Importance of Predilatation for CAS: Two Patients for Whom Balloons Were Mis-selected

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Objective: We report two patients for whom balloons for carotid artery stenting (CAS) were mis-selected, and review balloon selection for CAS and the purpose of predilatation.

Case Presentations: Case 1: A 73-year-old man developed amaurosis fugax on his right eye. An unstable, plaque-abundant stenotic lesion of the right internal carotid artery with calcification was detected. Under flow reversal, a Carotid WALLSTENT 8 mm x 29 mm was inserted, and postdilatation was performed using a Jackal 4.5 mm x 30 mm until a nominal pressure was achieved. In-stent plaque protrusion was noted. A Carotid WALLSTENT 8 mm x 21 mm was overlapped, and the procedure was completed. Subacute thrombosis (SAT) with North American Symptomatic Carotid Endarterectomy Trial (NASCET) 40% restenosis was observed 5 days after CAS. Anticoagulant therapy gradually reduced SAT.

Case 2: An 83-year-old woman presented an asymptomatic acute phase ischemic lesion in left cerebral hemisphere by scheduled MRI as a follow-up study of medical checkup. An irregular, plaque-abundant, markedly stenotic lesion of the left internal carotid artery with calcification was detected. Under flow reversal, predilatation was performed using a Sterling 3 mm x 40 mm (Boston Scientific, Marlborough, MA, USA) until a nominal pressure was achieved, and a PRECISE 9 mm x 40 mm (Cardinal Health, Inc., Dublin, OH, USA) was inserted. It was impossible to pass an Aviator 4 mm x 30 mm (Cardinal Health, Inc.) for postdilatation through the site of stenosis, and a Gateway 2.5 mm x 12 mm (Stryker, Kalamazoo, MI, USA) and Jackal 4.5 mm x 30 mm (Kaneka Medix Corp., Osaka, Japan) were used. Dilatation was achieved.

Conclusion: To improve the results of CAS, it is important to establish the purpose of balloon dilation and select a balloon in accordance with its purpose, as indicated for the selection of embolic protection devices (EPDs) and stents.

Keywords ▶ tailored carotid artery stenting, predilatation, balloon for dilatation

Introduction

Currently, several stents and embolic protection devices (EPDs) are available. A study reported the efficacy of tailored carotid artery stenting (CAS),13 in which devices are selected for individual patients through detailed preprocedural evaluation. In our hospital, approach routes and EPD/stent types are selected by performing the anatomical assessment of access routes/stenotic lesions using preprocedural CTA or DSA and evaluating the presence or absence of calcification/its grade, passage at the site of stenosis, degree of collateral flow, and properties of plaque/extent of lesions on magnetic resonance (MR) angiography, involving black-blood MR images (BBMRs). As a rule, the transfemoral approach is selected. As an EPD, a distal protection device is adopted. However, the combination of proximal and distal protection devices is considered when treating lesions in which device passage at the site of stenosis is expected to be difficult or unstable plaque. Concerning stents, closed- or open-cell-type ones are selected based on the properties of plaque and vascular shape. On the other hand, balloons for dilatation must be selected based on the vascular diameter. However, in most

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patients, balloons measuring 3.5 mm × 40 mm in diameter are selected for predilatation, and those measuring 4.5 mm × 30 mm for postdilatation; the balloon type is not selected in accordance with individual lesions, differing from EPDs or stents. Furthermore, differences in performance among products have not particularly been considered. In this study, we report two patients for whom balloons for dilatation may have been mis-selected, and review the role of balloon dilatation in the CAS procedure and importance of balloon selection in accordance with its role.

### Case Presentations

**Case 1**

A 73-year-old man developed amaurosis fugax on his right eye. Detailed examination showed stenosis at the origin of the right internal carotid artery, and therapeutic intervention was planned. CTA revealed calcification, and BBMRs showed an extensive T1-weighted high-signal-intensity area, suggesting an unstable lesion with a large plaque volume (Fig. 1). Based on the patient’s wishes, CAS was planned, but the lesion’s properties suggested the risk of distal embolism during the procedure. Therefore, the procedure was performed using the flow reversal method, in which a filter was combined with a proximal protection device. The most stenotic site of the lesion measured 1.7 mm, and the distal internal carotid artery diameter was 4.2 mm. The proximal common carotid artery diameter was 6.6 mm. The degree of stenosis was 60% according to the North American Symptomatic Carotid Endarterectomy Trial (NASCET) criteria. The lesion length was approximately 3 cm. As a stent, a Carotid WALLSTENT 8 mm × 29 mm (Boston Scientific, Marlborough, MA, USA) was used. A MOMA ultra 9 Fr (Medtronic, Minneapolis, MN, USA) was guided into the external carotid artery through the common carotid artery to confirm the state of flow stasis. It was connected to a 6 Fr sheath, which had been placed in the femoral vein, to promote flow reversal. Subsequently, a Filter Wire EZ (Boston Scientific) was guided into the distal internal carotid artery, and deployed. Angioplasty was performed using Jackal 3.5 mm × 40 mm (Kaneka Medix Corp., Osaka, Japan) for 10 seconds until a nominal pressure was obtained. Vessel dilatation was promptly achieved. A Carotid WALLSTENT 8 mm × 29 mm was inserted, and postdilatation was conducted using Jackal 4.5 mm × 30 mm for 8 seconds until a nominal pressure was obtained. In addition to flow reversal, manual aspiration through the guiding catheter was performed several times, and proximal blockage was relieved. To confirm the state of stenting, angiography was performed. In the stent, there was a filling defect, suggesting plaque protrusion (Fig. 2B). Although we considered to repeat balloon angioplasty, another Carotid WALLSTENT 8 mm × 21 mm was overlapped inside, speculating that angioplasty may further deteriorate plaque protrusion. After the stent was superimposed, angiography was repeatedly performed at certain intervals. However, there was no new plaque protrusion, and the procedure was completed (Fig. 2C). On diffusion-weighted imaging (DWI) the day after procedure, there was no procedure-related distal embolism. There was no deterioration of neurologic symptoms, but CTA showed an intra-stent filling defect.
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marked flexion was noted. As a stent, a PRECISE 9 mm × 40 mm (Cardinal Health, Inc., Dublin, OH, USA), which is flexible, was used. Based on our experience (Case 1), we selected dilatation with a balloon measuring 3 mm in diameter, smaller than balloons (3.5 mm) routinely used for predilatation, considering the risk of dilatation-related plaque rupture. A Spider FX 6-mm filter (Medtronic) was used, considering lesion passage. A MOMA ultra 9 Fr (Medtronic) was guided into the external carotid artery through the common carotid artery to confirm the state of flow stasis. Subsequently, it was connected to a 6 Fr sheath, which had been placed in the femoral vein, and allowed to pass through the lesion using a 0.014-inch CHIKAI (Asahi Intecc Co., Ltd., Nagoya, Japan) under flow reversal. However, the Spider FX filter did not follow the guidewire, and, initially, predilatation was performed using a Sterling 3 mm × 40 mm (Boston Scientific). Dilatation was performed for 10 seconds until a nominal pressure was obtained. The balloon opened without resistance, standing straight. This state was maintained for 20 seconds. The Spider FX passed through the lesion. After deploying it, a PRECISE 9 mm × 40 mm was inserted, and an Aviator 4 mm × 30 mm (Cardinal Health, Inc.) was guided, but there was a resistance at the residual stenotic site of the stent, making passage impossible. Cervical compression and rotation were attempted, but it was impossible to insert the Aviator beyond the residual stenotic site of the stent. To confirm the state, the proximal protection device was removed, and angiography was performed. The balloon may have interfered with a stent strut with

5 days after CAS. DSA revealed 40% restenosis (NASCET), suggesting plaque protrusion-related subacute thrombosis (SAT) (Fig. 2D). The degree of stenosis was advanced, but the thrombus was not mobile and localized in edge of vascular lumen. Anticoagulant therapy with heparin was started, and follow-up was strictly continued. After 1 week, additional examination showed the reduction of stenosis, and follow-up was conducted without additional treatment (Fig. 2E).

Case 2

An 83-year-old woman presented an asymptomatic acute phase ischemic lesion in left cerebral hemisphere by scheduled MRI as a follow-up study of medical checkup. Subsequent detailed examination showed marked stenosis of the left internal carotid artery, and treatment was planned. CTA revealed calcification along the outer vascular wall. The lumen was coral-shaped and irregular, but there was no marked calcification. T1-weighted BBMRs showed an iso- to high-intensity signal, and the plaque volume was expected to be large (Fig. 3). Due to a high-level lesion at the advanced age, CAS was planned, but crossing the lesion was considered difficult. The procedure was performed using the flow reversal method, in which a filter was combined with a proximal protection device. The most stenotic site of the lesion was filamentous, and the distal internal carotid artery diameter was 4.2 mm. The proximal common carotid artery diameter was 7.8 mm. The degree of stenosis was 95% (NASCET). The lesion length was approximately 3 cm. In the distal blood vessel,
inversion (Fig. 4B and 4C). Additional proximal protection was conducted. After flow reversal, a Gateway 2.5 mm × 12 mm (Stryker, Kalamazoo, MI, USA) was navigated to the residual stenotic site of the stent, and dilated to 8 atm (nominal: 6 atm). Subsequently, the Aviator was guided, but it was impossible to pass it. A 0.018-inch CHIKAI Black was newly inserted to the distal site of the lesion without changing the Spider FX’s position. A Jackal 4.5 mm × 30 mm, which was navigated using the above CHIKAI Black, was dilated to 10 atm (nominal: 8 atm) to achieve lesion dilation (Fig. 4D). DWI the day after procedure showed only a slightly punctiform high-signal intensity, and there were no neurologic sequelae. CTA was performed to confirm the state of stenting 5 days after CAS. There was no filling defect suggestive of SAT.
## Discussion

Based on the results of a randomized controlled trial (RCT), it was indicated that the periprocedural risk of acute-stage CAS for symptomatic lesions was higher than that of carotid endarterectomy (CEA). However, periprocedural minor stroke may occur in most patients.

A study reported that the results of tailored CAS in which devices were adequately selected for high-risk patients for CEA were similar to those of CEA, with recent advances in protection procedures. In particular, a proximal protection device, MOMA, has facilitated safe treatment for patients in whom CAS was previously considered to be difficult. In the two patients presented above, CAS was expected to be difficult based on the properties of the lesions, but we considered that complete protection under flow reversal was possible based on the preoperative assessment of an access route and collateral flow. Considering the patients’ wishes, we selected CAS. In the two patients, unexpected events occurred during procedure, requiring angiography under blockage discontinuation. However, the procedure could be completed in the absence of intraoperative distal embolism due to the use of a filter.

In Case 1, procedure was completed in the absence of problems, but SAT occurred after CAS. Although percutaneous transluminal angioplasty (PTA) or stent superimposition under strict protection is effective for SAT, we selected strict follow-up with an anticoagulant to avoid further compression of unstable plaque, considering that additional stent superimposition may reduce the lumen size. Fortunately, anticoagulant therapy led to an improvement. With respect to the pathogenesis of SAT, Ozaki et al. speculated that soft plaque rupture/protrusion might induce turbulence, leading to thrombus formation. In Case 1, SAT may have been related to plaque rupture on postdilatation. When performing postdilatation, there may have been no lateral extension of the blood vessel due to the calcified area of the lesion, overlapping with the stent and resulting in plaque rupture, as reported by Barrett et al. This patient had a narrow vascular diameter, and it was necessary to consider more careful postdilatation.

In Case 2, calcification was marked. Tsutsumi et al. reported that the calcification angle in the vascular circumference at the most stenotic site was associated with residual stenosis. In the present case, we considered CAS possible, assuming that the calcification angle may be localized. Based on our experience regarding Case 1, we speculated that a large volume of plaque might be pushed out by markedly dilating the stenotic site with the calcification along the outer vascular wall. As the balloon used for predilatation measured 3 mm in diameter, it rapidly dilated, standing straight. Based on this, we assumed that the vascular lumen might be maintained by autodilation of the PRECISE stent. There were no problems regarding stent delivery, but the lesion was hard, and the open-cell stent showed inversion; interference by a strut made it difficult to navigate a balloon for postdilatation. In the present case, in which it was difficult to navigate a device, a Gateway, which is the most easy-to-navigate balloon, was selected. Although the Gateway reduced the degree of stenosis, the Aviator did not follow the wire; therefore, a Jackal with another 0.018-inch wire was navigated for postdilatation.

Choices of EPDs have been increased, and CAS under adequate protection has markedly decreased the incidence of intraoperative distal embolism. However, issues of plaque protrusion and SAT after removing a protection device remain; a strategy to avoid plaque rupture is necessary. We have considered that the purpose of predilatation is to pass a device. Balloons measuring 3.5 mm in diameter have been basically selected, but approximately 3-mm dilatation is sufficient only for device delivery. On the other hand, for markedly calcified lesions, predilatation with a large-diameter balloon has generally been recommended due to elastic recoil or open-cell-stent strut protrusion. To avoid plaque rupture on predilatation in calcified lesions, it was necessary to devise the rate of dilatation, dilating pressure, and duration during which dilatation is maintained, but not to reduce the balloon size. For postdilatation, we have considered it necessary to adhere a stent to the vascular wall, but a recent study suggested that postdilatation is associated with thrombotic complications. There is a method in which predilatation is conducted using a large-diameter balloon on the assumption that postdilatation may be restricted or omitted for plaque protection. If the purpose of predilatation is not limited to device delivery, it may be necessary to select a purpose-matched balloon after understanding the properties of each product. A summary of major balloons for angioplasty is shown in Table 1. The prescribed pressure of an Aviator is higher than those of other balloons; it is appropriate for dilating hard lesions. However, an Aviator is not applied the coating for considering to navigate markedly stenotic lesions.

Among 0.014-inch wire products, a Gateway for intracranial PTA may be the most easy-to-navigate balloon. A COYOTE (Boston Scientific) also has a small entry...
profile (0.017 inch), facilitating guiding, as indicated for a Gateway. A SHIDEN (Kaneka Medix Corp.) is also matched to 0.014-inch wire, facilitating passage. It provides dilatation at a higher pressure in comparison with a COYOTE. Sterling and Jackal, which facilitate dilatation to a larger diameter, are easy to navigate even when adopting 0.014-inch wire, but their essential performance is achieved on guiding with 0.018-inch wire. The use of two-layered stents may overcome problems, such as distal embolism and SAT, after protection-device removal. However, currently, the well-devised selection of balloons for dilatation may be a strategy to avoid plaque rupture. To improve the results of CAS, the balloon size, dilatation time, and pressure should be established, considering the vascular diameter, degree of dilatation (for device delivery or postdilatation), hardness of lesions, and events (bradycardia, hypotension).

### Conclusion

When performing tailored CAS, it is important to select a balloon for dilatation, as indicated for EPD/stent selection. To utilize it in accordance with purposes, the properties of each product should be understood.

### Disclosure Statement

There is no conflict of interest regarding this article for the main author or coauthors.

### References


