population consisted of 26 patients with congenital COA, for which they underwent aortic stenting angioplasty. There were 18(65.4%) males and 9(34.6%) females. Nineteen (73.1%) patients had native COA and 7 (26.9%) re-COA. Of those with re-COA, 4 had balloon angioplasty, 2 patch aortoplasty, and one end-to end anastomosis operation.

The demographic data of the patients such as age, weight, stent size, balloon size, procedure duration, and follow-up duration were divided into native COA (Table 1) and re-COA (Table 2) groups.

All the patients were prescribed heparin 50 u/kg/6hr for 24 hours, Plavix 1mg/kg/day for one month, and A. S. A 3-5 mg/kg/day for 6 months.

The stents used were the Bare Cheatham Platinum (CP) Stent in 13 cases, Covered CP Stent in 9 cases, Max LD (EV3) Stent in 3 cases, and Pre-mounted Racer (Medtronic) Stent in one case. The balloons utilized were BIB (Numed) in 23 cases and Z-Med in 2 cases. In one patient, who had middle aortic syndrome, the Pre-mounted Racer (Medtronic) Stent was used.

Of the 19 cases with native COA, 8(42.1%) patients



Table 1. Characteristics of patients with native COA (n=19)

	Age (y)	Weight (kg)	Stent size (cm)	Balloon diameter (mm)	Procedureduration (min)	Follow-up (mo) duration
Min	4	16	1.8	7	60	12
Max	19	90	3.9	26	180	56
Mean	12.87	41.84	3.30	15.76	72.63	24.27
SD	5.43	23.21	0.63	3.10	30.52	12.21

COA, Coarctation of aorta; Min, Minimum; Max, Maximum; SD, Standard deviation

Table 2. Characteristics of patients with re-COA (n=7)

	Age (y)	Weight (kg)	Stent size (cm)	Balloon diameter (mm)	Procedure duration (min)	Follow-up (mo) duration
Min	8	27	2.8	12	60	12
Max	19	55	3.9	18	90	42
Mean	13.86	39	3.41	14.86	68.57	22.85
SD	4.14	12.79	0.32	2.54	14.63	9.97

Re-Coa, Recurrent coardtation of aorta; Min, Minimum; Max, Maximum; SD, Standard deviation

developed minor early complications, consisting of 2(10.52%) cases of transient abdominal pain and 6(31.57%) cases of pulse weakening in the limb of the vascular access. The early complications, consisting of apnea, bradycardia, and severe bleeding of the procedure site necessitating intubation, blood and fresh frozen plasma transfusion, and vitamin K injection, developed in only one (5.26%) case: This was an 8-year-old, 20-kg patient with long segment COA.

Of the 7 cases with re-COA, 2(28.5%) patients developed early minor complications, consisting of transient nausea and vomiting, one patient suffered minor bleeding of the vascular access site, and one patient had urinary retention and minor bleeding of the vascular access site. There were no cases of major early complications in the re-COA patients.

During the follow-up period of the 19 cases with native COA, mild re-COA was detected in 6(31.57%) patients without need for re-intervention. The late complications such as systemic hypertension, aneurysm formation, and aortic dissection were not detected in any of the patients.

During the follow-up period of the 7 cases with re-COA, moderate re-COA was observed in 2(28.57%) patients, for whom stent re-dilation was done, and mild re-COA was seen in 3(42.85%) patients, who had no need for re-intervention. In one patient in this group, chronic systemic hypertension was detected, for which drug therapy was commenced. Aneurysm formation and aortic dissection were seen in none of the patients of this group.

#### Discussion

COA, first described by Morgagni in 1760, encompasses a wide spectrum of presentations from cardiogenic shock in the

neonate to murmur and upper-limb hypertension in adults. In 1982, balloon dilation was introduced as an alternative to surgery. Stents were first used in the early 1990s to treat COA in children. Since then, balloon-expandable endovascular stents have been drawn upon successfully to handle large vessel stenoses, including COA. Angioplasty with a stent creates a 'controlled tear' in the aortic wall supported by the framework of the stent upon dilation, minimizing the risk of dissection or aneurysm formation, which could occur after balloon dilation alone. Studies have shown excellent results in short and intermediate follow-up, with success rates approaching 97% in selected patients.

Complications of stent placement are generally well tolerated and rarely serious. These include aortic disruption, arterial access problems, balloon rupture, stent migration, aneurysm formation, late restenosis due to intimate hypoplasia, death in 0-1.4% of cases, neurological damage in 0-3.7% of cases, stent fracture, balloon rupture, paradoxical hypertension, endocarditis, and occlusion of the major branches of the aortic arch. Stent replacement requires the application of large diameter sheaths, which creates limitations in the use of this device in pediatrics, especially in infants. To our knowledge, there is a paucity of data in the existing literature on complications in young patients, particularly those with native COA. It is also worthy of note that some studies have reported no major complications in children.<sup>17-21</sup>

The present study was conducted in children and adolescents, most of them with native COA. The bulk of the acute complications in our study population was minor and temporary; early major complications occurred in only one of our patients. During the follow-up period of 12 - 56 months, while none of the native COA group patients developed late complications, in the re-COA group, 28.57%

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of the patients had re-stenosis and 14.28% had chronic systemic hypertension, necessitating drug therapy. These results, in comparison with those reported by earlier studies, are noteworthy.<sup>22-25</sup>

The present study has some limitations, first and foremost amongst which are its small sample volume and insufficient follow-up duration.

### Conclusion

Our investigation into the complications in patients with native COA and re-COA demonstrated that COA treatment by stent implantation could be an effective and safe method even in young patients with native COA, if selected appropriately. Availability of low profile stents and balloons affords the application of this treatment modality in low weight patients and infants. Further studies with larger populations and longer follow-up periods are required to evaluate the long-term outcome in such patients.

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