Treatment of Acute Stanford Type B Aortic Dissection With a Novel Cylindrical Balloon Catheter in Dogs

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Background—Despite recent progress in medical and surgical treatment, acute type B aortic dissection still carries a high mortality rate. We have developed a novel cylindrical balloon catheter for less invasive treatment to block the entry of the dissection and induce thrombotic occlusion of the false lumen. The balloon has the shape of a sheet when deflated but a double-cylinder shape when inflated. Therefore, aortic blood flow is maintained through the cylindrical lumen during balloon inflation.

Methods and Results—Six beagle dogs underwent a left thoracotomy at the 6th intercostal space. An acute dissection of 4-cm length was created surgically on the descending aorta. The balloon catheter was inserted through the distal descending aorta and advanced to the entry site. The balloon catheter was inflated for 6 hours. The blood flow in the descending aorta and the position of the balloon was monitored by color Doppler echovasculography. Four dogs were killed humanely on the following day and 2 dogs 10 days after the surgery. The descending aorta was examined macroscopically and microscopically in all dogs. In all dogs, the false lumen was occluded by thrombi. Although no dog had clinical evidence of distal thromboembolism, 2 of the 4 dogs that were killed on the second postoperative day had fresh mural thrombi in the true lumen.

Conclusions—The false lumen of the acute type B aortic dissection was effectively occluded by the novel cylindrical balloon catheter in the canine experimental model. The thrombus formation in the true lumen is the problem to be solved. (Circulation. 2000;102[suppl III]:III-259-III-262.)

Key Words: aorta ■ aneurysm ■ balloon ■ catheters ■ thrombus

Long-term survival of patients with type B aortic dissection is poor, whether the patients are treated surgically or medically.1–10 Thus, there is a need to develop a more effective and less invasive therapeutic method for type B aortic dissection. On the other hand, it is known that the false lumen becomes occluded spontaneously by thrombi in the acute phase of some patients, and their prognosis is relatively good.11–14

To make the type B aortic dissection that of thrombotic occlusion type, we have developed a novel cylindrical balloon catheter to block the entry of the dissection.

In the present series, we evaluated the effectiveness of the treatment by using the catheter in a canine type B aortic dissection model.

Methods

Design of the Balloon

This balloon consists of 2 layers of polyethylene membrane. It has the shape of a sheet when deflated, therefore it can be easily rolled up around the shaft (when this balloon is rolled up around the shaft, its diameter is 4 mm). When inflated (diameter of the rolled shaft is ~4 mm), it has a double-cylinder shape, with a thickness of 4 mm (ie, an inner diameter of 11 mm and an outer diameter of 15 mm, Figure 1).

The blood flow distal to the balloon is maintained through the inner cylindrical lumen during the balloon inflation. Hence, the balloon can be inflated for 1 hours’ duration without compromising hemodynamics, allowing effective occlusion of the entry of the dissection.

Anesthesia

Six adult beagle dogs, weighing 10 to 12 kg, were used. Anesthesia was induced with an intramuscular injection of 0.05 mg/kg atropine sulfate, 5 mg/kg xylazine, and 12 mg/kg ketamine hydrochloride. After intratracheal intubation, anesthesia was maintained with 1.0% halothane with mechanical ventilation. (Popular77).

Creation of Canine Model of Stanford Type B Dissection

We approached the descending aorta through the left thoracotomy at the 6th intercostal space. We created a dissection ranging from the descending aorta just distal to the take-off of the left innominate artery (ie, entry) to the aorta 4 cm distally (ie, reentry) in the following way.15 The aortic adventitia was incised at the 2 sites described above. At the proximal site, the aortic media was dissected distally by injecting normal saline to the distal site. Under cross-clamp of the aorta on both sides of the proximal incision, the intima

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was incised and all layers of the aortic wall of the proximal side and only adventitia of the distal side (ie, dissection side) were sutured (ie, entry was created at the proximal site). Similarly, reentry was made at the distal site. In our preliminary experiment, the patency of the false lumen of the dissection model was confirmed for up to 2 years totally in 10 dogs.

**Balloon Insertion and Maintenance**

The distal descending aorta was exposed by a left thoracotomy at the 10th intercostal space. The balloon catheter was inserted into the aorta through a purse-string suture on it at just proximal to the diaphragm with the open Seldinger method, and the catheter was advanced to the entry site of the aorta (Figure 2).

The blood flow in both true lumen and false lumen and the position of the balloon catheter was monitored by color Doppler echovasculography (Sonolayer® SSA-260A, Toshiba).

The balloon was inflated for 6 hours and then was deflated. After confirming by echovasculography that the flow in the false lumen had disappeared, the balloon was removed.

Four dogs were killed humanely on the day after the operation and 2 dogs 10 days after that; the latter 2 dogs received aortography just before they were killed.

The aorta was excised en bloc in each animal. After the macroscopic examination, the aorta was fixed in 1% formalin solution, and histological sections were made and stained with hematoxylin and eosin.

All operations and euthanasia were performed in accordance with the Animal Welfare Regulation Guidance of the Animal Experimentation Committee of Kyoto University (1989).

**Results**

Before the balloon inflation, sufficient flow was observed in both true and false lumina. After inflation of the balloon, the blood flow in the false lumen diminished immediately, and only slight reversal flow from the reentry site was observed in the false lumen. When we deflated the balloon 6 hours later, no flow remained in the false lumen, and sufficient flow was recognized in the true lumen. The false lumen was occluded by the thrombus (Figure 3). After the operation, all dogs recovered uneventfully, and none showed any sign of arterial thromboembolism, such as colon ischemia, claudication, and leg necrosis.

Aortography showed neither intimal flap nor ulcer-like projection 10 days after the surgery. Macroscopic examination showed that all the false lumina were occluded by thrombi in all of the 6 dogs (Figure 4). However, mural thrombi in the true lumen were seen in 2 dogs out of 4 that were killed on the day after the operation.

**Microscopic Examination**

On the day after the operation, all the false lumina were occluded entirely by fresh (or red) thrombi. Ten days after the surgery, old (or white) thrombi were dominant in the false lumen (Figure 5).

**Discussion**

Recently, stent graft therapy has been developed as a less invasive method for treatment of type B aortic dissection. However, it is accompanied with the risk of the rupture of the aorta or migration of the graft, and it has not yet been used clinically as a routine procedure in an acute phase. This may be in part because the stent graft method for the aortic dissection poses a conceptual dilemma in itself; the stent graft must be expanded oversize to avoid its migration, and consequently considerable tension is placed onto the aortic wall by the graft. Under this situation, the fragile aortic wall may have more propensity to rupture.

We have developed the cylindrical balloon to reduce this type of concern. Theoretically, if the outer diameter of the balloon and inner diameter of the aorta are exactly matched and if the balloon has the same curvature as the aorta, no pressure will be placed to the aortic wall, since the position of the balloon is maintained by its shaft, not by the friction between the balloon and aortic wall.
Akaba et al.\textsuperscript{23} reported a similar idea, but the inner cylinder of their balloon was solid and the outer diameter of the catheter became large even during the balloon deflation; therefore the balloon had to be introduced proximal to the femoral artery, which requires a surgical approach.

In contrast, our balloon has a sheet shape when deflated, and can be rolled up around the shaft to reduce its diameter. We inserted the balloon surgically through the lower descending aorta only because the experiments were done in small beagle dogs, but in the clinical setting, it would be inserted through the femoral artery by means of the routine Seldinger method. We inflated the balloon for 6 hours in the descending aorta, and it occluded the false lumen by thrombi in all animals.

In our preliminary experiments, the balloon was inflated for 4 hours and then was deflated, but the aorta developed redissection after the deflation. Echovasculography showed that the blood flow into the false lumen began at the entry site and the blood flow reached the reentry site. Thus, we believe that the entry site must be blocked until the thrombi in the false lumen become stable.

Because 1-week antihypertensive therapy is now clinically performed as an internal medicinal treatment for the aortal dissection, in the present study we followed up 10 days after treatment. Though longer follow-up may be desirable, we think that the possibility of the redissection is lower after 10 days. As we demonstrated in this study, at 10 days the thrombi became almost organized.

We observed mural thrombi in 2 of 4 dogs that were killed on the second postoperative day but no thrombi in the 2 dogs that were killed on the 10th postoperative day.

Since no dog showed any sign of thromboembolism, all the mural thrombi might have been absorbed, although there are not enough data to prove it.

The cause of mural thrombi can be speculated in 2 ways. One is incomplete fitting of the balloon to the aortic wall; under this condition, little blood flows through the narrow space between the balloon wall and the aortic wall, which might lead to gradual thrombi formation. The other possible mechanism is that the polyethylene membrane produced thrombi on its surface, which might have become attached to the aortic surface.

Because this balloon was not treated with an anticoagulant such as heparin or urokinase, the blood coagulated on the surface of the membrane and formed mural thrombus. We speculate that the former mechanism is more likely because no thrombi were found on the inner surface of the balloon after its removal.

Therefore, further investigation will be necessary including the improvement of the shape and possibly material of the balloon so that it fits the aortic wall gently but completely.
This novel cylindrical balloon was manufactured and supplied by Tokai Medical Co.

References


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