Successful Endovascular Treatment for Thrombotic In-Stent Iliac Occlusion with In-House-Devised Optimo®-Like Embolic Protection System

Hiroshi Kubota, Tetsuya Nomura, Yusuke Hori, Kenichi Yoshioka, Daisuke Miyawaki, Ryota Urata, Takeshi Sugimoto, Masakazu Kikai, Natsuya Keira, and Tetsuya Tatsumi

1Department of Cardiovascular Medicine, Nantan General Hospital, Nantan City, Kyoto 629-0197, Japan
*Corresponding author: Tetsuya Nomura, MD, Department of Cardiovascular Medicine, Nantan General Hospital 25, Yagi-Ueno, Yagi-cho, Nantan City, Kyoto 629-0197, Japan. Tel: +81-0771422510, Fax: +81-0771422096, E-mail: t2ya82@yahoo.co.jp

Received 2016 August 07; Accepted 2016 September 21.

Abstract

Introduction: In practical settings of endovascular treatment, we sometimes encounter difficulties in treating lesions with massive thrombi, which may cause distal thromboembolism.

Case Presentation: We encountered a case of severe critical limb ischemia involving in-stent iliac occlusion with massive thrombi. We had to overcome the critical issue of how to treat the massive thrombi in the iliac artery while avoiding thromboembolism. Therefore, we devised a very simple but possibly very useful protection system without any special devices based on the concept of the Optimo® balloon-tipped occlusion catheter.

Conclusions: Although various endovascular treatment (EVT) devices and techniques have since been developed, little tips and tricks during EVT procedures are sometimes markedly useful.

Keywords: Endovascular Treatment, Chronic Total Occlusion, Thrombus, Embolic Protection System, Balloon Occlusion

1. Introduction

Various procedures of endovascular treatment (EVT) for chronic total occlusion have been established, and a higher success rate and acceptable rate of complications has been achieved with recanalization. To set up a bidirectional approach system in the EVT procedure is relatively easy and very useful for facilitating procedural success. However, we sometimes encounter difficulties in treating lesions with massive thrombi, which may cause distal thromboembolism. We encountered a case for which we devised a very simple but possibly very useful protection system to avoid distal thromboembolism without any special devices. Although various sophisticated EVT devices have been developed, small tips and tricks during EVT procedures are sometimes markedly useful.

2. Case report

A 94-year-old female, who had critical limb ischemia on the right side (Rutherford class 5), was admitted to our hospital for revascularization in the right lower extremity. Her ankle brachial blood pressure index (ABI) on the right side could not be measured due to the pulselessness of the ankle. Duplex ultrasound on arteries of the right lower extremity showed total obstruction from the proximal part of the common iliac artery (CIA) to the distal part of the superficial femoral artery (SFA). Diagnostic angiography demonstrated total occlusion proximal to the right CIA (Figure 1A).

EVT for these long occluded arteries on the right side was performed with a left trans-brachial approach. A 6Fr Parent plus guiding sheath (Medikit Co., Ltd., Tokyo, Japan) was introduced to the terminal aorta. We successfully penetrated the proximal cap of the occlusion with a Ruby hard guidewire (KANEKA Corp., Osaka, Japan) under Eagle Eye Platinum ST (VOLCANO Corp., CA, USA) Intra-Vascular Ultrasound (IVUS) guidance. We exchanged the 0.014-inch guidewire with a 0.035-inch Radifocus 1.5-mm J-shaped-tip guidewire (Terumo Corp., Tokyo, Japan) and advanced it under the support of a 4Fr CXI catheter (Cook Medical, IN, USA). The guidewire successfully reached the common femoral artery (CFA). There remained a small unobstructed luminal area around the CFA. However, the SFA (Figure 1B arrows) was totally occluded at its proximal part, and the deep femoral artery (DFA) (Figure 1B, arrowheads) supplied very low-level blood flow distally to the collateral vasculature. We deployed three self-expandable Epic stents (Boston Scientific Corp., CA, USA) in the right occluded iliac artery and inflated a balloon catheter with a 6.0-mm diameter in the CFA (Figure 1C). Thereafter, we tried further advancement of a guidewire into the occluded SFA with IVUS guidance, yet the maneuverability of the guidewire worsened and we finally gave up recanalizing the SFA in this...
session. We finished the EVT procedure with only delayed blood flow in the right iliac artery due to insufficient blood out-flow distally from the CFA (Figure 1D).

We started the second session of EVT via the left CFA, two days after the first session. Initial angiography demonstrated recurrence of total occlusion in the right iliac artery with massive thrombi (Figure 2A). The proximal edge of the occlusion was relatively hard so we used a TEMPO catheter (Cordis Corp., CA, USA) to provide the guidewire with a sufficient back-up force. A 0.035-inch Radifocus 1.5-mm J-shaped-tip guidewire was able to penetrate into the occluded iliac artery and advance to the CFA (Figure 2B). Next, a Treasure XS 12 guidewire (ASAHI INTECC Co., Ltd., Aichi, Japan) was successfully passed through the occluded SFA to the popliteal artery with IVUS guidance (Figure 2C). Then, we deployed two self-expandable INNOVA
stents (Boston Scientific Corp., CA, USA) in the SFA after predilation with a 4.0-mm balloon catheter (Figure 2D).

Next, we punctured the right groin and inserted the tip of an 8Fr regular sheath in the distal part of the external iliac artery (EIA). Then, we delivered a SHIDEN balloon catheter (KANEKA Corp., Osaka, Japan) with a 4.0-mm diameter from the left CFA to the same position as the tip of the 8Fr sheath from the right CFA, and inflated it with a pressure of 4 atmospheres side by side with the 8Fr sheath to occlude the EIA (Figure 3A, arrow). We confirmed the stasis of blood flow from the findings of contrast medium pooling in the iliac artery (Figure 3A, arrowheads). We delivered a balloon catheter, with a 6.0-mm diameter, retrogradely from the 8Fr sheath and inflated it in the proximal part of the CIA to crush the thrombi (Figure 3B). We strongly aspirated the crushed thrombi from the aspiration port of the 8Fr sheath simultaneously with deflation and retrieval of the balloon catheter (Figure 3C).

After performing this aspiration procedure twice, radiolucent masses which were considered to be thrombi in the iliac artery almost disappeared (Figure 3D). Thereafter, the puncture site of the right groin was sutured with the ProGlide closure system (Terumo Corp., Tokyo, Japan) and, at the same time, we inflated a balloon catheter with a 6.0-mm diameter in the right CFA for five minutes for the purpose of both dilating the CFA and ensuring hemostasis of the right puncture site. Final angiography demonstrated good patency from the aortic bifurcation to plantar artery (Figure 3E). The ABI on the right side improved to 0.89.

3. Discussion

We encountered a case of severe critical limb ischemia involving a long occlusive vessel from the ostium of the CIA to the distal part of the SFA. The vascular lumen around the CFA was partially patent and the DFA supplied very low-level blood flow distally to the collateral vasculature. In the first session of EVT, we were able to pass a guidewire antegrade, as far as the CFA and deployed self-expandable stents in the iliac artery. Although we tried to further advance the guidewire into the occluded SFA, the maneuverability of the guidewire with a left brachial approach was restricted due to strong friction of the long vascular route, and we finally failed to penetrate the occluded SFA. We initially expected the blood flow distally from the DFA, which supplied the collateral vasculature, to be sufficient to improve blood flow in the recanalized iliac artery. However, contrary to our expectation, we achieved an insufficient blood stream with flow delay in the iliac artery due to the poor vascular bed distal to the CFA. At the second session of EVT two days after the first one, the iliac artery exhibited in-stent occlusion with fresh massive thrombi. This time, the guidewire could pass through the occluded SFA as far as the popliteal artery due to good guidewire maneuverability via a left femoral approach.

However, we had to overcome the critical issue of how to treat the massive thrombi that were subacutely generated in the stents that had been deployed in the iliac artery just two days previously. Distal thromboembolism during EVT is a major concern due to potential serious ischemic consequences. In-stent and complex native lesions are considered as higher risks for distal thromboembolism during EVT for lower extremities (1). However, this phenomenon is typically reversible with EVT procedures and has been reported to have no significant effect on patency rates or limb salvage. Embolic protection devices can be categorized to three different systems based on their mechanism of action during EVT on various lesions and scenes: flow preservation devices (2), distal balloon occlusion devices (3), and proximal protection devices (4). There are pitfalls and advantages inherent to each protection device system (5).

In our case, we wanted to establish a system to protect against thromboembolism. There have been several reports about the usefulness of the Optimo® balloon-tipped occlusion catheter (Tokai medical products, Inc., Aichi, Japan) for preventing distal thromboembolism during EVT (3). However, this catheter was not available at our institute at that time of the procedure, and so we decided to establish a system similar to the Optimo® catheter. Because the lumen diameter of the distal CIA was about 6 mm from the IVUS findings, we delivered a 4.0-mm balloon catheter from the left groin to obstruct the vascular lumen in the right CIA by trapping side by side with an 8 Fr sheath inserted from the right groin for the purpose of aspirating the thrombi. When simultaneously deflating and retrieving a balloon catheter with a 6.0-mm diameter from the 8Fr sheath, we strongly aspirated from the sheath port. This technique effectively resulted in prevention of distal thromboembolism and avoidance of additional stent deployment to seal the mural thrombi in the iliac artery.

In this report we demonstrate a schema of the embolic protection system developed in this case (Figure 4A). Unlike the Optimo® catheter, which has a specification that the sheath and occlusion balloon share the same axis, those two components run along side by side in the artery in our method (Figure 4B, C). Because of this characteristic, this system cannot completely occlude the vascular lumen. However, we could confirm the stasis of blood flow, and no clinical problematic thromboembolism occurred after the procedure. When using distal balloon occlusion devices, vessel mismatch is one of the most important problems. The target artery is occasionally too large for the dis-
tal occlusion balloon to be occlusive. Particularly with our method, determining the size and inflation pressure of the occlusion balloon was relatively difficult. A larger sized balloon or a higher pressure of balloon inflation can more effectively occlude the target artery, yet this involves the risk of causing deformity of the aspiration sheath (Figure 4D, E). We found that to inflate an optimal sized balloon catheter with a lower pressure is the most useful for this technique (Figure 4B, C), because the minimum inflation of the occlusion balloon is thought to be sufficient to exert a sufficient space-occupying effect in the artery and also cause minimal deformation of the aspiration sheath.

One of the shortcomings of this system was considered to be that delivering the occlusion balloon catheter involves risk of distally scattering of thrombi while antegrade passing through the thrombosed lesions. How-

Figure 2. Panel A, initial angiography demonstrated recurrence of total occlusion in the right iliac artery; panel B, a J-shaped-tip guidewire could be advanced in the iliac artery to the CFA; panel C, a Treasure XS guidewire could be successfully advanced through the occluded SFA to the popliteal artery with IVUS guidance; panel D, two self-expandable INNOVA stents were deployed in the SFA.
ever, we think that the risk is not very critical because the iliac artery has a large vessel diameter. Moreover, arterial dissection and vasospasm are the most common complications seen using distal balloon occlusion devices. In this regard, an optimal sized balloon catheter with a lower pressure is recommended.

Here, we demonstrated a very simple but possibly very useful distal protection system when treating massive thrombotic lesions in the iliac artery. Although various EVT devices and techniques have since been developed, little tips and tricks during EVT procedures are sometimes markedly useful. Because many devices are often required for the completion of complex EVT procedures, it is important to minimize the total number of EVT devices used in order to reduce medical costs in practical settings.

Footnote

Authors’ Contribution: Both Hiroshi Kubota and Tetsuya Nomura were the primary authors of this paper. Yusuke Hori, Kenichi Yoshioka, Daisuke Miyawaki, Ryota Urata, Takeshi Sugimoto, and Masakazu Kikai critically reviewed the manuscript. Natsuya Keira and Tetsuya Tatsumi made major contributions to the conception and design. All authors read and approved the final manuscript.
Figure 4. Panel A, a schema of the embolic protection system devised for this case; panel B - E, a replication test was performed to examine the relationship between the occlusion balloon catheter and aspiration sheath in the vessel model. The occlusion balloon with a 4.0-mm diameter was inflated with different pressures (B, C: 4 atmospheres; D, E: 12 atmospheres) side by side with an 8Fr-sheath inside the vessel model with a 6-mm inner lumen size. The short axis view (B, D). The long axis view (C, E).

References


