Original article

The use of a handmade balloon-expandable covered stent for native coarctation of the aorta in an adult patient: A report of a first case in Japan

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Summary
In western countries, the use of a balloon-expandable covered stent is recommended for the treatment of native coarctation of the aorta (CoA) in adult patients because endovascular bare stents cannot completely prevent complications such as aneurysms or aortic rupture. However, such a product that is appropriate and officially approved is not available in Japan. We developed and used a handmade balloon-expandable covered stent in a 32-year-old patient with native CoA and achieved a good outcome. A Palmaz-Schatz stent (XL 10-series 4010; Johnson & Johnson, Warren, NJ, USA) was covered with an Ube woven-graft (WST series; 18 mm across; Ube Junken Medical, Tokyo, Japan). Because the stent shortens when dilated, one end of the graft was firmly sutured to one end of the stent, whereas the other end of the graft was stitched loosely to the other end of the stent so that it could slide along the struts of the stent to accommodate foreshortening. After meticulous \textit{in vitro} simulations, the covered stent was implanted with right ventricular overdrive pacing. No complications were observed, and the pressure gradient disappeared. These results indicate that angioplasty using a balloon-expandable covered stent is highly safe and effective for correcting native CoA in adult patients and hopefully in children.

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Introduction

Balloon-expandable endovascular stent implantation has become an accepted modality for treatment of native and recurrent coarctation of the aorta (CoA) in adolescents and adults [1]. However, even with these stents, aneurysms or aortic ruptures may occur as major acute complications [2—5].

In patients at a high risk of Turner’s syndrome or hypoplastic aortic arch, and in adult patients suspected to have fragile blood vessels, treatment with a covered stent is recommended for safety purposes [6,7]. However, a balloon-expandable covered stent is not available in Japan. Hence, it is necessary to develop an appropriate covered stent for clinical use.

Recently, we developed a handmade balloon-expandable covered stent in collaboration with a company, and used it for an adult patient with native CoA. This is the first report describing a case in which a successful implantation was achieved using a handmade balloon-expandable covered stent for transcatheter treatment of CoA in a patient in Japan.

Case histories

A 32-year-old female patient who showed no symptoms of hypertension was diagnosed with hypertension when she was aged 20 years, and had been regularly followed up under the diagnosis of essential hypertension. When she was aged 29 years, she underwent further examination during her pregnancy. Her blood pressure (BP) was found to vary between the upper and lower extremities and was detected by ankle brachial index examination. The BP in the upper and lower extremities was 150/79 mmHg (mean, 112 mmHg) and 94/67 mmHg (mean, 80 mmHg), respectively, showing a pressure gradient of approximately 60 mmHg between the upper and lower extremities. No difference in BP was observed between the right and left extremities. A systolic murmur of Levine 2/6 was audible at the second left sternal border and on the back. Pulsation in the femoral and dorsal pedal arteries was faint. According to these findings, the patient was diagnosed with CoA. A chest radiograph showed mild cardiomegaly with a cardiothoracic ratio of 53%, and left ventricular hypertrophy was observed on an electrocardiogram. The echocardiogram showed concentric hypertrophy of the left ventricle (LV). The left ventricular end-diastolic dimension (LVEDD) dilated to 59 mm, whereas the left ventricular ejection fraction (LVEF) decreased to 41%. A ventricular aneurysm was observed at the apex of the LV. Blood flow in the abdominal aorta showed a pattern typical of CoA. Cardiac magnetic resonance imaging revealed that the smallest CoA diameter was 4 mm × 3.5 mm, and the isthmus was mildly hypoplastic (diameter, 11 mm) (Fig. 1A and B). The entire length from the left subclavian artery to the CoA was 35 mm, and the descending aorta distal to the CoA was dilated to 18 mm. A ruptured cerebral aneurysm of approximately 5 mm in the right middle cerebral artery.

After taking surgical risk into consideration, we chose to perform a less invasive treatment using a handmade balloon-expandable covered stent for the patient; documented informed consent was obtained before treatment. The treatment was approved by the Committee on Clinical Research Ethics (Ehime University Medical Ethics No. 0812005).

Methods

A Palmaz-Schatz stent (XL 10-series 4010; length, 40 mm; maximum expanded diameter, 25 mm; Johnson & Johnson, Warren, NJ, USA) was covered with an Ube woven-graft (WST series; 18 mm across; Ube Junken Medical, Tokyo, Japan) (Fig. 2). The stent includes 11 struts and when dilated, its length reduces by approximately 5 mm. Hence, one end of the graft is firmly sutured to the end of the stent, whereas the other end of the graft is stitched loosely to the other side of the stent so that it can slide along the struts of the stent to accommodate foreshortening. Five 6-0 polypropylene needles were also used. Meticulous in vitro simulations were performed to confirm that there was no problem with the system. Because an 18-Fr sheath (Cook, Bloomington, IN, USA) is necessary to deliver this stent, the femoral artery was secured by the cut-down method. Subsequently, the covered stent was mounted on a Mullins balloon catheter (balloon diameter, 12 mm; length, 4 cm), and inserted into the short sheath, which was used as the loader. Because
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Results

Because the distal aortic arch was hypoplastic in this patient (Fig. 3), the P4010 Palmaz stent, which is long in length, the 18-Fr long sheath has no hemostatic valve, a 16-Fr short sheath was inserted from the back end of the long sheath as a substitute for a hemostatic valve.

Discussion

The usefulness of a stent for correcting CoA was reported at the catheterization and cardiovascular interventions meeting held in 2007 [2]. In this report, it was mentioned that 588 patients were treated between 1989 and 2005 with a
high success rate of 98.6%. The complications were as follows: 2 procedure-related deaths (0.3%) and events such as stent migration (4.8%), balloon rupture (2.2%), intimal tears (1.3%), aortic dissection (1.5%), aneurysm formation (2.2%), cerebral vascular accident (1.0%), and significant femoral access vessel injury (2.6%). After this report, there has been an increase in the use of the covered stent over the years [6,7]. It is suggested that stent implantation is a safe procedure for patients with severe CoA, including those with fragile blood vessels as in the case of Turner’s syndrome [8] or with hypoplastic aortic arch, adult patients likely to experience greater complications on the aortic wall, and those who require treatment and restoration for CoA-related complications caused by the use of a conventional stent.

It is said that angioplasty for CoA using a stent should not exceed 3.5 times the narrowest diameter [9]; hence, it is necessary to determine the size of the expanded stent in which case the use of a balloon-expandable stent is appropriate. In addition, this stent can decrease the risk of the complications on the aortic wall, such as ruptures, to a greater extent than a self-expandable stent. A self-expandable covered stent has been clinically used for aortic aneurysms in adults, and recently, approved products have become available. On the other hand, with regard to a balloon-expandable covered stent, although the clinical use of covered Cheatham-platinum stents (NuMed Inc., Hopkinton, NY, USA) has been tried, it has not yet been approved [7]. Further, in Japan, suitable stents are not available or are not approved.

An artificial blood vessel is required to have sufficient durability and compatibility with body tissues to be used in a covered stent. The Ube woven-graft that we used in this study is a popular device used for clinically treating thoracic and abdominal aneurysms of the aorta. It is important that the surface of the artificial vessel grafted to living tissue be covered with fibrin, and pseudointima formation is observed during the healing process. In a previous histological study on a dog, the membrane of the artificial vessel used consisted of compact fibrin, and neointima formation was observed [10]. Therefore, this artificial blood vessel is considered appropriate and sustainable for the treatment of CoA.

This report is valuable because we produced a handmade balloon-expandable covered stent, used it in a clinical setting, and achieved a satisfactory level of performance.

In conclusion, an adult patient with native CoA was treated with a handmade balloon-expandable covered stent without any complications. This is the first report describing such a case in Japan. Angioplasty using the balloon-expandable covered stent, which we produced, is safe and effective for correcting CoA in adults. The results indicate that the technique used here can be applicable for children with CoA in the future.

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