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Technical Note

Proximal Balloon Protection during Carotid Artery Stenting via the Transradial Approach

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Objective: We report two patients for whom the proximal balloon protection (PBP) method was used during transradial carotid artery stenting (TR-CAS).

Case Presentations: Case 1 was a 79-year-old male. TR-CAS for acute occlusion of the internal carotid artery was performed. A 6 Fr balloon guiding catheter was introduced into a 6 Fr guiding sheath, and CAS was conducted by passing through the lesion under PBP. Case 2 was an 83-year-old male. TR-CAS was performed to treat marked stenosis of the internal carotid artery. It was difficult to pass the catheter through the lesion, but PBP with a balloon guiding catheter enhanced the supporting power, facilitating lesion passage, and CAS was successful.

Conclusion: No study has reported PBP during TR-CAS, but we were able to perform PBP during TR-CAS by adopting this method, and the support for lesion passage may be enhanced. This method may be useful for patients at risk of distal embolism or for those in whom lesion passage is difficult.

Keywords ▶ carotid artery stenting, transradial approach, lesion cross, proximal balloon protection, flow reversal method

Introduction

For vulnerable plaques or marked stenosis patients in whom distal embolism may occur, carotid artery stenting (CAS) can be safely performed by adopting the proximal balloon protection (PBP) method with a balloon guiding catheter.[1–4] Regarding transbrachial carotid artery stenting (TB-CAS), several studies reported a method of CAS under PBP with a balloon guiding catheter,[5–8] but no study has adopted the PBP method during transradial carotid artery stenting (TR-CAS). We report two patients for whom TR-CAS using a 6 Fr Simmons-type guiding sheath was performed by inserting a 6 Fr balloon guiding catheter coaxially for stenotic-site passage under PBP and then switching to distal balloon protection. This method facilitated PBP during TR-CAS, demonstrating its usefulness.

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Case Presentations

Case 1

Patient: A 79-year-old male.
Medical history: Hypertension.
Family history: Not contributory.
Present illness: Left hemiplegia suddenly occurred. Acute infarction involving the white matter of the right cerebral hemisphere and a portion of the cortex was observed (**Fig. 1A**). Detailed examination revealed 85% stenosis at the origin of the right internal carotid artery in accordance with the North American Symptomatic Carotid Endarterectomy Trial (NASCET) criteria (**Fig. 1B**). Cervical ultrasonography and magnetic resonance (MR) plaque imaging suggested the presence of soft plaques. Single photon emission computed tomography with N-isopropyl-p-[123I] iodoamphetamine (^{123}I-IMP-SPECT) at rest demonstrated a reduction in the cerebral blood flow volume in the right middle cerebral artery region.

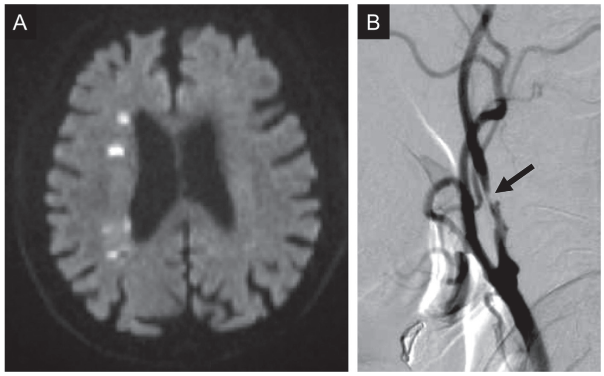

Fig. 1 A 79-year-old male with symptomatic stenosis of the right cervical internal carotid artery. (**A**) Diffusion-weighted image on preoperative MRI. Multiple high-signal-intensity lesions were detected in the right cerebral hemisphere white matter and cortex. (**B**) Lateral cervical view on preoperative right common carotid angiography. Marked stenosis of the internal carotid artery (arrow) was observed.

Therapeutic strategies: Embolic and hemodynamic mechanisms related to marked stenosis of the right internal carotid artery were considered to be etiologically involved in the cerebral infarction. 3D-CTA confirmed the absence of a blockage in the access route involving the right upper limb, and TR-CAS was selected. Although marked stenosis and unstable plaques were suggested, we considered it possible to cross the lesion, and planned for CAS under distal balloon protection. Aspirin at 100 mg/day and clopidogrel at 75 mg/day were orally administered for 14 days before surgery.

Endovascular treatment: Under general anesthesia, a 4 Fr sheath was inserted into the right radial artery. Angiography confirmed favorable development of the ulnar artery. A 4 Fr catheter (kink-resistant catheter, Seiya JB-2; Medikit Co., Ltd., Tokyo, Japan) was guided into the ascending aorta. Into this catheter, a 0.035-inch 260-cm stiff-type radifocus guidewire M (Terumo Corporation, Tokyo, Japan) was inserted, and the 4 Fr catheter and sheath were removed. Using this wire, a 6 Fr Simmons-type guiding sheath (Axcelguide Stiff-J-1 90 cm; Medikit Co., Ltd.) was guided into the right subclavian artery. Subsequently, the 6 Fr guiding sheath was reversed in the ascending aorta using an accessory 6 Fr catheter (6 Fr SY-2; Medikit Co., Ltd.), and guided into the right common carotid artery. Heparin was intravenously administered to maintain the activated clotting time at ≥250 seconds. Angiography demonstrated occlusion of the cervical internal carotid artery (**Fig. 2A**), which was an unexpected finding. Based on the clinical course, a diagnosis of acute occlusion was made, and revascularization by CAS was selected. Considering the presence of debris or thrombus at the lesion site and risk of distal embolism on lesion passage, the strategy was promptly switched to CAS under PBP. A T-connector (Fuji Systems Corp., Tokyo, Japan) was connected to the 6 Fr guiding sheath, and a 6 Fr balloon guiding catheter (Optimo 100 cm; Tokai Medical Products, Aichi, Japan) was coaxially guided into the common carotid artery (**Fig. 2B**) to block the common carotid artery through inflation. A 4 Fr sheath was inserted into the right femoral vein, and connected to a 6 Fr balloon guiding catheter to establish a flow reversal circuit. Contrast medium was slowly infused through the 6 Fr balloon guiding catheter. It stagnated in the common carotid artery. After the start of flow reversal, the disappearance of contrast medium was confirmed. A 200-cm Carotid Guardwire PS (Medtronic, Minneapolis, MN, USA) was inserted into the 6 Fr balloon guiding catheter to pass it through the lesion (**Fig. 2C**), and guided into the distal internal carotid artery to achieve inflation at 5.5 mm (**Fig. 2D**). The 6 Fr balloon guiding catheter was deflated and collected after confirming blockage of the internal carotid artery using angiography. Subsequently, predilation under distal balloon protection, which is routinely adopted, insertion of an 8-mm × 40-mm PRECISE Pro RX (Cordis, Miami, FL, USA), postdilation, and debris aspiration were carried out (**Fig. 2E**). At the puncture site of the right radial artery, hemostasis was performed using a pressing instrument for hemostasis (XEMEX Hemostatic Device T type; Zeon Medical inc., Tokyo, Japan).

Postoperative course: After surgery, there was no abnormality at the site of puncture. There was no new neurologic deficit. Cephalic MRI the day after surgery did not reveal any new cerebral infarction. On cervical ultrasonography 10 months after surgery, stent-mediated blood flow was favorably maintained, and there was no event suggestive of ischemia.

Case 2

Patient: An 83-year-old male.

Medical history: Hypertension, obstructive arteriosclerosis.

Family history: Not contributory.

Present illness: Left hemiplegia occurred. Acute infarction involving the white matter of the right cerebral hemisphere was observed (**Fig. 3A**). Detailed examination revealed marked stenosis involving the distal right common carotid artery to the origin of the internal carotid artery (NASCET: 95% stenosis) (**Fig. 3B**). The plaque diagnosis suggested hard plaques comprising calcification. IMP-SPECT at rest

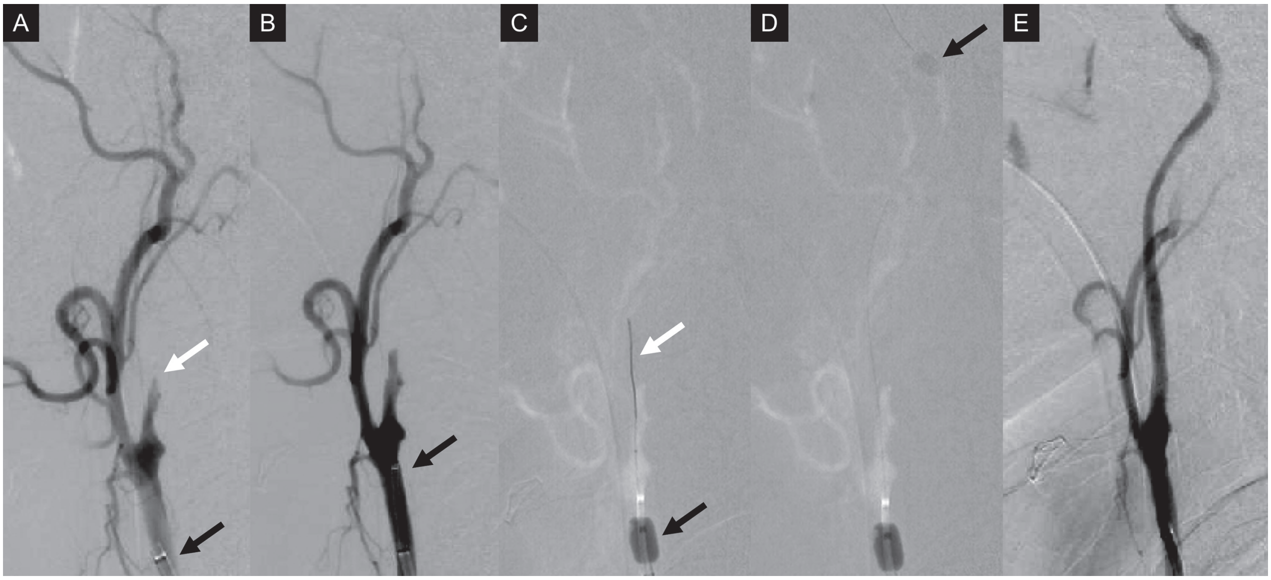

Fig. 2 Intraoperative lateral views of the right carotid artery. (**A**) Angiography was performed by guiding 6 Fr Simmonds-type guiding sheath (black arrow) into the right common carotid artery. Occlusion of the cervical internal carotid artery was observed (white arrow). (**B**) A 6 Fr balloon guiding catheter (black arrow) was inserted into a 6 Fr Simmons-type guiding sheath. (**C**) A 6 Fr balloon guiding catheter was inflated (black arrow), and a Carotid Guardwire (white arrow) was passed through the lesion under PBP. (**D**) A Carotid Guardwire was inflated in the distal cervical internal carotid artery (black arrow), and CAS was performed by switching PBP to distal balloon protection. (**E**) Lateral view on right common carotid angiography after CAS. Favorable dilation was confirmed. CAS: carotid artery stenting; PBP: proximal balloon protection

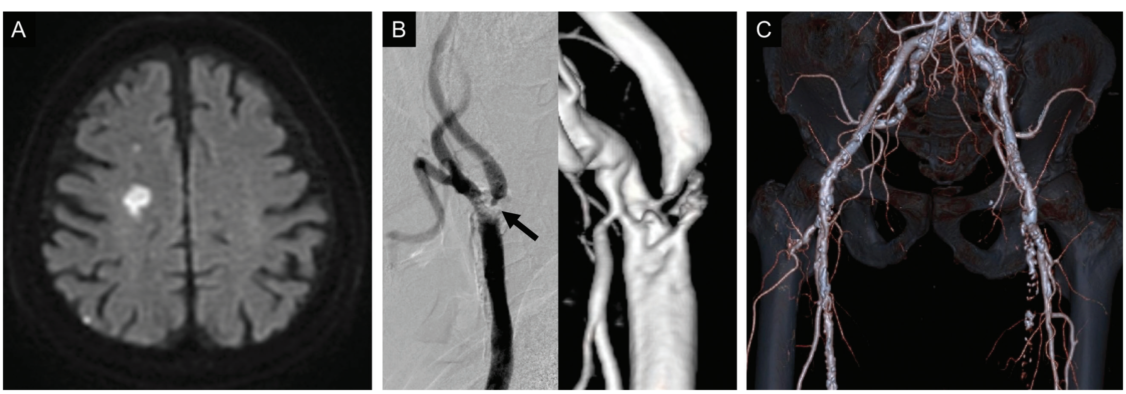

Fig. 3 An 83-year-old male with marked symptomatic stenosis of the right cervical internal carotid artery. (**A**) Diffusion-weighted image on preoperative MRI. High-signal-intensity lesions were scattered throughout the right cerebral hemisphere. (**B**) Lateral cervical view on preoperative right common carotid angiography (left), there-dimensional rotational angiography (right). Marked stenosis with calcification involving the distal common carotid artery to the origin of the internal carotid artery was observed. (**C**) Three-dimensional computed tomography angiography. Marked arteriosclerosis of the bilateral lower limb arteries was observed.

demonstrated a reduction in the cerebral blood flow volume in an extensive area of the right middle cerebral artery. Marked arteriosclerosis of major arteries of the bilateral lower thighs was noted (**Fig. 3C**).

Therapeutic strategies: A hemodynamic mechanism related to marked stenosis of the right internal carotid artery was considered to be etiologically involved in the cerebral infarction. CTA confirmed the absence of blockage in the access route, and TR-CAS was selected. Although stenosis was marked, we planned CAS under distal balloon protection because the risk of distal embolism on lesion passage was low based on the plaque diagnosis. Aspirin at 100 mg/day and clopidogrel at 75 mg/day were orally administered for 14 days before surgery.

Endovascular treatment: As described for Case 1, a 6 Fr Simmons-type guiding sheath (Axcelguide Stiff-J-1 90 cm) was guided into the right common carotid artery using the right transradial approach under general anesthesia (**Fig. 4A**). We attempted to pass a Carotid Guardwire through the lesion, but flexion at the site of stenosis was marked, and it

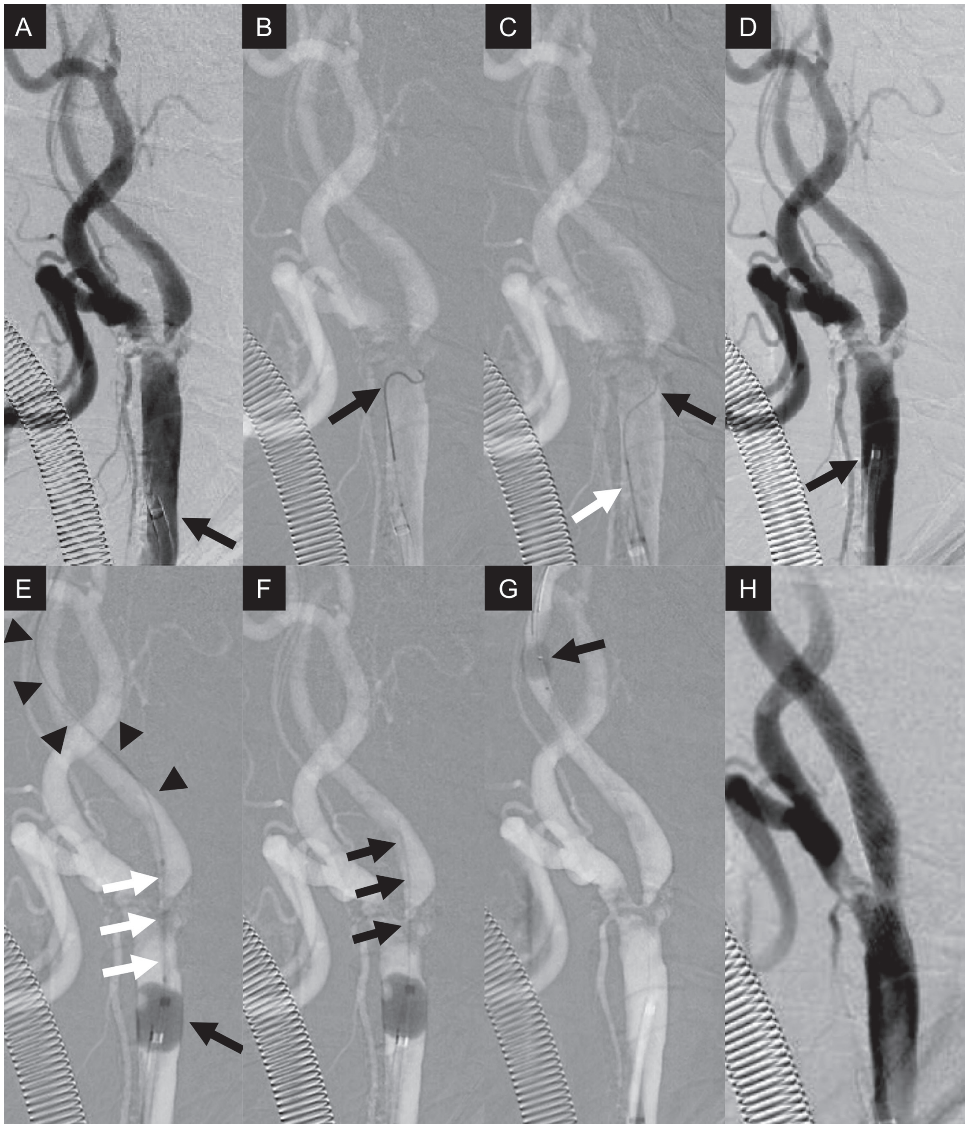

Fig. 4 Intraoperative lateral views of the right carotid artery. (**A**) Lateral cervical view on preoperative right common carotid angiography. A 6 Fr Simmonds-type guiding sheath was guided into the right common carotid artery (black arrow). Marked stenosis was observed at the origin of the internal carotid artery. (**B**) Lesion crossing was attempted using a Carotid Guardwire (black arrow), but it was impossible. (**C**) Using a microcatheter (white arrow) as a back-up system, lesion crossing with a 0.014-inch microguidewire (black arrow) was attempted, but it was impossible. (**D**) A 6 Fr balloon guiding catheter (black arrow) was inserted into a 6 Fr Simmons-type guiding sheath. (**E**) A 6 Fr balloon guiding catheter was inflated to block the common carotid artery (black arrow). Under PBP, a microguidewire was passed through the lesion (arrow head), and the lesion site was dilated using a PTA balloon catheter (white arrow). (**F**) Under PBP, a Carotid Guardwire (black arrow) was smoothly passed through the lesion. (**G**) A Carotid Guardwire was inflated in the distal cervical internal carotid artery (black arrow). CAS was performed by switching PBP to distal balloon protection. (**H**) Lateral view on right common carotid angiography after CAS. Favorable dilation was confirmed. CAS: carotid artery stenting; PBP: proximal balloon protection; PTA: percutaneous transluminal angioplasty

was impossible to cross the lesion (**Fig. 4B**). We then attempted to pass a 182-cm Transend EX (Stryker, Minneapolis, MN, USA) or 200-cm ASAHI CHIKAI black (Asahi Intecc, Tokyo, Japan) through the lesion using an Excelsior SL-10 (Stryker) or 45° Echelon 10 (Medtronic) as a back-up system. However, it was impossible to pass them through the lesion site (**Fig. 4C**), similar with the Carotid Guardwire. To increase the supporting power and prevent distal embolism on lesion passage, we decided to insert a 100-cm 6 Fr balloon guiding catheter into a guiding sheath, as described for Case 1, to allow for lesion passage under PBP. Initially, a 6 Fr balloon guiding catheter was inserted into a 6 Fr guiding sheath (**Fig. 4D**) to block the common carotid artery through inflation and establish a flow reversal circuit. Common carotid angiography was slowly performed using a small volume of contrast medium. After confirming proximal protection, flow reversal was started. It was possible to smoothly pass a CHIKAI black through the lesion under the stable back-up system with the inflated 6 Fr balloon guiding catheter and guide a 45° Echelon 10 into the distal internal carotid artery. The CHIKAI black was changed to a 300-cm ChoICE PT Extra Support (Boston Scientific, Marlborough, MA, USA). The lesion was dilated using a percutaneous transluminal angioplasty (PTA) balloon catheter (WALKER RX PTA balloon catheter, 1.5 mm × 20 mm; Goodman, Aichi, Japan) (**Fig. 4E**) and collected with the ChoICE. Additionally, a Carotid Guardwire was passed through the lesion (**Fig. 4F**), and the distal area of the internal carotid artery was inflated to 5.5 mm. The 6 Fr balloon guiding catheter was deflated, and angiography confirmed blockage of the internal carotid artery. The 6 Fr balloon guiding catheter was then collected (**Fig. 4G**). As described for Case 1, predilation, insertion of a 10-mm × 24-mm Carotid Wallstent (Stryker), postdilation, and debris aspiration were carried out under distal balloon protection as standard procedure. As plaque protrusion was observed in the stent, the stent-in-stent procedure was conducted using an 8-mm × 40-mm PRECISE Pro RX (**Fig. 4H**). At the puncture site of the right radial artery, hemostasis was achieved using a pressing instrument (XEMEX Hemostatic Device T type).

Postoperative course: After surgery, there was no abnormality involving the site of puncture. MRI did not reveal any new infarction. On cervical ultrasonography 3 months after surgery, stent-mediated blood flow was favorably maintained.

Discussion

The PBP method to prevent distal embolism during CAS was introduced as a flow reversal method by Parodi et al.[4)] Subsequent large-scale studies, such as the ARMOUR Pivotal Trial, EMPiRE Clinical Study, and PROFI Study, demonstrated that the incidence of ipsilateral cerebral embolism was low when adopting the PBP method.[1–3)] In particular, it was reported that this method is useful for treating lesions that may cause embolism on lesion passage such as marked stenosis with flexion and false occlusion. The PBP method requires an 8-9 Fr balloon guiding catheter. CAS has commonly been performed using the femoral artery approach. However, recently, many studies reported the efficacy of CAS via an upper limb approach based on problems with approach routes and postoperative resting.[9–11)] According to several studies regarding TB-CAS, CAS was performed under PBP by inserting a 9 Fr balloon guiding catheter or Mo. Ma Ultra (Medtronic) in the absence of a sheath, and guiding it into the common carotid artery.[5,6)] However, caution is needed to not damage the balloon on insertion into blood vessels. Furthermore, Nishida et al.[7)] reported TB-CAS in which a 5.2 Fr balloon catheter (5.2 Fr Serecon MP catheter; Terumo Clinical Supply Co., Ltd., Gifu, Japan) was inserted into a 7 Fr Shuttle (COOK Medical, Bloomington, IN, USA), and PBP was switched to total distal balloon protection (TDBP) using two Carotid Guardwires.[7)] This procedure is slightly complex, requiring puncture similar to that with a 7 Fr sheath. Ohshima et al.[8)] reported a CAS procedure involving insertion of a 100-cm 6 Fr balloon guiding catheter into a 90-cm 6 Fr Simmons-type guiding sheath through a hemostatic valve on the brachial artery approach, placement of two Carotid Guardwires into the catheter, and switching of PBP to TDBP. This method facilitates low-profile treatment.

In this study, we introduced a 100-cm 6 Fr balloon guiding catheter into a 90-cm 6 Fr Simmons-type guiding sheath, as described by Ohshima et al.,[8)] via the transradial approach, crossed the lesion under PBP, and completed the procedure safely. The following points were different from the methods described by Ohshima et al.[8)]: 1) the transradial approach was adopted; 2) a T connector, not a hemostatic valve, was connected to a 6 Fr guiding sheath; 3) angiography was performed after common carotid blockage with a 6 Fr balloon guiding catheter, and blood flow was evaluated, and 4) PBP with a 6 Fr balloon guiding catheter was utilized as a back-up system. Regarding 1), we positively select TR-CAS when development of the ulnar artery is confirmed to not have problems, such as hypoplasia/marked torsion of the radial artery or presence of an ulnar loop. A previous study reported that when adopting the transradial approach, the incidences of complications, such as large-volume subcutaneous hematoma at the site of puncture, median nerve paralysis, pseudoaneurysm formation, forearm ischemia, and compartment syndrome, were lower than when adopting the transbrachial approach, suggesting the safety of the transradial approach.[12)] This is because the volume of soft tissue in the brachial/elbow regions is large, and insufficient compression on flexion of the elbow may lead to hematoma formation, whereas the volume of soft tissue in the distal radial area is small, facilitating compressive hemostasis.[13)] Regarding 2), the balloon

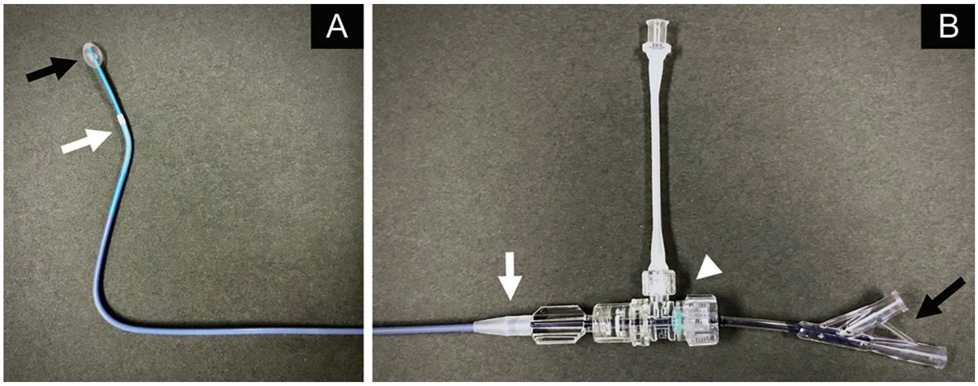

Fig. 5 The catheter end and part for hand operation (A 6 Fr balloon guiding catheter [6 Fr Optimo, 90 cm; Tokai Medical Products, Aichi, Japan] were inserted by connecting a T connector to a 6 Fr Simmons-type guiding sheath [6 Fr Axcelguide Stiff-J-1, 90 cm; Medikit Co., Ltd., Tokyo, Japan]). (**A**) End of the catheter. A 6 Fr balloon guiding catheter (black arrow) was extruded out of the tip of a 6 Fr Simmons-type guiding sheath (white arrow). (**B**) Hand operation of the catheter. A 6 Fr balloon guiding catheter (black arrow) was inserted by connecting a T connector (white arrow head) to a 6 Fr Simmons-type guiding sheath (white arrow).

of the 6 Fr balloon guiding catheter can be extruded out of the tip of a 6 Fr Simmons-type guiding sheath even in the presence of a T connector (**Fig. 5**). If a T connector is connected, a balloon or stent can be smoothly inserted into a 6 Fr guiding sheath after removal of the 6 Fr balloon guiding catheter; therefore, a T connector is useful. For 3), we confirmed whether contrast medium stagnates in the common carotid artery, antegradely flows in the internal carotid artery, or regurgitates from the internal to the external carotid artery by slowly infusing a small volume of contrast medium through a 6 Fr balloon guiding catheter after establishing PBP and flow reversal circuit. As described by Minami et al.,[14] we simultaneously blocked the external carotid artery using a Carotid Guardwire for lesion crossing when blood flow from the external to internal carotid artery was observed. In the present two cases, we confirmed that contrast medium had stagnated in the common carotid artery without flowing in the internal carotid artery. In Case 1, the internal carotid artery was occluded, and angiography under PBP revealed the retention of contrast medium in the common carotid artery and disappearance of contrast medium at the start of flow reversal; therefore, the lesion was crossed without blockage of the external carotid artery. In Case 2, marked stenosis related to hard plaques made lesion passage difficult. Angiography under PBP did not indicate any blood flow into the internal carotid artery, and the plaque properties suggested the risk of distal embolism on lesion passage to be low; therefore, the lesion was crossed without blocking of the external carotid artery. Regarding 4), in Case 2, this procedure facilitated lesion crossing under flow reversal, providing strong support. This may have contributed to successful CAS for a markedly stenotic lesion, which makes lesion passage difficult.

PBP was not initially scheduled for the two patients, but it was considered to be necessary based on angiography with a 6 Fr guiding sheath guided into the common carotid artery. Thus, even when PBP is urgently required, this procedure facilitates CAS through lesion passage under PBP, with no need to change the 6 Fr guiding sheath inserted into the common carotid artery using the transradial approach.

In this study, we performed PBP by inserting a 100-cm 6 Fr Optimo (Tokai Medical Products) as a 6 Fr balloon guiding catheter. However, a 6 Fr CELLO (Medtronic) measuring 102 cm in effective length may also be available.

Conclusion

In this study, we reported the PBP method with a balloon guiding catheter during TR-CAS. This method facilitates the prevention of distal embolism during TR-CAS, providing strong support for lesion crossing. Even when PBP is unexpectedly required during TR-CAS using a 6 Fr guiding sheath, PBP is easily established by this method without changing the guiding system.

Disclosure Statement

There is no conflict of interest regarding this article.

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