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First-in-Man Use of a Tapered Endovascular Stent Graft for Treatment of Aneurysm After Coarctation Repair

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Objectives: Endovascular stenting of aneurysms late after surgical repair of coarctation may have to deal with marked changes in aortic diameter proximal and distal to the aneurysm. We report our first-in-man successful use of a custom-made tapered (variable diameter) covered stent. Methods: The aneurysm was 42 mm in diameter with a length of 40 mm. On MRI, the aorta measured 19.6 mm proximal and 13.3 mm distal to the aneurysm. The aim was to oversize the stent by 10–20%. A covered Cheatham-platinum stent was designed so that cranial portion of the stent would expand to 22 mm and the caudal portion to 15 mm with a length of 8.5 cm when fully inflated. The stent was mounted on a balloon-in-balloon delivery system and was delivered through an 18 F femoral arterial sheath. Rapid-pacing technique was used for deployment. Results: The stent was successfully deployed without complications. After deployment, the stent diameter measured 21.2 mm cranially and 15.6 mm caudally. A mild distal endoleak due to inadequate fixation of the stent graft was resolved by post dilation expanding the stent diameter to 22.1 mm and 15.9 mm, respectively. The femoral access site was closed using two percutaneous closure devices and the patient discharged the day after the procedure. Follow-up CT-angiography showed continued successful exclusion of the aneurysm. Conclusions: A new custom-made balloon expandable covered stent-design enabled successful treatment of an aortic aneurysm. This design may offer greater potential for more favorable initial angiographic results and potentially long-term outcomes due to superior apposition to the aortic wall.

Key words: aortic aneurysm; coarctation; custom-made covered balloon-expandable stent

INTRODUCTION

Aneurysm formation is known to occur in about 5–30% of patients late after surgical repair for coarctation, depending amongst other on the age at coarctation repair and repair technique [1–6]. Small (<5 cm), asymptomatic aneurysms without tendendency to rapidly enlarge can be treated conservatively [7,8]. This is reflected by the low overall mortality risk from a ruptured aortic aneurysm [3,4]. However, as the aneurysm increases in size, the risk of rupture increases. In some long-term follow-up studies, conservative (medical) therapy of aneurysms carried a very high mortality [1]. In patients who develop aneurysm after coarctation repair, treatment is justified for either symptom relief (chest pain, hemoptysis in case of erosion into the lung) or to improve survival (in aneurysms >5 cm diameter or fast growing aneurysms).

Reoperation with resection of the aneurysm is considered standard treatment. However, this is associated with significant mortality (as high as 30%) and morbidity including paraplegia in 4–14%, bleeding, stroke, cardiac events, and renal failure [9–11]. Endovascular stenting appears to be a promising alternative to surgery in several small series with good procedural and midterm outcome [12–16].

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Previous series of endovascular stenting for aneurysms after coarctation repair used commercially available endografts (e.g., Talent and Valiant Medtronic stents, Santa Rosa, CA or Zenith TX 1 or TX2 endograft, Cook, Bloomington, IN) [13–15]. However, because coarctation often involves hypoplasia of the aortic arch, marked changes in the diameter of the aorta proximal and distal to the coarctation site are not uncommon and can present a challenge to ensure good stent apposition when the goal is to exclude an aneurysm.

We report our first-in-man use of a custom designed endovascular stent graft and delivery system for treatment of an aneurysm following surgical coarctation repair, which enabled effective management of the marked change in aortic diameter between the proximal and distal limits of the aneurysm.

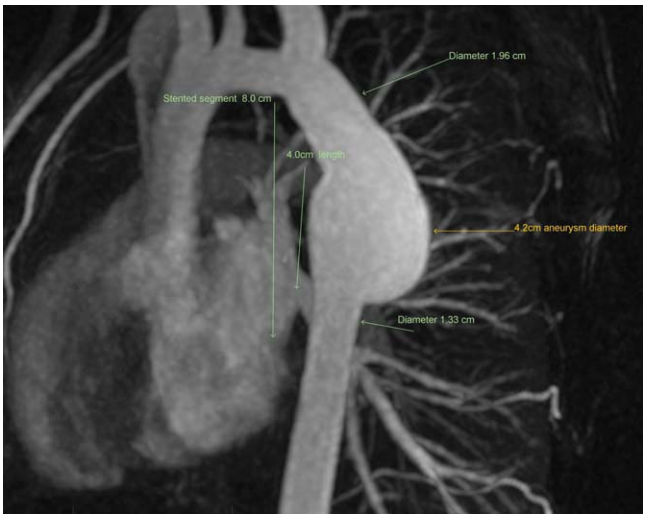

Fig. 1. Magnetic resonance image: the aneurysm measured 4.2 cm × 4.0 cm. The stent had to cover a distance of at least 8 cm, with the proximal part sealing a 1.96 cm diameter vessel and the distal part tapering down to 1.33 cm.

METHODS

Patient

A 25-year-old female patient had a surgical repair of her coarctation 16 years previously. The repair used a 16 mm Hemashield graft. A routine follow-up echocardiogram showed a dilated descending aorta and lead to an MRI confirming the diagnosis of an aneurysm, measuring 4.2 cm in diameter with a length of 4 cm (Fig. 1). Co-morbidities included a small muscular ventricular septum defect that was not clinically significant and residual hypertension (blood pressures: right arm 149/77 mm Hg, left arm 131/84 mm Hg). On echocardiography, there was no significant gradient across the aortic arch (peak-gradient 18 mm Hg), which could account for the residual hypertension. Given the small gradient across the aortic arch and the only mild arch hypoplasia on MRI, the joint interdisciplinary decision was that the hypoplastic arch did not need to be addressed (e.g., arch augmentation was not required).

The indications for exclusion of the aneurysm in this particular patient were prognostic (fast growing aneurysm), underlined by the fact that there was a desire for pregnancy with the potential of aggravation of the hypertension and a higher risk of rupture of the aneurysm [17]. Furthermore, the patient also complained of some atypical chest pains, which were attributed to the aneurysm.

Anatomical Considerations

The diameter of the aorta just distal to the left subclavian artery and proximal to the aneurysm was measured on MRI to be 1.96 cm, the diameter of the thoracic aorta beyond the aneurysm was, however, only 1.33 cm (Fig. 1). The length of aorta to be covered was estimated to be at least 8 cm. To ensure exclusion of the aneurysm as minimizing the risk of over dilation of the distal aorta, we investigated the feasibility of a balloon expandable stent that would expand to different diameters on either end on initial deployment.

To minimize the risk of paraplegia due to damage to the artery of Adamkiewicz, we identified the distal landing zone to be more cranial than the level T9 (most common origin of the artery of Adamkiewicz is between T11 and T9) and assured that the origin of the artery did not have its origin at or cranial to the expected caudal stent landing zone on angiography.

Angiographic measurements were made using the on line quantitative angiography package in the General Electric Innova cath lab (GE Milwaukee, WI).

Stent and Delivery System Design

The design of the stent system was a covered Cheatham-platinum stent^{TM} (NuMed, Hopkinton, NY). Permission to use this device was obtained through the Special Access Program of the Therapeutic Products Directorate (Health Canada, Ottawa, ON). The stent is an expanded polytetrafluoroethylene (ePTFE)—covered 90% platinum and 10% iridium frame with a strut thickness of 0.013 inches. The stent configuration consists of eight strut cells, allowing expansion from 8 mm to 24 mm. The novelty of this stent/delivery system was the design of the placement catheter, consisting of a balloon-in-balloon catheter (NuMed, Hopkinton, NY). The inner balloon measured 12.5 cm × 10 mm and the outer balloon was asymmetrical with the cranial 3.5 cm of the outer balloon expanding to 22 mm (3.5 cm × 22 mm) when fully inflated and the

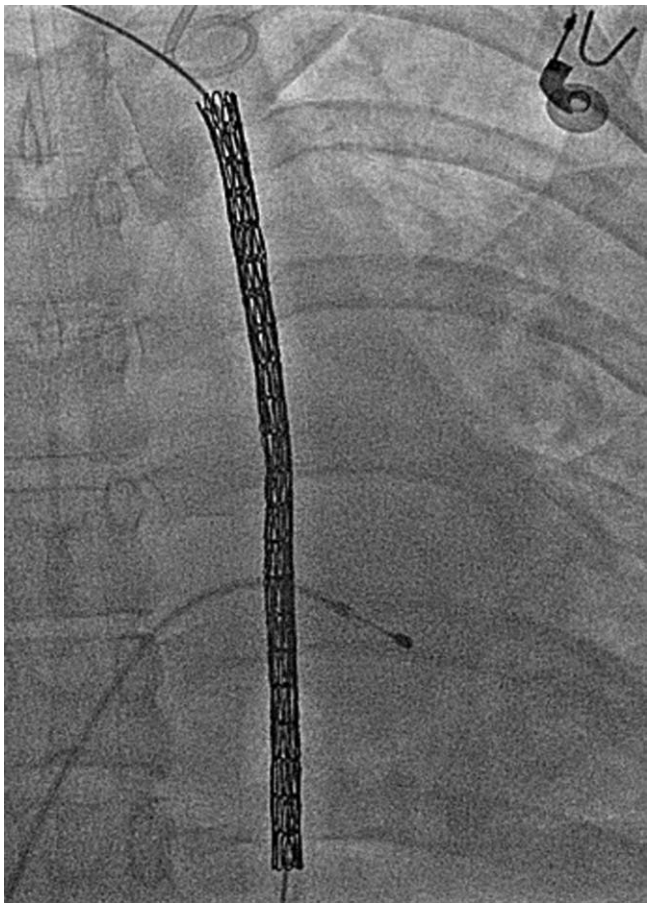

Fig. 2. Insertion of the balloon mounted endovascular stent.

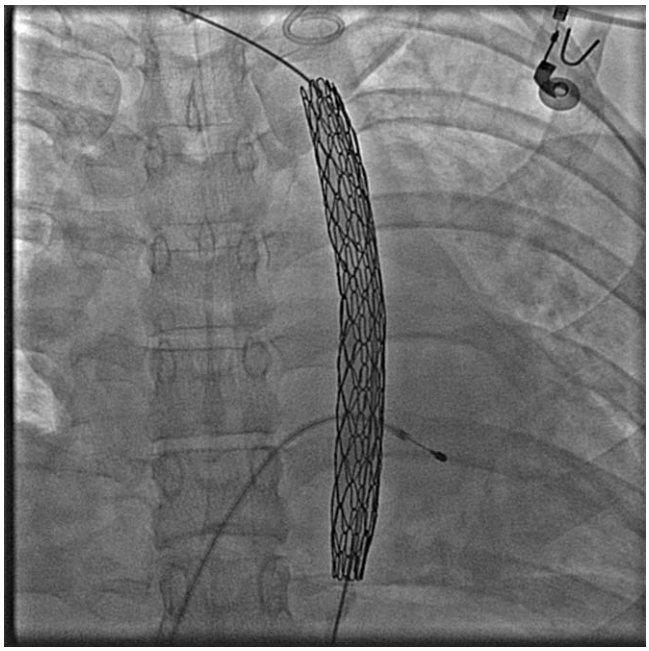

Fig. 3. Inflation of the inner balloon with partial expansion of the stent.

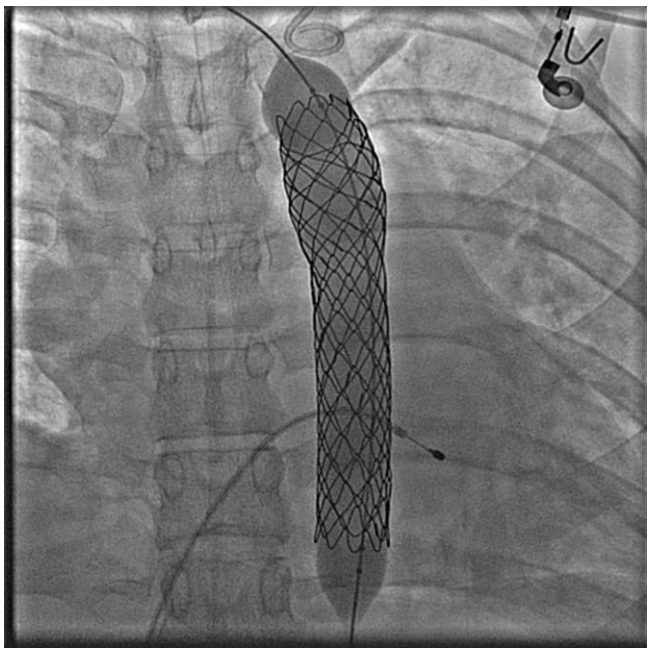

Fig. 4. Inflation of the outer balloon.

caudal 9 cm expanding to 15 mm (9 cm × 15 mm). As this stent expands, it progressively shortens; hence, it is necessary to accommodate greater shortening (up to 30%) of the larger diameter portion of the stent than at the smaller distal part of the stent, where shortening was anticipated to be 15%. The ePTFE covering was sized to accommodate the largest stent diameter and would tolerate a diameter as large as 30 mm without risk of damaging the integrity of the ePTFE.

Inflation of the inner balloon leads to partial expansion of the stent, allowing final adjustment of the position, as there is still blood flow around the stent. Inflation of the outer balloon then leads to final deployment and apposition of the stent.

Procedure

The procedure was performed in the catheterization laboratory under awake sedation. Right femoral arterial and venous and left radial arterial access was gained. In the right femoral artery, two 6 F percutaneous suture devices (ProGlide, Abbott Laboratories, Abbott Park, IL) were inserted for access site closure at the conclusion of the case. A temporary pacemaker was advanced through the venous sheath to the right ventricle to enable rapid ventricular pacing during stent deployment to reduce cardiac output and further minimize the risk of distal displacement of the stent [18,19]. Via the femoral and radial arterial access, pigtail catheters were

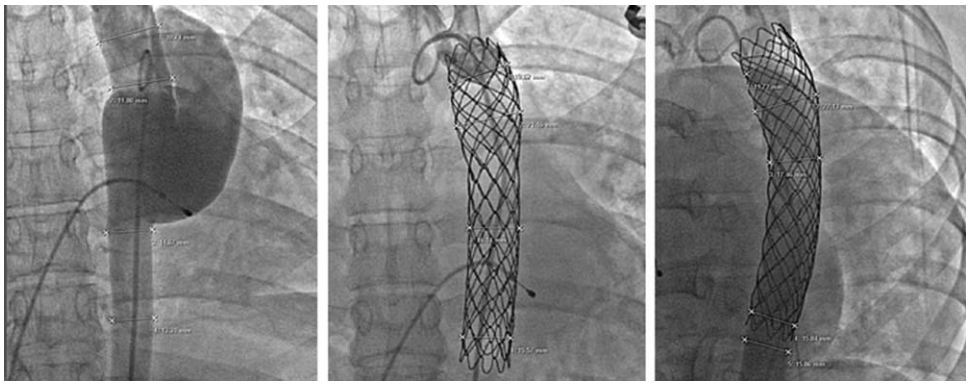

Fig. 5. Aortic measurements on fluoroscopy before the procedure (A), immediately after stent deployment (B), and the final result after post dilation (C).

advanced and cine images of the aneurysm were obtained in the AP- and LAO-projections. Via the right femoral artery, an Amplatz extra stiff wire was advanced to the right subclavian artery. Then the 6-F right femoral sheath was removed, and the puncture site was serially dilated up to 12 F before the 18 F delivery sheath was inserted.

Heparin (5,000 IU) was administered, and the endovascular stent and delivery system were inserted via the 18 F sheath and positioned to accommodate the anticipated shortening (Fig. 2). Placement was guided by fluoroscopy using the pigtail catheter from the left subclavian artery with hand injections of 5 mL contrast dye.

The inner balloon was inflated and final adjustments of the position were made (Fig. 3), rapid pacing (200 bpm) was initiated, resulting in a drop of blood pressure below 60 mm Hg and a reduction in pulse amplitude below 10 mm Hg. The outer balloon was inflated to deploy the stent (Fig. 4). Once the stent was fully deployed and the balloon partially deflated, rapid pacing was stopped and the delivery system removed. Control aortograms showed evidence of a minimal distal endoleak due to inadequate fixation of the stent graft, which was successfully treated with a repeat inflation of the delivery balloon and using an 18 mm $\times$ 3 cm Z-Med balloon (NuMed, Hopkinton, NY) in the mid and distal stent. These inflations were done cautiously using a hand inflated syringe to low pressure to ensure good apposition and avoid over dilation.

The femoral sheath was removed and the access site closed using the previously inserted percutaneous suture devices. The left radial access was closed using a Terumo radial band (Terumo TR band^{TM}, Terumo Medical Corporation, Somerset, NJ).

The patient was transferred to the acute ward and discharged the following morning. She was given aspirin intended for an indefinite duration and clopidogrel for 3 months.

TABLE I. Aortic Dimensions Before and After Stenting (mm) as Measured by Fluoroscopy

	Baseline	Post-deployment	Post-redilatation
Proximal stent landing zone	19.7	19.6	19.7
Proximal to pseudo-aneurysm	19.8	21.2	22.1
Distal to pseudo-aneurysm	14.7	16.4	17.5
Distal stent landing zone	13.3	15.6	15.9

RESULTS

Fluoroscopy time was 13.5 min and a total of 370 mL nonionic contrast dye (Visipaque) was used. Procedural success was achieved with complete exclusion of the aneurysm from blood flow. The stent dimensions before and after postdilation showed further expansion of the stent to its final dimension with a slight oversize by $\sim$10–20% as compared with the baseline measurements (Fig. 5A–C and Table I).

There were no procedural complications and stent deployment did not compromise the ostium of the left subclavian artery. Percutaneous femoral closure was successful with prompt hemostasis.

Follow-up

At 1-month follow–up, the patient was well and symptom free. Specifically, there were no neurological symptoms or evidence of vascular compromise. CT angiography at day 35 showed excellent apposition of the stent along its whole length and no endoleak (Fig. 6A–C).

DISCUSSION

The method described for endovascular graft stenting of an aneurysm late after coarctation repair is new in the custom design of the covered stent endograft system

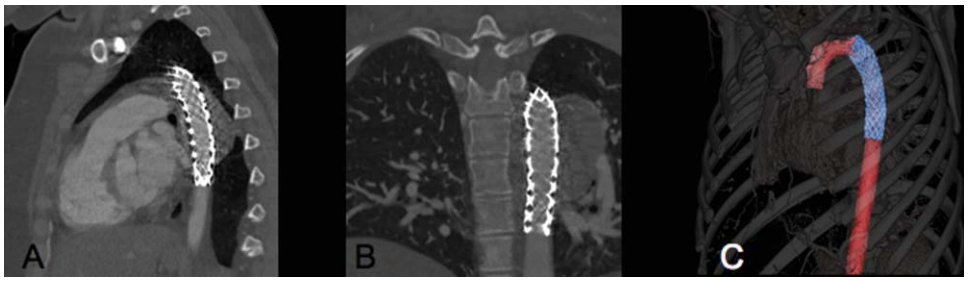

Fig. 6. CT angiogram in sagittal oblique (A) and coronal (B) projections and volume rendered 3-D reconstruction (C) of the thoracic aorta with the covered stent excluding the aneurysm with no residual endoleak.

to accommodate the specific morphology of this patient. This design increased the likelihood of complete apposition of the stent along its entire length and effective sealing to exclude the aneurysm as minimizing the risk of aortic rupture. This procedure used left radial access for a pigtail catheter to guide positioning as previously described [20,21]. It was preferred to not cover the left subclavian artery and use of the pigtail catheter facilitated determination of the proximal landing zone. Because the stent shortens as it expands, it must be positioned such that it is proximal to its final intended location as balloon inflation begins with anticipating shortening in the range of 20–30%. A third aspect for this procedure was the successful use of rapid pacing for stent deployment as previously described [19]. Although the "balloon-in-balloon" design aids placement, rapid pacing reduces blood pressure and pulse amplitude, both of which are important to reduce movement of the stent during deployment.

Previous groups have mainly used cylindrical stents. This design would risk incomplete apposition of the stent when the diameter of the artery changes significantly. Nitinol-based self-expanding stents have the ability to accommodate different diameters to a certain degree, and therefore, might be a good alternative to custom made balloon-expandable stents. However, in a series of 68 patients with mostly degenerative aneurysms and aortic dissections, endovascular stenting with self-expandable stents resulted early endoleaks in 7% despite preoperative screening with restrictive exclusion criteria in terms of anatomic conditions [22]. This is probably at least in part due to the lower radial strength [23] resulting in more distal endoleaks due to inadequate fixation of the stent graft. It is further known, that self-expanding stents can have late enlargement of the aortic neck, resulting in more endograft migrations than balloon-expandable stents [24].

The 18 F femoral sheath was required and in previous series using large diameter sheaths, the access site was typically closed by surgical cut down. Although effective, this complicates the procedure and is more time consuming.

Limitations

Given the "first-in-man" use of this device, our report is limited to this single case and the follow-up was short. However, we have demonstrated the feasibility and success of the use of the device for this purpose.

We refer to the treated lesion as an aneurysm implying a broad neck and an endothelial lining. There is potential that it may have been a false aneurysm related to the previous surgical patch repair and a suture line leak. Given the uncertainty, we refer to it simply as an aneurysm and believe that the described method and stent device for accommodating the varying aortic diameter is equally suitable for either a true or a false aneurysm.

CONCLUSIONS

Endovascular graft stenting of an aneurysm late after coarctation repair was successful using a newly designed tapered balloon resulted in effective exclusion of the aneurysm and a good anatomical result with the final stent shape adapted perfectly to the aortic wall. This stent design may offer advantages in situation where there are marked changes in the vascular diameters.

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