

Carotid Artery Stenting Using Balloon-Expandable Coronary Stent: Intentional Use for Staged Angioplasty

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Objective: We report carotid artery stenting (CAS) using balloon-expandable coronary (BECo) stent. The materials in this study consist of 15 cases of high-grade stenosis in internal carotid artery (ICA) in which self-expanding carotid (SECa) stent was not utilized. There were two groups why BECo stent was used instead of SECa stent: alternative group and intentional group. The alternative group was subdivided into two groups: access difficulty of guiding catheter and access difficulty of SECa stent.

Case Presentation: The alternative group included 11 cases (access difficulty of guiding catheter in 10 and access difficulty of SECa stent in 1), and the intentional group included 4 cases. There were four cases using transbrachial approach. All the intentional group cases were the first stage of staged angioplasty (SAP). The second stage of SAP was PTA in two and SECa stent over the BECo stent in two. There was no complication related to CAS.

Conclusion: CAS using BECo stent is one of the choices for the first stage of SAP, if stent placement instead of PTA is required at the first stage. It is also the useful alternative for the patient having difficulty of SECa stent.

Keywords ▶ balloon-expandable stent, coronary stent, self-expanding stent, carotid stent, staged angioplasty

Introduction

One of the causes of cerebral infarction or stroke is internal carotid artery (ICA) stenosis. While medical treatment is the main approach taken for mild to moderate stenosis, severe cases may require revascularization. Carotid endarterectomy (CEA) has already been established as a revascularization procedure for severe stenosis of ICA.^{1,2)} In addition to this, carotid artery stenting (CAS) has gradually begun being used since the late 1990s.^{3,4)} When it was first introduced, the number of CAS cases was small as the procedure was limited only to patients that could not undergo

CEA. However, the scope of indication of CAS has since then widened owing to the development of various distal embolic protection devices (EPDs) and a variety of stents.⁵⁾ In the present report, we will provide a summary of a case that used a balloon-expandable coronary (BECo) stent for the CAS procedure.

Case Presentation

Between January 2014 and June 2020, we handled 220 CAS procedures. The present report concerns 15 of these cases, for which the BECo stent instead of self-expanding carotid (SECa) stent was used for CAS (**Table 1**).

The patients were started on treatments with Cilostazol 200 mg and Atorvastatin 10 mg at the time of the outpatient consultation.⁶⁾ In addition to the above, the patients were administered Clopidogrel 75 mg and Aspirin 100 mg 3 days prior to CAS. In accordance with the above, we made sure that emergency cases had been administered the three antiplatelet drugs prior to the CAS procedure. Aspirin use was continued up to 30 days after surgery while Cilostazol and Clopidogrel use was continued at least for 6 months after surgery. After this, the patients continued to receive either two drugs or one drug depending on their condition. The CAS procedures were performed under local anesthesia,

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Table 1 Patients profile

	Age (years)	Gender	Side	Symptomatic (days from last attack)	Reason	Sheath size [F]	EPD	Stent size (diameter [mm]*length [mm])	Remarks
1	63	M	Lt	No	ADGC	6	CGW	2.75*20	
2	63	M	Rt	No	ADGC	6	CGW	3.5*16	TB
3	72	F	Lt	No	ADGC	9	CGW	4*16	
4	77	M	Lt	No	ADGC	6	CGW	4*16	TB
5	72	M	Rt	No	ADGC	6	CGW	4*23	TB
6	66	M	Lt	No	ADGC	6	CGW	4*24	TB
7	94	M	Rt	Yes (6)	ADGC	6	CGW	3.5*23	
8	84	M	Lt	Yes (2)	ADGC	6	CGW	4*20	
9	78	M	Lt	Yes (15)	ADGC	8	CGW	3.5*18	
10	74	M	Lt	Yes (6)	ADGC	8	CGW	4*18	
11	89	F	Rt	Yes (0)	ADCaS	8	CGW	3*15	
12	82	M	Rt	Yes (5)	ICoS	9	Mo.Ma	3*22	PTA (3 weeks later)
13	80	M	Lt	Yes (90)	ICoS	9	Mo.Ma	3*15	CWS (3 weeks later)
14	72	M	Lt	Yes (2)	ICoS	8	Modified Mo.Ma	3*15	PTA (4 weeks later)
15	74	M	Rt	Yes (2)	ICoS	9	Mo.Ma	2.5*15	CWS (3 weeks later)

ADCaS: access difficulty of self-expanding carotid stent; ADGC: access difficulty of guiding catheter; CGW: Carotid Guardwire; CWS: Carotid Wallstent; EPD: embolic protection device; ICoS: intentional use of balloon-expandable coronary stent; F: female; Lt: left; M: male; Mo.Ma: Mo.Ma Ultra; Modified Mo.Ma: combination of 8F balloon introducing catheter into common carotid artery and CGW into external carotid artery; PTA: percutaneous transluminal angioplasty; Rt: right; TB: transbrachial approach

and after performing diagnostic imaging using a 4F sheath and a catheter, the sheath was replaced and a 9F Mo.Ma Ultra (Mo.Ma; Medtronic, Minneapolis, MN, USA) or 8F guiding balloon catheter was introduced to the common carotid artery (CCA) of the affected side. The distal EPD was guided to the distal part of the lesion, pre-dilation was performed using the percutaneous transluminal angioplasty (PTA) balloon, the SECa stent was deployed from healthy portion of ICA to healthy portion of CCA, and post-dilation was performed using another PTA balloon. The above are the standard procedures for CAS followed at our hospital. Our standard procedure is to cover CCA, so a stent with the diameter of 8 mm or larger is required. Such a stent requires more than 8F guiding catheter. BECo stent was used in the event of one of the following three reasons.

(1) Access difficulty of SECa stent (Alternative group 1)
Although same as regular CAS up to pre-dilatation, the BECo stent was used when the SECa stent did not pass through during stent deployment.

(2) Access difficulty of guiding catheter (Alternative group 2)

A 6F guiding catheter was introduced instead, due to difficulty of introducing the regular guiding catheter. Among these, there were cases in which a 6F guiding catheter was introduced transbrachially.

(3) Intentional use of BECo stent (Intentional group)

The procedure is performed from the beginning with the use of BECo stent in mind for those cases where use of the BECo stent is deemed more appropriate than the SECa stent. This approach is used when the target lesion is severe stenosis, and in many cases this requires proximal balloon protection using Mo.Ma. For this reason, 9F sheath placement is often performed.

As BECo stent use was intended for the intentional group even before the start of procedure, patients were asked to provide informed consent in advance. As BECo stent was not planned from the beginning in the alternative group, the patients were asked to give informed consent after the end of treatment. Our hospital has established clinical ethics committee in this year of 2020. CAS using BECo stent was submitted to the clinical ethics committee and was accepted (RinRin20-6). CAS using BECo stent is now permitted by clinical ethics committee in our hospital.

There were 13 male patients and 2 female patients. The patient ages ranged from 63 to 89 years old, and the mean age was 76 years old. There was 11 cases in the alternative group and 4 cases in the intentional group.

For all cases, the stent used was bare metal BECo stent. The diameter of the stent was 3.5 mm or more in 9 out of 11 cases in the alternative group, whereas 2.5 mm or 3 mm in all four cases in the intentional group.

EPD was used in all cases, Carotid Guardwire PS (Medtronic) was used in the alternative group, and Mo.Ma or an equivalent method was used in the intentional group.

All cases in the intentional group were undergoing staged angioplasty (SAP) for the first time, and PTA or SECa stent deployment was performed additionally later.

No complications were observed.

Representative case 1: Case 4 (Fig. 1)

A 77-year-old male patient with diabetes and renal dysfunction was found to have severe stenosis of the left ICA as a result of whole-body examination. He had also abdominal aortic dissection. We selected transbrachial approach due to aortic dissection. A 6F catheter was introduced to the left CCA from the right brachial artery, and a BECo stent was placed. The patient showed favorable postprocedural clinical course, and was discharged to return home during the first week after the procedure.

Representative case 2: Case 11 (Fig. 2)

An 89-year-old female patient had been admitted to our hospital 5 days earlier for mild cerebral infarction, and had been discharged 2 days earlier. On this occasion, the same patient was urgently transported to the hospital again after experiencing left-sided paralysis and dysarthria. Severe stenosis of the right ICA was thought to be the cause, and CAS was planned immediately after the patient arrived. The plan was to perform CAS using a SECa stent. After pre-dilatation using a 2.5 mm balloon, SECa stent was delivered but did not pass through the lesion. After the second pre-dilatation using the same 2.5 mm balloon, SECa stent did not pass through the lesion and the third pre-dilatation using new 3.0 mm balloon also failed the dilatation enough for SECa stent. So, BECo stent was finally selected and succeeded. The patient was discharged to return home 18 days after the CAS procedure.

Representative case 3: Case 12 (Fig. 3)

An 82-year-old man was urgently transported to the hospital with transient weakness of the left half of his body. MRI scans showed diffused high DWI signals in the right hemisphere of the brain, and MRA identified nuclear occlusion of the right ICA. Single photon emission CT showed decreased blood flow in the right hemisphere. On Day 5

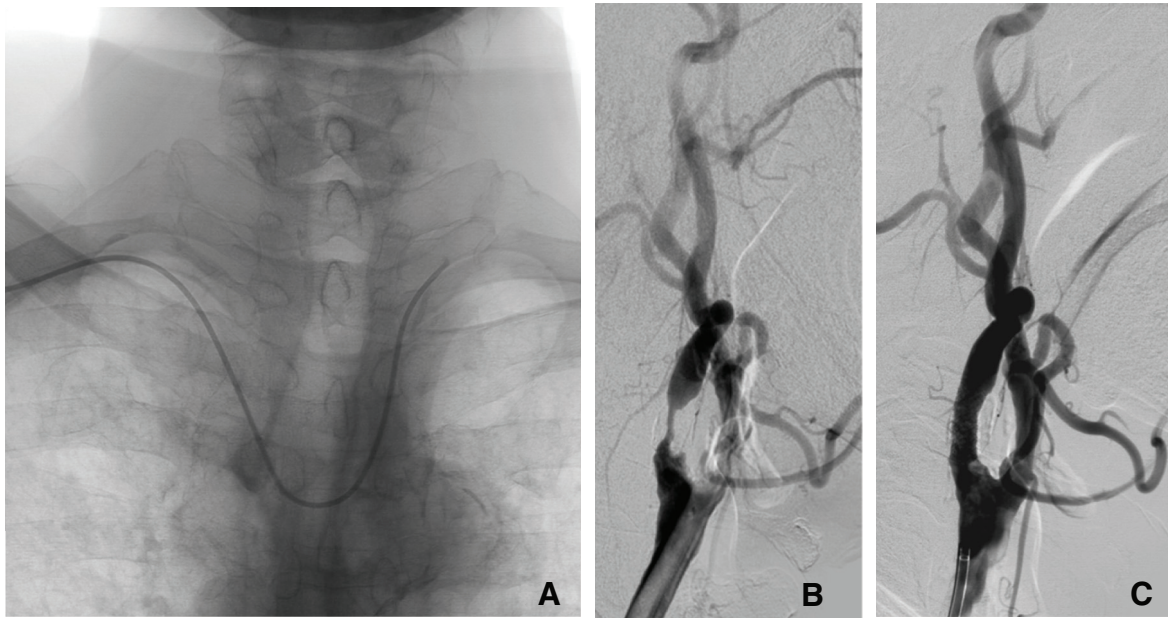


Fig. 1 Chest X-p (A) and left CCA angiograms, lateral views (B, C), during CAS of Case 4. (A) Guiding catheter is introduced into left CCA via right brachial artery. (B) Left CCA angiogram just prior to CAS showing tight stenosis of left internal carotid artery. (C) An angiogram just after CAS showing successful dilatation by BECo stent. BECo: balloon-expandable coronary; CAS: carotid artery stenting; CCA: common carotid artery



Fig. 2 Right CCA angiograms, lateral views, during CAS of Case 11. (A) A 3D DSA just prior to CAS showing tight stenosis of right ICA. (B) Right CCA angiogram just prior to CAS. (C) An angiogram during introduction of SECa stent system. The SECa stent did not overcome most stenotic portion (arrow). (D) An angiogram just after deployment of BECo stent showing good dilatation of ICA. BECo: balloon-expandable coronary; CAS: carotid artery stenting; CCA: common carotid artery; ICA: internal carotid artery; SECa: self-expanding carotid

after disease onset, we planned a CAS procedure for the patient with SAP in mind. The right ICA had severe stenosis, and the blood flow was delayed to parts of the ICA beyond the stenotic part. Although this was considered an indication for SAP, due to a risk of restenosis/occlusion by PTA, we planned for maintenance of minimum dilation

using a BECo stent. During the first treatment, a 3 mm stent was deployed at minimum dilation pressure, and we were able to keep the vessel diameter at 1.2 mm. Post-dilation was performed additionally 3 weeks later using a 4 mm balloon. The patient was discharged to return home one week after the second treatment.

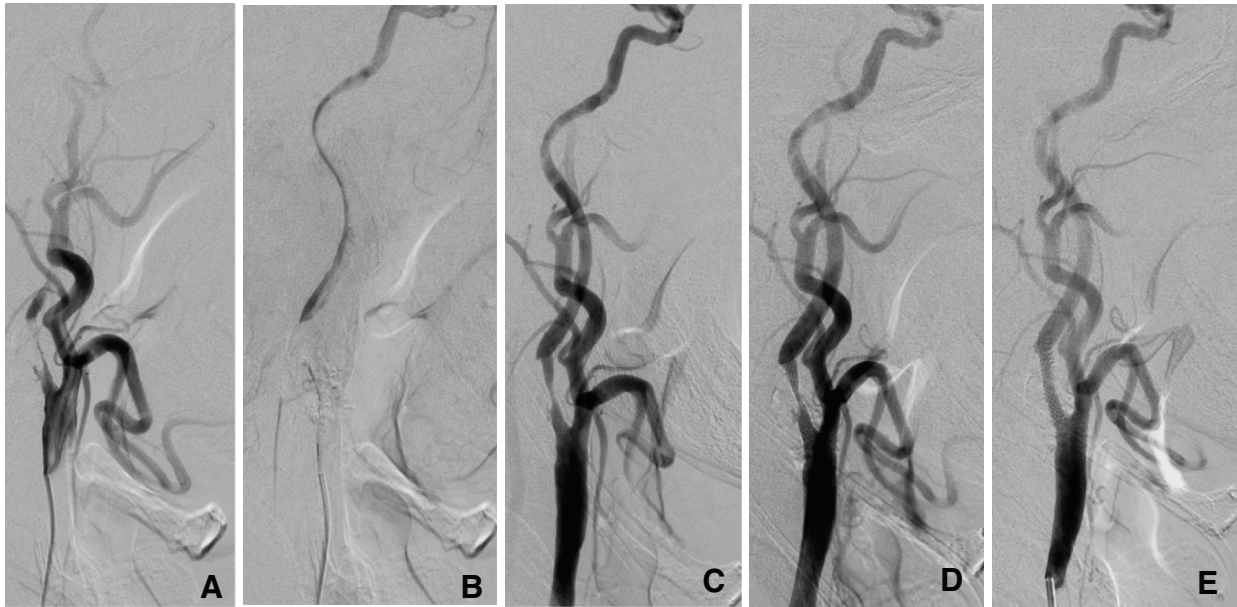


Fig. 3 Right CCA angiograms, lateral views, during CAS of Case 12. (A, B) Angiograms just prior to CAS. An early phase (A) showing tight stenosis of right ICA. A late phase (B) shows ICA is very restricted after stenosis. (C) An angiogram just after deployment of BECo stent showing slight dilatation of ICA. (D) An angiogram just prior to second

session, 21 day after the first session, showing no difference as to stenotic ratio of ICA. (E) An angiogram just after second session of PTA showing good dilatation of ICA. BECo: balloon-expandable coronary; CAS: carotid artery stenting; CCA: common carotid artery; ICA: internal carotid artery; PTA: percutaneous transluminal angioplasty

Representative case 4: Case 13 (Fig. 4)

An 80-year-old male patient who was unable to undergo MRI scans as he was undergoing artificial dialysis and wearing a pacemaker. Dysarthria had manifested 3 months earlier, and severe stenosis of the left ICA was indicated. As such, it was decided that the patient would undergo CAS. The patient's left ICA had suffered severe stenosis accompanied by an ulcer, and this was considered an indication for SAP. In the first treatment, the BECo stent was placed using Mo.Ma. The second treatment was performed 3 weeks later. The stent patency was favorable but there were no changes to the ulcer. The second treatment was a post-dilatation performed using a 4.5 mm balloon, but since there were no changes to the ulcer, a SECa stent was used additionally without post-dilatation. The patient was discharged to return home 1 week later.

Discussion

The standard stent used for CAS is the SECa stent, and many cases can be handled this way. However, in some situations, there may be difficulties using SECa stents, and BECo stents prove more useful. BECo stents can be more useful than SECa stents for CAS procedures for the following reasons: (1) The stent is thinner and can be introduced using a thinner guiding catheter, (2) The stent is thin and

flexible, which makes it suitable for use in bent lesions and highly constricted lesions, and (3) The stent does not expand autonomously because it is balloon-expandable. In our study, we used the BECo stent to take advantage of any of the above points (1)–(3).

First of all, with regard to access difficulty of guiding catheter, as ICA stenosis occurs frequently in elderly patients and often develop based on arteriosclerosis, many cases of ICA stenosis are accompanied by bent and meandering arteries. Introduction of SECa stent requires an 8F or larger guiding catheter in our strategy, but this can prove difficult at times. There would be several solutions in such a situation: 6F guiding sheath, snare technique, direct puncture of CCA, etc. A 6F guiding catheter is easiest among them. There is a marked difference in handling between 8F and 6F guiding catheters, and we often encounter scenarios in clinical practice where the 6F guiding catheter is capable of guidance in situations where the 8F guiding catheter fails. However, the 6F guiding catheter could not be located distal enough in such a situation; for example a 6F guiding catheter with sidewinder shape is inserted at the origin of CCA (e.g. Case4, Fig. 1A). The BECo stent is thinner than the SECa stent, and is compatible with a 6F guiding catheter under such a situation. Several kind of SECa stent is able to be delivered though 6F guiding catheter, but it requires more distal location of the guiding catheter. And its size is

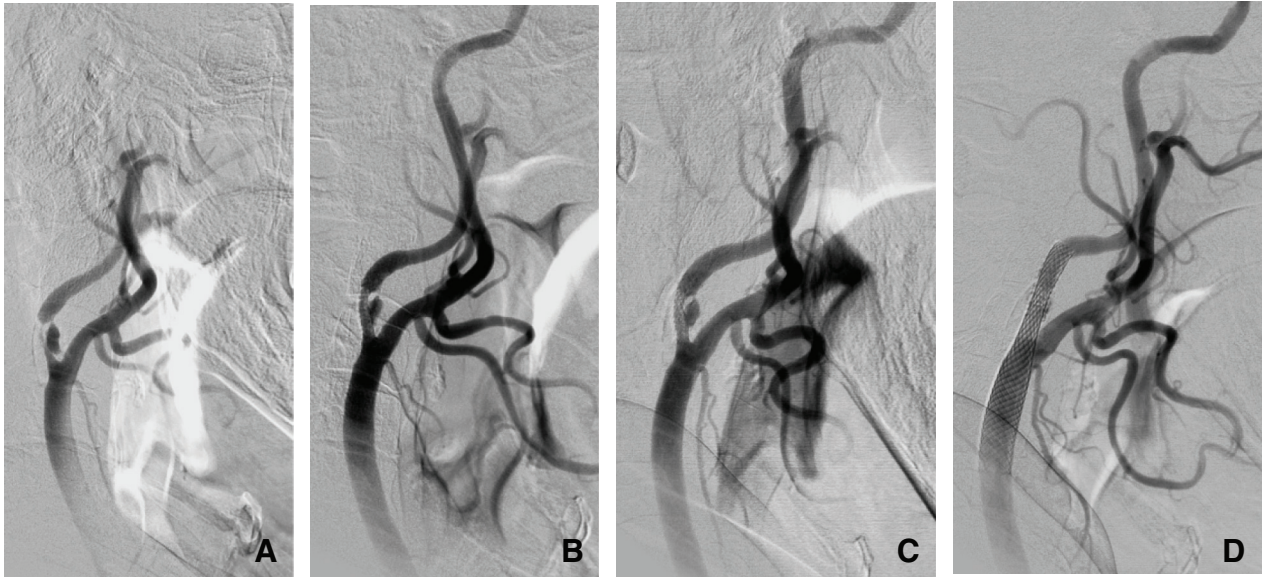


Fig. 4 Left CCA angiograms, lateral views, during CAS of Case 13. **(A)** An angiogram just prior to CAS showing tight stenosis and flow restriction of left ICA with marked ulceration. **(B)** An angiogram just after deployment of BECo stent showing slight dilatation of ICA and still visualized ulceration. **(C)** An angiogram just prior to second session, 21 day after the first session, showing no difference as to

stenotic ratio and ulceration of ICA. **(D)** An angiogram just after second session of SECa stent deployment showing good dilatation of ICA. Note that ulceration is not observed. BECo: balloon-expandable coronary; CAS: carotid artery stenting; CCA: common carotid artery; ICA: internal carotid artery; SECa: self-expanding carotid

up to 8 mm in diameter. Using 8 mm SECa stent, the proximal portion of the stent located in CCA will not adhere enough to CCA. On the other hand, BECo stent is relatively short, so the deployed portion is restricted only in ICA so that smaller size is acceptable for BECo stent. We are occasionally using BECo stents as a solution to these situations.

Next, we will discuss about access difficulty of SECa stent. Even if the 8F guiding catheter can be placed without any problems, at times the stent system fails to pass through the lesion. The stent system of SECa stents is harder and thicker than that of devices used for intracranial neurointervention. In contrast to this, the BECo stent is flexible and thin enough to be guided into the skull. For this reason, BECo stents may be able to pass through severe stenotic lesions that SECa stents would fail to pass. In addition to this, as the compatible guidewire is 0.014 inch in size for both SECa and BECo stent, the SECa stent has more difficulty following the guidewire. For example, when the external carotid artery (ECA) branches straight and the ICA branches with an acute angle, the SECa stent would run straight along with the ECA without following the guidewire, but even in these situations, the BECo stent would often follow the 0.014 inch guidewire along the curvature.

We utilized BECo stent alternatively in 5% (11/220). This ratio seems to be higher than that of other hospitals. The reasons would be as follows. We perform CAS in more than 90%

of surgical treatment of carotid artery stenosis. So, we tend to perform alternative CAS using BECo stent in the cases in which CEA would be performed in the other hospital.

The alternative group utilizes the property of “coronary” for small arteries, the intentional group takes advantage of the property of “balloon-expandable.”

Rather than performing CAS over a single stage for severe stenotic lesions of ICA with hemodynamic compromise, SAP involves a mild angioplasty procedure first to try and bring about mild improvements to the cerebral blood flow (CBF), followed by the final treatment by CAS to suppress the occurrence of hyperperfusion syndrome.⁷⁾ The Sundt classification mentions hemodynamic compromise as a high-risk factor for CEA,⁸⁾ and CAS, which can be combined with SAP, is expected to be effective. One should keep in mind here that the CBF does not increase or decrease proportionally with the diameter of the ICA.^{9,10)} Even if the vessel diameter is 80% of normal, the CBF remains normal rather than being 80% of normal because there is autoregulation of CBF. Although it depends on the development of collateral blood flow, CBF is said to be maintained up to 50%–70% stenosis.^{1,11,12)} Suppose a simple model of an ICA having a diameter of 6 mm, where the CBF remains normal up to 50% stenosis and decreases proportionally with the lumen at stenosis levels greater than 50%. This means that in this vessel, the CBF remains at 100% until 3 mm vessel

diameter, reduces to 67% at 2 mm diameter and to 33% at 1 mm diameter. If we consider a scenario of SAP being performed for a 90% stenosis (0.6 mm vessel diameter) of this vessel model, vessel dilation to 2 mm would realize 67% of normal perfusion and a dilation to 3 mm would return the blood flow to 100%, which would mean there is no sense to performing SAP. In other words, what is important for SAP is to keep vessel dilation to an extent that the blood flow does not return to 100%, and this would mean that vessel dilation must be by 2–3 mm. The prototype of SAP involves balloon angioplasty as the first treatment, but if vessel dilation is kept to this level by balloon angioplasty, there is possibility of restenosis or occlusion occurring. As such, there are situations where stent placement is required from first treatment. In these situations, if the first treatment is stent deployment and the second treatment is post-dilation, it would still technically be a SAP, but since all carotid stents that are commercially available presently are self-expanding stents, there would be a certain level of automatic vessel dilation after stent deployment even without performing post-dilation. This is not an ideal situation, because as mentioned above, even a vessel dilation of 1 mm can be critical for cases that require SAP. Use of a balloon-expandable stent in these situations allow the vessel diameter to be kept at the intended size because the stent would not dilate the vessel on its own. In fact, as shown by **Figs. 3 and 4**, when the BECo stent was used, there were no changes to the vessel diameter to which the stent is placed from the end of the first treatment to the beginning of the second treatment, which suggests that the BECo stent is an ideal device to be used for the first treatment in SAP. However, in practice, it is very rare that the vessel diameter being 1 mm larger than the intended size makes the situation critical, and there are situations where the extent of autonomous dilation seen using self-expanding stents are acceptable. In these situations, it would be acceptable to use a SECa stent.

The problem with using BECo stents is that its use would be regarded as “off-label use,” which means that patients and family members need to be given sufficient explanation about the procedure before it takes place. We performed CAS using BECo stent in this series in the doctor’s discretion with an informed consent to patient and/or his/her families. CAS using BECo stent is now permitted by clinical ethics committee in our hospital as mentioned previously. However, even in these situations, the value of the device is subject to assessment, so it is necessary to reach a facility consensus on its use. There are several other disadvantages in using BECo stent: (1) The maximum dilation

diameter of BECo stents is smaller than that of SECa stents. Although it varies by product, the maximum dilation diameter of BECo stents is 5.5 mm. However, as routine CAS procedures rarely perform a post-dilation greater than 5.5 mm, we believe that this dilation diameter is within the acceptable range. (2) Positioning of BECo stent is more difficult than that of SECa stent. (3) The radial force of BECo stent is weaker than that of SECa stent. (4) Stent fracture is reported in the literature in BECo stent. Considering disadvantages above, BECo stent can be alternative of SECa stent in several cases.

When considering SAP, it is necessary to be careful of the sizing of BECo stents. The size variation in BECo stents is actually the size variation in the balloons that have been mounted to the stent, and there is little variation in the size of the stent itself. For example, while the stents used for Case 3 increases from 3 mm to 5 mm in 0.5 mm increments, the size of the actual stents are the same. This is why, as exemplified in this study, post-dilation can be performed additionally. In Case 3, when a 3-mm stent was deployed at a minimum dilation pressure of 7 atm, it dilated by 1.2 mm. It is necessary to be careful because, although the idea is to keep dilation to the minimum in the first treatment stage of SAP, the balloon does not detach unless the minimum dilation pressure is applied. As with Case 3, if the intended final dilation diameter is smaller than the maximum dilation diameter of the stent deployed during the first treatment stage, it suffices to perform PTA alone as the second treatment. However, at times, a thin stent is chosen to realize the dilation of around 2 mm that is aimed for in the first treatment stage of SAP, and in these situations the maximum dilation diameter of the stent would be 3.5 mm, which is less than the intended dilation diameter. In these situations, the intended dilation diameter is achieved by guiding a SECa stent over the BECo stent and crushing the BECo stent by post-dilation. If the SECa stent is dilated at around 8–10 atm, which is the pressure normally used for post-dilation balloons, dilation can be achieved without any particular difference to routine dilation, and the BECo stent ultimately gets crushed. We have treated one patient (Case 15) this way, and did not observe any particular adverse effects. This kind of stent crush method is already reported in peripheral lesion,¹³⁾ but is not established in cervical lesion, so utilization of this technique should be restricted.

Balloon-expandable stents were often used before the development of SECa stents,⁴⁾ but there have been very few reports of its use since the advent of SECa stents. One of the reasons why balloon-expandable stents were replaced by

SECa stents is stent fracture.^{14–16} So, we must keep in mind it when using BECo stent for CAS. We have fortunately no cases of fracture of BECo stent for CAS. The age of utilized cases were relatively high so movement of neck would be not so frequent. There have been several reports of its intracranial use for middle cerebral artery (MCA) stenosis or ICA stenosis, including drug-eluting stents (DES).^{17–19} However, if these stents can be successfully used for MCA and intracranial ICA, it is clear that they can also be used for more proximal extracranial ICAs. As such, BECo stents should be considered as an option for CAS procedures. Meanwhile, there are not many reports of balloon-expandable stents being used for SAP either, but we believe it would be prudent to consider BECo stent as a first choice in situations where a stent needs to be placed while keeping the dilation diameter between 2 and 3 mm during the first treatment stage of SAP.

Conclusion

1. CAS procedures using BECo stents is one of the choices as the first treatment stage of staged angioplasty, if stent placement instead of PTA is required at the first stage.
2. BECo stents can become one of the rescue methods when standard CAS procedures cannot be performed due to problems related to accessibility of stent system.

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Disclosure Statement

We declare no conflicts of interest.

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