Successful exclusion of an aortic aneurysm with a novel PTFE-tube covered cobalt-chromium stent in a pediatric patient with native coarctation of the aorta

Johannes Nordmeyer, MD, PhD | Peter Kramer, MD | Felix Berger, MD

Stephan Schubert, MD

1Department of Congenital Heart Disease/Pediatric Cardiology, German Heart Center Berlin, Berlin, Germany
2DZHK (German Centre for Cardiovascular Research), Partner Site Berlin, Berlin, Germany

Correspondence
Stephan Schubert, MD, Department of Congenital Heart Disease/Pediatric Cardiology, German Heart Center Berlin, Augustenburger Platz 1, D-13353 Berlin, Germany. Email: sschubert@dhzb.de

Abstract
Treatment of aneurysmal lesions in the context of coarctation of the aorta (CoA) is a challenging task and these lesions are rare in children. An 11-year-old boy was incidentally diagnosed with native CoA and concomitant complex aneurysmal lesions during medical check-up for arterial hypertension. Pre-catheterization imaging was performed with computed tomography (CT), which showed a mild CoA and two native aneurysms that were juxtaposed to the origin of the left subclavian artery. For planning and guidance of the catheter procedure, image fusion software was used with an overlay from pre-registered three-dimensional reconstruction images on live fluoroscopy. Here, we report the first case of successful treatment of an aneurysmal lesion in the context of native coarctation with a novel PTFE-tube covered cobalt-chromium stent (BeGraft, Bentley) in a pediatric patient.

KEYWORDS
BeGraft, congenital heart disease, interventional devices/innovation, pediatrics, pediatric intervention, stent-graft

1 | INTRODUCTION

Transcatheter treatment of coarctation of the aorta (CoA) with balloon angioplasty and stent placement has become the preferred treatment for older children and adults in many centers in accordance with current guidelines [1,2]. However, there is only limited published experience on the exclusion of aneurysmal aortic lesions in the pediatric population since these are uncommon [3–7]. A limited number of reports exist on the use of available covered stent-grafts such as the Cheatham-Platinum stent™ (NuMed, Hopkinton, NY) or Atrium Advanta V12™ (Atrium Hudson/Maquet Getinge Group, Rastatt, Germany) in children to treat secondary aneurysm formation after surgical or transcatheter CoA repair or chest trauma [5,8–11]. In November 2016, another pre-mounted cobalt-chromium stent-graft covered with micro-porous ePTFE tubing (BeGraft Aortic, Bentley Innomed, Hechingen, Germany) received CE-mark approval for use in native and/or recurring CoA in adolescent or adult patients.

2 | CASE REPORT

An 11-year-old asymptomatic boy (weight: 37 kg, height: 154 cm) was referred to our department after incidental diagnosis of CoA and concomitant complex aneurysms during medical check-up for arterial hypertension. Doppler echocardiography upon admission showed a mildly increased flow velocity across the aortic isthmus of 2.7 m/s corresponding to a maximum gradient of 28 mm Hg and a mean gradient of 11 mm Hg (Table 1). Furthermore, there was an estimated non-invasive blood pressure gradient between upper and lower extremities of 35 mm Hg; upper extremity blood pressure was hypertensive (>95th percentile for age and length). The patient was without medication.

Pre-catheterization imaging was performed with computed tomography (CT), which showed a mild CoA (8 mm diameter) and a complex aneurysmal lesion that was juxtaposed to the origin of the left subclavian artery (Figure 1A,B) with a large common entry. The distance from the origin of the left subclavian artery to the distal end of the aneurysm
was 55.2 mm. The 3D-DICOM data was reconstructed using image fusion software (VesselNavigator, Philips, Amsterdam, The Netherlands) to plan the procedure. Marker rings were placed to identify the landing zone for the CoA stent-graft (Figure 1A,B).

For the catheterization procedure, deep sedation and local anesthesia were applied. Arterial access was obtained through the right femoral artery (5 Fr sheath, Terumo, Tokyo, Japan). For guidance during the catheter procedure, image fusion was used to overlay pre-registered 3D reconstruction images on live fluoroscopy. Invasive hemodynamic assessment revealed a peak-to-peak pressure gradient of 19 mm Hg across the CoA and a minimum diameter of 8.4 mm. Diameter of the aorta proximal and distal to the CoA was 13.3 mm and 13.8 mm, respectively. Angiography confirmed the presence of the complex aneurysmal lesion (Figure 1C). After careful positioning of an Amplatzer extra-stiff wire (THSF 35–269 AES, Cook Medical, Bloomington, IN) in the ascending aorta, an 11-Fr introducer sheath was placed (Check-Flo MTS 11F-75cm, Cook Medical).

Subsequently, the novel cobalt-chromium aortic stent-graft covered with micro-porous ePTFE tubing (BeGraft Aortic 14 mm size of the delivery balloon/59 mm length of stent-graft) was positioned under angiographic monitoring and live guidance by the 3D overlay images. The stent was deployed with a pressure control gauge (nominal pressure: 7 atm, rated burst pressure: 11 atm; Figure 1D,E). After deployment, ~13% shortening occurred, resulting in a definitive length of the stent-graft of 51 mm, which was within the expected range (according to the product information provided by the manufacturer, length of the stent-graft at nominal pressure is 54 mm). Finally, the distal stent-graft

TABLE 1  Clinical details

<table>
<thead>
<tr>
<th>Pressure gradient (mm Hg)</th>
<th>Pre</th>
<th>Post</th>
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<tbody>
<tr>
<td>Invasive, peak-to-peak</td>
<td>19</td>
<td>0</td>
</tr>
<tr>
<td>Non-invasive, right arm versus leg</td>
<td>35</td>
<td>0</td>
</tr>
<tr>
<td>Echocardiography, max./mean</td>
<td>28/11</td>
<td>24/12</td>
</tr>
<tr>
<td>Min. diameter aortic isthmus, angiography (mm)</td>
<td>8.4</td>
<td>12.8</td>
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FIGURE 1  A,B, 3D reconstruction of the computed tomography DICOM image data using image fusion software with visualization of the CoA with a complex aneurysmal lesion. Marker rings (yellow and blue rings) were positioned to delineate the course of the aortic lumen and identify the landing zone for the stent-graft. C, Angiogram at 60° RAO projection showing the CoA and aneurysmal lesions. D,E, Imaging of covered aortic stent-graft implantation with fused fluoroscopic and 3D reconstruction imaging (D) and fluoroscopy (E) at 60° RAO projection. [Color figure can be viewed at wileyonlinelibrary.com]
was shaped to match dimensions of the descending aorta and to confidently exclude the aneurysmal lesions by post-dilatation with a 16 mm high-pressure balloon catheter (Atlas Gold, Bard Peripheral Vascular Inc., Tempe, AZ). There was a good hemodynamic outcome with no residual pressure gradient across the aortic isthmus according to invasive and non-invasive pressure measurements (Table 1). Procedural details can be described as follows: fluoroscopy time 10 min, dose area product 4422 mGy cm$^2$, contrast dye application 100 mL (2.7 mL/kg) and air kerma 46.6 mGy.

Final post-interventional angiography as well as CT on day 6 demonstrated complete exclusion of the complex aneurysmal lesion without endoleak. The origin of the left subclavian artery was partially covered by the stent-graft due to an atypical origin from the right lateral aspect of the distal aortic arch (Figure 2). However, there was preserved blood flow to the left subclavian artery (Figure 2). The CoA was successfully treated, with a resulting minimal diameter of 12.8 mm in the isthmus region and no residual peak-to-peak gradient (0 mm Hg). Blood pressure of the upper extremities normalized and there was no requirement for antihypertensive medication. The patient was discharged on the second post-procedural day after uneventful monitoring.

3 | DISCUSSION

The search for the optimal treatment of aneurysms in the context of CoA is a challenging task. Here, we report successful treatment of such a lesion with a novel PTFE-tube covered cobalt-chromium aortic stent-graft in a pediatric patient. When considering interventional treatment with a covered stent, the choice of material has to take into account
TABLE 2  Stent specifications according to the manufacturer

<table>
<thead>
<tr>
<th>Stent material</th>
<th>CoCr (L605)</th>
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<tr>
<td>Graft material</td>
<td>Micro-porous ePTFE tubing</td>
</tr>
<tr>
<td>Available stent diameters (mm)</td>
<td>12–24 (in 2 mm steps)</td>
</tr>
<tr>
<td>Available stent lengths (mm)</td>
<td>19–59</td>
</tr>
<tr>
<td>Guide wire</td>
<td>0.035&quot; for each stent</td>
</tr>
<tr>
<td>Introducer sheath sizes</td>
<td>9 Fr, stent diameter 12 mm</td>
</tr>
<tr>
<td></td>
<td>11 Fr, stent diameters 14, 16 mm</td>
</tr>
<tr>
<td></td>
<td>14 Fr, stent diameters 18, 20, 22, 24 mm</td>
</tr>
<tr>
<td>Post-dilation capabilities*</td>
<td>up to 20 mm</td>
</tr>
<tr>
<td></td>
<td>up to 24 mm</td>
</tr>
<tr>
<td></td>
<td>up to 30 mm</td>
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*These data correspond to in vitro testing data, provided by the manufacturer.

several aspects such as the available sizes and lengths, the radial force of the device, the strut dimensions to gain maximum luminal diameter, and the stent design including shortening properties during stent deployment and the design of the coverage to achieve complete exclusion of the aneurysm with prevention of endoleaks. In addition, in children and adolescents, a low profile delivery system to prevent damage to access vessels and the possibility of post-dilation of the stent to adapt its dimensions to the growth of the patient without significant shortening are particularly important. The stent-graft is available off-the-shelf in a range of diameters and lengths (Table 2).

The decision to implant this aortic covered stent-graft was based on the considerations discussed above. With strut dimensions of 0.205 × 0.215–0.265 mm and pre-mounting on a high-pressure balloon, the device was delivered via an 11 Fr introducer sheath. This profile is comparable to the introducer sheath required for delivery of an Atrium Advanta V12™ stent (Atrium/Maquet Getinge Group) and slightly less than the 12 Fr sheath required for a covered Cheatham-Platinum stent™ (NuMed) on a 14 mm balloon-in-balloon delivery system (NuMed). However, the maximum available length for the 8ZIG Cheatham-Platinum stent™ is only 45 mm. The Atrium Advanta V12™ is available in lengths up to 61 mm but is not CE- or FDA-approved for aortic use as yet.

According to the product information provided by the manufacturer, the implanted stent-graft (BeGraft Aortic 14 mm/59 mm) can be post-dilated to a luminal diameter of 20 mm, with a resulting shortening to 47 ± 2 mm. According to our own institutional experience, which is based on subjective assessment, the BeGraft Aortic stent seems to have more radial force than the Atrium Advanta V12™, but less than the Cheatham-Platinum stent™. It is of note, however, that there is no data available that compared either the radial force of the stents, or the stability and durability of the stent coverage objectively; thus, no definitive conclusions can be drawn at present. A potential drawback of this novel stent might be that—due to pre-mouthing of the stent-graft—stent delivery cannot be performed on a balloon-in-balloon system, which is helpful for accurate stent placement in some instances.

However, further research is necessary to assess the clinical utility of this novel device in larger case series.

4 CONCLUSION

The primary result of the interventional treatment of aneurysmal lesions in the context of native CoA with an aortic covered stent-graft is encouraging and a good, safe, and effective alternative to surgery. The BeGraft stent-graft represents an additional option for the interventional treatment of complex forms of CoA in children and adolescents.

CONFLICTS OF INTEREST

The German Heart Center Berlin holds a research contract for the use and assessment of the VesselNavigator image fusion software and acts as a reference center for Philips, The Netherlands. This report was not influenced or supported by this research activity. No author or co-author has a conflict of interest to declare.

AUTHOR CONTRIBUTIONS

All of the authors contributed to the literature review and manuscript draft, and reviewed and approved the final manuscript.

ORCID

Johannes Nordmeyer MD, PhD  http://orcid.org/0000-0001-6961-5773

REFERENCES


