Editorial

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Progress toward Approval of Stents in Coarctation of the Aorta

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Coarctation of the aorta (CoA), which was first described by Morgagni, accounts for 5-7% of all congenital heart disease.[1] Since the first successful surgical repair was performed in 1944 by Crafoord,[2] various methods including operative and transcatheter approaches have been developed with excellent outcomes. Neonates with severe CoA present with heart failure and shock after closure of the ductus arteriosus and deteriorate rapidly if left untreated. However, patients with less severe CoA may not be diagnosed until late childhood or adulthood. Hypertension is the most common presentation for these patients. Transcatheter balloon angioplasty has been used as an alternative option to surgical repair, especially for recurrent CoA. In 1982, balloon angioplasty was introduced by Lock et al.[3] for native CoA. Despite the high success rate of balloon angioplasty, high rates of re-coarctation and aortic wall injury compared to surgery remain a concern. A 15% rate of re-coarctation for balloon angioplasty of native CoA has been reported[4] and aortic aneurysm developed in 35% on long-term follow-up.[5] Balloon angioplasty alone is not currently recommended for treatment of CoA in adults.

Endovascular stents were first reported as a new option for treatment of CoA in 1991.[6] Endovascular stents provide structural support and prevent over-dilation, which can otherwise lead to aortic wall injury and restenosis. Several studies reported high success rates and lower complication rates in endovascular stent placement compared to balloon angioplasty or surgery. However, no endovascular stent has been approved by US Food and Drug Administration (FDA) for use in the aorta thus far. NuMed Inc. (Hopkinton, NY, USA) developed the Cheatham-Platinum (CP) stent for use in the aorta and The Coarctation of the Aorta Stent Trial (COAST) was conducted in 2007.[7] The COAST showed procedural success in all but one case, and no acute adverse events occurred. Two years after stent implantation, no surgical re-interventions were needed but transcatheter re-interventions in 19 (21%) patients were performed successfully due to aortic wall injury or stent re-stenosis.[8]

A covered endovascular stent was first used for CoA in 1999 for the purpose of reducing aortic wall complications. Covered stents may be used not only as a rescue therapy, but also as an initial therapy, especially in elderly patients with friable and calcified aortic tissue. For patients with very severe or complex CoA at high risk of aortic wall injury during balloon dilatation or bare metal stent implantation, covered stent implantation should be implemented. However, significant aortic branch occlusion needs to be avoided. A randomized trial comparing bare CP and covered CP stents in CoA treatment revealed better outcomes in covered CP stent implantation. The COAST II study that is expanded to covered stents for the intervention of CoA is currently seeking FDA approval.

Bassri et al.[9] committed favorable acute and delayed outcomes following transcatheter intervention with a stent for the correction of CoA in adult patients. These authors used mainly a bare CP stent, but a covered CP stent was used primarily for interruption of the aortic arch and for rescue immediately after aortic wall damage. There are guidelines from the American College of Cardiology and the American Heart Association that suggest the favorable potential for stent use in adult patients with CoA even though the supporting evidence is sparse. However, various treatment options should be considered according to patient age, aortic morphology,

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CoA site, genetic abnormality and combined anomalies.

Interestingly, a self-expanding stent was implanted in two patients, but there were no comments regarding the reasons for its use in this observational study. Some interventionists experienced favorable results with a self-expanding stent for treatment of CoA. A self-expanding stent might be beneficial for prevention of acute aortic wall damage. Nonetheless, covered stent is the key material to cope with the serious situation immediately after aortic wall damage. Therefore various materials and equipment should be prepared prior to transcatheter intervention for CoA.

Stent and balloon size are crucial to successful stent implantation and should be determined based on the size of the proximal aorta and descending aorta. The diameter of the CoA site should be considered as well, and the ratio of stent diameter to the diameter of the CoA site should not exceed 3.5.[10] Aortic aneurysm occurs rarely, but the true incidence remains unclear. However, most aortic aneurysms are so small that they are clinically insignificant that is similar to this observational study. Stent implantation for treatment of CoA near the subclavian artery might be challenging because of the associated arch hypoplasia and the different axis of the balloon and the arch. Some interventionists prefer to use the subclavian artery as the wire anchoring site instead of the ascending aorta and prefer a short balloon to a long balloon. Observing the sites of aneurysm might be helpful in analyzing the frequent aneurysm formation in patients with CoA near subclavian artery. Stent fracture rates associated with restenosis were reported with a broad range of up to 12% when minor fracture was included. When it comes to the procedural complications, the vascular injury at access site should be taken lightly.

The authors evaluated the impact of the arch shape on procedural outcomes. A few studies have demonstrated that a Gothic arch shape could be associated with late hypertension because of decreased aorta distensibility and increased loss of systolic wave amplitude. A circular arch shape after surgical repair could be ideal. Even though arch shape had no association with procedural complications in this observation, abnormal arch shape in CoA might be the cause of persistent hypertension after stent implantation. Therefore, in cases of abnormal arch shape in CoA, surgical repair might be preferable over endovascular treatment. In spite of significant reductions in hypertension, the prevalence of persistent hypertension even after successful treatment of CoA with a stent or graft stent remained high in this observational study. While old age is a risk factor for persistent hypertension after CoA repair, the reasons for persistent hypertension in this population need further investigation.

CoA has been regarded as a syndromic disease because of various morphologies and associated abnormalities. Therefore various surgical techniques and various advanced materials in endovascular treatment should be considered. We suppose FDA approvals is coming and this is exciting not only to patients but also to interventionists. However, some concerns still need to be addressed. Vascular complications associated with a large profile system and stent fracture need to be identified and improved. The indications and contraindications should be supported by evidence. As an interventionist in structural heart disease, I look forward to seeing approval of the use of stents and stent grafts not only for adult patients, but also for pediatric patients including neonates.

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