Original Contribution

Percutaneous bilateral pulmonary artery banding using a re-expandable covered stent: preliminary animal study

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Backgrounds: Bilateral pulmonary artery banding (bPAB) followed by ductal stenting has been reported as a stage 1 palliation of hypoplastic left heart syndrome (HLHS). However, hybrid strategy, which includes median sternotomy for bPAB, has been a common approach. In this preliminary experiment, we investigated the feasibility of a transcatheter bPAB followed by debanding using a re-expandable covered stent for comprehensive transcatheter stage 1 palliation.

Methods: Polyurethane was coated on Palmaz medium (Palmaz) or Express Vascular LD (large diameter) (Express) stents using the dipping method. The stent was mounted on a balloon, tied at the midpoint with a silk thread so as to implant the stent in the bilateral pulmonary arteries in a dumbbell shape, which consequently created bPAB. Under general anesthesia, we intended to create bPAB in 5 piglets whose median body weight was 10.1 kg. Once bPAB was created successfully, we performed debanding with balloon dilatation.

Results: Eight stents (Palmaz and Express, 4 each) were implanted in 4 piglets, but one piglet died while manipulating a long sheath in the right ventricular outflow tract associated with fetal arrhythmia. Meanwhile, debanding was attempted of 4 stents (Palmaz and Express, 2 each) in 3 piglets because another piglet died suddenly of right ventricular failure following bPAB. All of the Palmaz stents were successfully implanted in a dumbbell shape, while only 2 Express stents could be implanted in the dumbbell shape. The Palmaz stents were debanded successfully, while only one Express stent could be redilated sufficiently because cells of the mid-portion overlapped each other.

Conclusions: Transcatheter PAB could be created using a covered stent implanted in a dumbbell shape. The material and design of the stents were key issues not only for the creation of PAB but also for debanding. Further innovation of stents will be necessary for clinical utilization of this technique as a comprehensive transcatheter stage 1 palliation of HLHS.

Key words: hypoplastic left heart syndrome, bilateral pulmonary artery banding, stent, transcatheter

Introduction

Pulmonary artery banding (PAB), initially proposed by Muller and Danimann, has conventionally been indicated to reduce excessive pulmonary blood flow as well as pulmonary hypertension.1 PAB has been offered to patients with univentricular physiology complicated by pulmonary hyperflow to protect the pulmonary vascular bed until the next-step surgery of a right heart bypass can be performed, and with the transposition of the great arteries or corrected transposition complicated by a hypotrophic anatomical left ventricle indicating an arterial switch or a double switch operation. Furthermore, bilateral PAB (bPAB) combined with ductal stenting has been evolved as the first-stage palliation of hypoplastic left heart syndrome (HLHS).2-8

Several attempts have been made to develop transcatheter PAB; however, clinical applications have not been established due to the inherent limitations, such as the reliability of the method and the size of the device and its delivery system.

Implantation of a covered stent has been the first-choice of treatment for aortic aneurysm and aortic coarctation in adolescent and adult patients. It may be applicable for pediatric patients as a therapeutic catheterization for aortic or pulmonary artery aneurysm.

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following surgery or balloon dilatation, transcatheter completion of total cavopulmonary connection, and closure of fenestration or a residual leak after a total cavopulmonary connection. We have developed a re-expandable covered stent for such a clinical use in pediatric patients. In the present animal experiment, we examined the feasibility of this re-expandable covered stent to create a branch PAB. The objective of the present study was to investigate the feasibility of transcatheter branch PAB followed by debanding using a re-expandable covered stent for comprehensive transcatheter stage 1 palliation of HLHS.

Materials and Methods
Preparation of the covered stent was previously reported. Briefly, using a dipping method, a medium Palmaz stent (Johnson & Johnson Interventional Systems, Warren, NJ, USA) or an Express Vascular LD (large diameter) stent (Boston Scientific, Natick, MA, USA) was coated with commercially available biomedical-grade polyurethane (Tecoflex, EG-80A, Thermetics, Woburn, MA, USA), which was stretchable up to 700%. The stent was fixed over a handmade stainless steel cylinder, which had a smaller diameter than the internal diameter of the stent, with hooks of very thin steel wire on both ends of the cylinder. Subsequently, the stent on the cylinder was immersed for 5 seconds in the polymer solution. Following the evaporation of the solvent for 5 minutes, the stent, now mounted on the cylinder upside down, was reimmersed in the solvent for another 5 seconds and then removed to allow the solvent to evaporate for 30 minutes. The coating thickness was measured at four points on both edges in three covered stents using a Measuring Microscope (Mitsutoyo, Tokyo).

Stent implantation and redilation
The Kitasato University committee for Animal Experimentation approved the animal experiments. Five piglets (median weight, 10.1 kg; range, 9.6-10.2 kg), were anesthetixed with thiamylal sodium and midazolam and maintained with sevoflurane. We exposed either the left or right femoral vein and emplaced a 9F or 10F long sheath into it. Following the main pulmonary angiogram, we measured the diameter of the bilateral pulmonary arteries proximal to the first branching. The covered stent balloon was manually crimped to a diameter of 1-2 mm or larger. The balloon was tied at the mid point with a silk thread to implant the stent in a dumbbell shape, which consequently created the desired narrowing of the

Figure 1. A, B, C. A covered stent was remounted on a 9 mm balloon, the mid-portion of which was ligated with a thread so as to dilate the covered stent in a dumbbell shape.
Percutaneous pulmonary artery banding using a covered stent

bilateral pulmonary arteries (Figure 1). We introduced a catheter with an end-hole to the peripheral pulmonary artery while under fluoroscopic monitoring and inserted a 0.035-inch Amplatz Super Stiff Guidewire through the catheter. After insertion of the long sheath into the peripheral pulmonary artery, we implanted the balloon catheter and stent through the sheath into the right or left proximal pulmonary artery. Following several manual injections of the contrast medium from the long sheath to confirm the stent position, the balloon was dilated with a diluted contrast medium using an inflation device. Because the upper lobe branch was usually taken off proximally, it was jailed by the distal portion of the covered stent. After implantation, we confirmed the position of the stent within the pulmonary artery by pulmonary angiography. After the unilateral narrowing was successfully created, the contralateral stenting was performed similarly (Figure 2). Following confirmation with pulmonary angiography, we dilated the narrowing of the stent using a normal balloon catheter with a diameter similar to the balloon that was used for stenting as a model procedure of debanding.

The animals were killed with intravenous pentobarbital sodium and potassium chloride, the stents were then surgically removed for macroscopic examination.

Results

Eight stents (Palmaz and Express, 4 each) were implanted in 4 piglets. One piglet died during the manipulation of a long sheath in the right ventricular outflow tract

Figure 2. A. The position of the stent within the pulmonary artery using pulmonary angiography. B, C. Pulmonary arterial angiography after bilateral stent implantation. After unilateral narrowing was successfully created, contralateral stenting was performed.
associated with fetal arrhythmia. Another piglet died shortly after completion of bPAB due to right ventricular failure. Consequently, debanding was attempted for 4 stents (Palmaz and Express, 2 each) in 3 piglets. All the Palmaz stents were successfully implanted in a dumbbell shape, but only 2 Express stents could be implanted in the dumbbell shape. The Palmaz stents were all debanded successfully, but only one Express stent could be redilated sufficiently because the cells of in the mid-portion overlapped each other.

Discussion
Several preliminary studies have shown the possibility of temporally obstructing the pulmonary blood flow using a balloon catheter; however, none have shown a permanent clinical application for the technique. Bilateral intravascular branch pulmonary artery blood flow limiting devices had been used in infants with HLHS, although they are no longer in clinical use because they were excessively invasive invasive for a neonate or a small infant. Mollet et al. reported animal experiments with a transcatheter PAB device developed with a self-expandable stent covered with a polytetrafluoroethylene (PTFE) membrane. Except for temporally banding with a balloon catheter, these devices must be surgically removed for debanding.

We attempted to create transcatheter pulmonary banding that can be debanded in the catheterization laboratory. A flared stent has occasionally been used to prevent migration of the stent, while it may be implanted in the unlimited vascular communication to close as an anchoring device of an embolus. Most covered stents in clinical use are covered by a graft such as polyester or PTFE sewn to the surface, while polyurethane is a less commonly used covering material on stents for large vessels because of the concern of its durability as a sealing material in a high pressure vascular system. However, such durability will not be a critical issue to create a narrowing in the low-pressure system like within the pulmonary artery, while the use of polyurethane ensures a low profile and permits delivery through a long sheath, only 1-2 F larger than the size recommended for an uncoated stent. However, in a clinical setting, in the neonatal period, patients with HLHS have high pulmonary artery pressure and high pulmonary artery vascular resistance. Further study is necessary to investigate the durability of the covered stent in a high-pressure setting. Furthermore, as reported previously, this covered stent could be over-dilated after 28-70 days of implantation. These properties make it possible not only to create pulmonary artery banding but also to release it in the catheterization laboratory.

The length of the stent that is required to create adequate narrowing in the pulmonary artery by the available stents in Japan is one of the limitations of this method, particularly for small infants. With a covered stent that is too long, "jailing" a major side branch by a coating is a critical concern, particularly for a Fontan candidate. Stent material and cell design are other issues that need further innovation. As shown in our experiment, the covered stent made from the old Palmaz stent could create narrowing in the branch pulmonary artery, which could be debanded by simple balloon dilation, in a piglet; however, its delivery system, 8-9 F, it still too large for a neonate. The Express Vascular LD stent, which goes through a slightly smaller delivery system, could not be debanded because of the ultra-flex geometry with semi-open cell design. For actual clinical utilization of our covered stent in a small infant, a novel stent will be essential that has the following properties: 1. a closed cell design with a radial strength similar to a Palmaz stent, 2. able to go through a 5-6 F sheath, 3. length of approximately 10 mm, and 4. dilatable up to 10-12 mm.

A transcatheter PAB was created using a covered stent implanted in a dumbbell shape. The stent material and design were key issues not only for creation of PAB but also for debanding using a covered stent. Further innovation of stents will be necessary for clinical utilization of this technique as a comprehensive transcatheter stage 1 palliation of HLHS.

References


