

## Original Article

# Transcatheter intervention for coarctation of the aorta\*

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### Abstract

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COARCTATION OF THE AORTA IS A RELATIVELY common form of CHD, with an estimated incidence of three in 10,000 live births, and accounts for ~5% of all cases of CHD.<sup>1,2</sup> The lesion was first eloquently described by Giovanni Morgagni, and the first surgical intervention was performed by Crafoord in 1944.<sup>3,4</sup> Although there has been a fascinating evolution of surgical techniques for the treatment of coarctation, we limit the scope of this review to catheter-based options. Balloon angioplasty of the aorta was first described by Singer in 1982 and by Lock et al in 1983.<sup>5,6</sup> Since then significant controversy has surrounded this interventional method for the treatment of coarctation, especially for native lesions. Nine years after balloon angioplasty for coarctation was introduced, the first endovascular stent placement was reported.<sup>7</sup> Since then, the endovascular stent technique has evolved via improved technology and multi-institutional studies. In recent times, results on covered stents have become available, and larger studies are ongoing. We will review the catheter-based options for treatment of coarctation of the aorta, including the history of these procedures, technical considerations, available data, and future contemplations.

### Early history

From the mid-1900s until the first reported balloon angioplasty, treatment for coarctation was exclusively surgical. This progressed from circumferential end-to-end anastomosis, prosthetic patch, subclavian flap, interposition graft, to extended end-to-end anastomosis.<sup>8–11</sup> In the early 1980s, angioplasty was reported for the treatment of coarctation. Since its first report, multiple studies have shown that, although acute results are promising, late complications have prevented this treatment from being the modality of choice in native coarctation. Another catheter-based intervention was needed, and endovascular stent placement for coarctation was reported in 1991. Since then, there have been multiple modifications to this therapy, including changes to technique, mounting balloons, and the stents themselves, which have made this modality more applicable to the paediatric population. The early experience with catheter-based techniques has driven the field towards improved options, with better results and lower rates of procedural complications.

### Technical considerations

Percutaneous interventions of the aorta are usually performed via a retrograde approach following femoral arterial access. Other options include an antegrade approach via venous access and a transseptal catheter course. Access from a carotid cut-down or percutaneous carotid approach has been reported.<sup>12,13</sup> The procedure should be performed under

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general anaesthesia as stretching and/or tearing of the aortic wall is painful and could cause patient movement at a critical point. Haemodynamics are typically performed by direct pullback across the area of interest. Angiography of coarctation is best highlighted with a biplane system, the anteroposterior camera at 0°, or left anterior oblique with the lateral camera at 90°. This is usually performed with a marker catheter for accurate calibration to precisely assess the size of the normal portion of the aorta as well as the minimal lumen diameter. Multiple advances in imaging, including three-dimensional rotational angiography with image overlay, MRI overlay, and/or MRI-based intervention, have been described. As coarctation is an anatomically heterogeneous lesion, proper imaging will help in the planning of the intervention, including determining the wire position, balloon size, and stent type and size. Balloon/stent size is usually determined by the diameter of the normal portion of the transverse aortic arch or the aortic size at the level of the diaphragm.

The decision to move forward with an aortic intervention will typically follow the American Heart Association's published guidelines for catheter intervention of coarctation.<sup>14</sup> Once the diagnostic portion of the case is complete, it is important to gain a stable wire position. A stiff wire with a floppy tip is preferred to help stabilise the balloon during inflation while lowering the risk for distal wire injury. Wire position options include the left ventricle, the ascending aorta, or the right subclavian artery. Although the right subclavian artery may offer more stability, it carries a slightly increased risk of dissection of the innominate artery.<sup>15</sup> To further increase the stability of the balloon, rapid right ventricular pacing can be used, especially in older patients with higher stroke volumes.<sup>16</sup> A ventricular rate that causes at least a 50% reduction in systolic blood pressure is preferred.

After obtaining adequate wire position and aortic measurements, a balloon is selected for angioplasty. A low-pressure balloon can be used initially to better understand the compliance and narrowing of the vessel. If inflation with the low-pressure balloon is not therapeutic and there is a significant residual waist, a higher-pressure balloon can be used. Serial dilation with larger balloons can be performed; however, a pullback gradient and angiogram to assess the response and any vessel wall injury should be performed. The largest balloon used is limited to the size of the adjacent aorta or, historically, to three times the minimal lumen diameter of the aorta coarctation site.

Stent placement in the aorta requires even more attention to balloon stability and accurate angiographic measurements (Fig 1). There are mixed

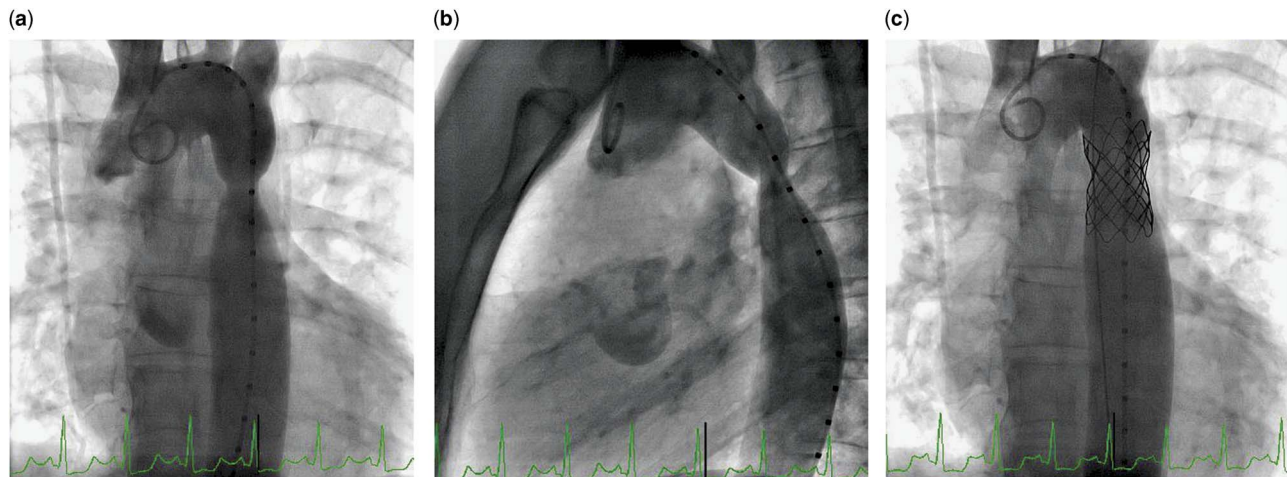
opinions regarding compliance testing with a low-pressure balloon before stent placement to avoid vessel wall injury. If there is a waist on the compliant balloon at full inflation, a smaller balloon is used to mount the stent, with intention to return at a later date for further dilation.<sup>17</sup> Stent selection, including bare metal versus covered, depends on the size, location, and complexity of the narrowing. There are many options for use as mounting balloons; however, the Balloon in Balloon™ (NuMed, New York, United States of America) allows for more uniform stent dilation and significantly decreases the risk for stent displacement during inflation. This balloon does require a larger sheath limiting its use in smaller patients. A long sheath is used and placed past the coarctation site. The mounted stent is placed across the narrowing, the sheath is pulled back, and hand injections of contrast are used to confirm stent position before deployment. Rapid ventricular pacing is initiated, if desired, and the stent is deployed. Post intervention, pullback and angiography is performed and further dilation of the stent can be performed if indicated. Post-implantation modifications have been described, including flaring the ends of the stent for better apposition to the aortic wall, dilation of the cells of a bare metal stent to head/neck branch vessels, and puncture of covered stents to restore flow to the left subclavian artery.

## Outcomes

### *Balloon angioplasty for native coarctation*

Multiple studies performed in the 1990s through the early 2000s report adequate acute and mid- to long-term efficacy of balloon angioplasty for native coarctation with acute success rates as high as 100%.<sup>18–21</sup> In 2014, the Congenital Cardiac Intervention Study Consortium (CCISC) published its multi-centre data on 76 patients who had undergone angioplasty of native coarctation.<sup>22</sup> Overall, 73% of patients left the hospital with upper- to lower-extremity blood pressure gradient <15 mmHg. Acute vessel wall injury was reported in 11% of patients. When combining two of the larger studies there was no procedural mortality in 143 patients.<sup>20,22</sup>

Although the acute outcomes appeared promising, there was growing concern over the long-term results of angioplasty for native coarctation. The rate of recurrent coarctation is reported to be between 15 and 25% in all patients and as high as 83% in neonates.<sup>20</sup> The accepted mechanism of action of angioplasty includes disruption of the vessel wall; therefore, it is not surprising that the rate of wall injury is reported at 25–43%.<sup>22,23</sup> Overall, in the CCISC cohort, there was a 57% total complication



**Figure 1.**

*Stent implantation in an adult patient with coarctation of the aorta. (a) Anterior and (b) lateral projections showing coarctation of the aorta distal to the take-off of the left subclavian artery with ~50% narrowing. (c) Angiogram post-implantation of a Cheatham-platinum covered stent demonstrating a well-positioned stent with improved diameter of the aorta and no evidence of aortic wall injury.*

rate at intermediate-term follow-up, including wall injury and recurrent coarctation.

#### *Balloon angioplasty for recurrent coarctation*

As balloon angioplasty has fallen out of favour for native coarctation, it has gained popularity for recurrent coarctation. It is the preferred method at most centres for addressing this lesion and is supported by the American Heart Association consensus statement.<sup>14</sup> Patients who have undergone surgical arch reconstruction as part of a single-ventricle palliation are especially at risk for complications associated with recurrent coarctation. This complication can increase single-ventricular dysfunction and atrioventricular valve regurgitation. In a large study of 549 single-ventricle stage I arch reconstructions, 18% required re-intervention on the aortic arch, with good short-term results.<sup>24</sup> Success rates of angioplasty on recurrent coarctation are reported to be as high as 93%.<sup>25</sup> In the CCISC study, 80% of patients had a post-procedural systolic gradient <15 mmHg on upper- versus lower-extremity blood pressure testing.

Longer-term results for balloon dilation of recurrent coarctation are variable. Re-coarctation rates as high as 50% have been reported.<sup>25,26</sup> An overall 39% of patients in the single-ventricle study required another intervention after balloon dilation for recurrent coarctation.<sup>24</sup> Interestingly, in the CCISC study 94% of patients had a blood pressure gradient <15 mmHg at intermediate follow-up, suggesting further remodelling of the coarctation site in this subset of patients. The incidence of aortic wall injury is reported to be as low as 1% in this population. It is believed that scar tissue that develops from the initial

surgical intervention helps protect this portion of the aorta during subsequent percutaneous interventions. In the CCISC cohort, only 17% of patients who had undergone balloon dilation of recurrent coarctation had signs of wall injury, compared with 43% of those who had undergone angioplasty of native coarctation. These data suggest that balloon dilation of recurrent coarctation is a safe option with acceptable results.

#### *Coarctation stent placement*

The principle of endovascular stents in the treatment of coarctation holds multiple theoretic advantages. There is an obvious advantage of radial strength that is thought to decrease recoil and therefore recurrent coarctation. There is no requirement for an intimal tear with a stent and hence, theoretically, the risk for aortic wall injury is lower. A large retrospective study published in 2007 examined 565 patients over the age of 4 years and showed acute success in 98% of them with a rate of aortic wall injury <4%.<sup>27</sup> The CCISC published their acute and long-term results in 2010 that were very similar to those of the retrospective study.<sup>28</sup> There was a 96% success rate defined as no significant blood pressure gradient or need for re-intervention. Wall injury was seen only in 1% of the population.

The Coarctation of the Aorta Stent Trial was started in 2007 as a prospective multi-centre trial to examine stent placement for coarctation.<sup>1</sup> In 2015, mid-term results were reported, which showed that 104 of 105 patients had undergone a successful implantation, with 100% success in those patients who had received the stent.<sup>29</sup> There were no acute adverse events. At 2-year follow-up the most

common complication was stent fracture in 23 patients, although none resulted in loss of stent integrity or function. There were six patients with small aortic wall aneurysms at follow-up. In total, 19 patients required re-intervention for either treatment of wall injury (five patients) or for planned stent dilation. As per the study design, 60-month data will be published when available.

With the recognised risk for stent fracture and aortic wall injury, covered stents were studied as a rational option for those with previous stent-related complications, coarctation with aneurysm, or complex coarctation anatomy at higher risk for stent complications. Covered stents were recently approved by the Food and Drug Administration but have been widely available outside the United States of America for over a decade. In 2006, results were reported from 30 (14 native) international patients using the Cheatham-platinum covered stent (NuMED).<sup>30</sup> There was a mean decrease in coarctation gradient from 36 to 4 mmHg, and all patients who had undergone covered stent placement for aortic wall aneurysm had 100% exclusion. There were two acute stent fractures noted, one requiring a second covered stent. Follow-up data showed that four patients required re-intervention, all planned as a staged approach.

Earlier this year, mid-term results of the Coarctation of the Aorta Stent Trial II trial were published, and at around the same time the Cheatham-platinum covered stent was approved by the Food and Drug Administration.<sup>31</sup> In total, 158 patients across 19 centres received covered stent placement either for treatment of aortic wall injury in patients with coarctation (83 patients) or for prevention (75 patients) in those thought to be at high risk for wall injury associated with catheter-based treatment. There was both a statistically significant drop in pullback gradient immediately post implant and by blood pressure gradient at 30-day follow-up. Complete wall injury coverage was achieved in 92% of the treatment group. There were no new wall injury events reported.

## Discussion

The long-standing debate on the best treatment modality for coarctation is not likely to end any time soon. One observational paper attempted to compare the results of coarctation repair between balloon angioplasty, stent placement (using the CCISC data), and surgery.<sup>32</sup> Although there was no difference in the rate of unplanned surgery at follow-up (mean of 1.7 years), those in the stent group had a higher rate of planned re-intervention. The balloon angioplasty group had a higher rate of aortic wall injury. In 2012, a Cochrane review was attempted to determine the

most effective method between surgery and stent placement; however, no conclusions could be formed.<sup>2</sup>

As technologies and techniques improve, the answer to this question is most likely a moving target. We have already seen a significant decrease in the incidence of aortic wall injury associated with percutaneous treatment of coarctation, and as balloon/stent profiles continue to improve, access site complications will continue to decrease. As new technology becomes available, more studies are needed to specifically examine deployment techniques and their relation to results and adverse events. Although there will always be a role for surgery in the treatment of aortic arch anomalies, in the future we hope to provide less invasive, equally effective, and safer percutaneous approaches to a larger subset of patients requiring treatment for coarctation of the aorta.

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