

## A balloon-supported embolism protection technique during vertebral/subclavian artery angioplasty stenting

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With high rates of morbidity and mortality, posterior circulation stroke accounts for 20% of ischemic strokes, and approximately 25% occurs in patients with stenosis in the vertebral and/or basilar arteries.<sup>[1]</sup> On the other hand, the risk of posterior circulation ischemic stroke reaches 30% in patients with symptomatic vertebral artery (VA) stenosis after 5 years.<sup>[2]</sup> Subclavian artery (SA) occlusion, although with a low prevalence in the general population,<sup>[3]</sup> is also an important cause of posterior circulation stroke.

Due to the relatively high morbidity rate as a result of surgical treatment, medical therapy used to be a mainstay of vertebrobasilar artery disease.<sup>[4]</sup> Since the 1990s, stent placement for extracranial VA stenosis has become a viable treatment. It was reported that stenting in extracranial VA stenosis appeared safe with low complication rates, which was also supported by the Vertebral Artery Ischemia Stenting Trial in 2017.<sup>[5]</sup>

Embolism protection devices (EPDs) are always used in the treatment of carotid stenosis. However, EPDs are not always an ideal option in regard to VA. For example, endovascular treatment of VA ostial (VAO) stenosis requires the proximal end of the stent protruding into the SA; hence, it is challenging to retrieve the EPDs. To further improve the safety and success rate of the endovascular treatment of symptomatic VA stenosis and SA occlusion, a balloon-supported embolism protection technique (BEPT) was developed.

This study was approved by the Committee for the Protection of Human Subjects at Zhongshan Hospital, Fudan University. Written informed consent was obtained from each patient included in the study. From March 2018 to July 2020, ten patients (11 procedures) who underwent BEPT in our center were enrolled in this study. The

patients' demographics, including sex, age, target lesion, etc and procedural data, were recorded.

For patients with VA stenosis, the femoral artery was punctured while under general anesthesia. Systemic heparinization was performed, and a 6-Fr 90 cm sheath (COOK, Bloomington, IN, USA) was placed at the SA. Then, a 5-Fr 55 cm sheath (COOK, Bloomington, IN, USA) was placed at the left axillary artery distal to the left VAO via left brachial access. With blood pressure elevation to 20% higher than that at baseline, a balloon catheter was introduced through the 6-Fr sheath into the SA proximal to the VAO that was then inflated to block the inflow. An angiogram through the 5-Fr sheath was performed to confirm the reverse flow from the VA. The VA was cannulated with a 0.014 inch Support BareWire (Abbott, Santa Clara, CA, USA) through the 5-Fr sheath. The stenosed VA was predilated (if necessary) and then stented with a balloon expandable stent. After deployment, the balloon of the stent was deflated for a few seconds and inflated again. The SA balloon was deflated to flush out the potential debris, followed by VA balloon deflation. Afterward, blood pressure was decreased to the baseline level [Figure 1A–E].

For patients with SA occlusion, femoral artery access was established while under local anesthesia. After systemic heparinization, a 7-Fr 90 cm sheath (COOK, Bloomington, IN, USA) was placed at the proximal stump of the SA. After passing the SA lesion, the ipsilateral branchial artery was punctured, and a 4-Fr sheath (COOK, Bloomington, IN, USA) was placed. The ipsilateral VA was cannulated, and a balloon catheter was placed at the VAO. After inflation of the VA balloon, the SA was predilated, and a balloon expandable stent was deployed across the SA occlusion. The SA balloon was deflated for a few seconds and then inflated again, as was the VA balloon. Finally,

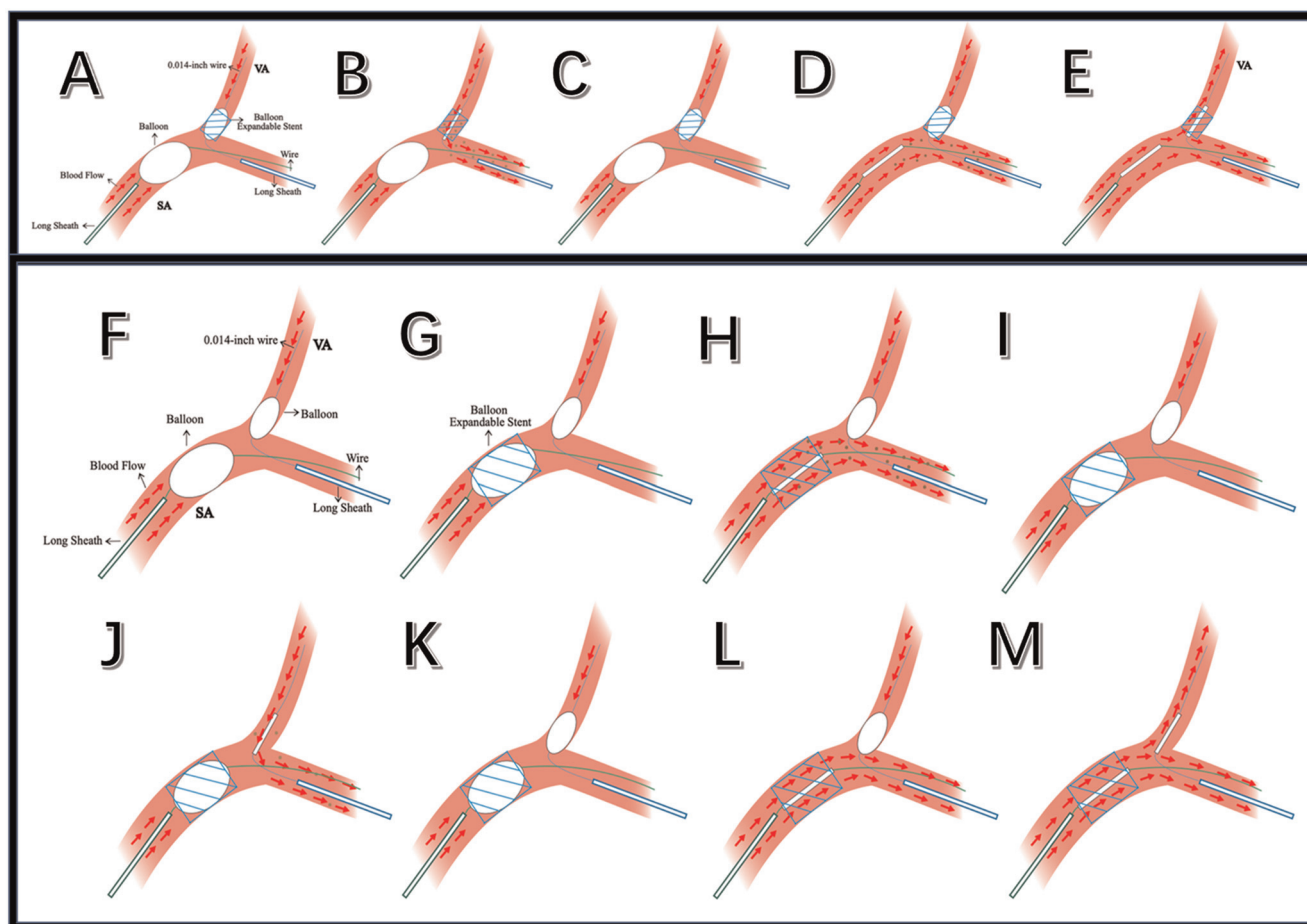
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**Figure 1:** The balloon inflation and deflation sequence in patients with VA stenosis (A–E) or SA occlusion (F–M). SA: Subclavian artery; VA: Vertebral artery.

the SA and VA balloons were deflated successively [Figure 1F–M].

Technique success was defined as successful performance of BEPT without intraoperative stroke. Perioperative complications such as death, cerebrovascular events, bleeding, pseudoaneurysm, and adverse events during the follow-up were recorded. In-stent restenosis was defined as luminal stenosis  $\geq 50\%$  located within the stent that was detected by computed tomographic angiography (CTA), ultrasound, and/or digital subtraction angiography (DSA).

Patients were routinely followed up at 3, 6, and 12 months after treatment and annually thereafter. Patients underwent CTA as the first-choice modality during the follow-up.

The quantitative data are shown as the mean  $\pm$  standard deviation or as the median with the interquartile range, depending on their distribution. Categorical variables are presented as frequencies and percentages. All tests were performed using PASW software, version 19 (IBM Corporation, Armonk, NY, USA).

This study comprised ten patients (six men and four women; mean age  $61.7 \pm 8.2$  years [range, 48–79 years]) who underwent BEPT in our center from March 2018 to July 2020. Of the ten patients, four patients had unilateral

VA stenosis (two left and two right), one had bilateral VA stenosis, four had left subclavian artery (LSA) occlusion, and one had left VA stenosis and LSA occlusion. One VA stenosis patient was admitted with bilateral posterior circulation stroke, which was confirmed by brain magnetic resonance imaging; two were admitted with transient ischemic attack, and two were admitted with unalleviated dizziness after medical treatment for  $>1$  month. Four patients with occluded SA were admitted with significant upper limb ischemia, and one was admitted with progressive dizziness  $<1$  month. The patient with left VA stenosis and LSA occlusion was admitted with upper limb ischemia and unalleviated dizziness. The baseline characteristics of the ten patients are shown in Supplementary Table 1, <http://links.lww.com/CM9/B146>.

BEPT was employed in all patients. No procedure-related complications were observed, and the characteristics of the intervention are shown in Supplementary Table 2, <http://links.lww.com/CM9/B147>. The mean follow-up was  $16.3 \pm 4.4$  months (range, 8–24 months). Significant relief of symptoms  $<1$  month was observed in all patients except for one patient with bilateral VA stenosis. The patient underwent endovascular treatment of the contralateral VA, and symptoms were relieved within the following month. During the follow-up period, no adverse

events occurred, and all VA and SA stents remained patent.

BEPT during VA/SA stenting was employed to prevent potential posterior circulation stroke. To date, there are no specialized EPDs or other well-established methods to prevent stroke during angioplasty stenting of symptomatic VA stenosis or SA occlusion. Although post-VA/SA intervention stroke was not common, the prevention of such an occurrence cannot be overemphasized, given that posterior circulation stroke was associated with catastrophic consequences.

The rationale of BEPT is to directly block the VA in patients with SA occlusion or to generate reverse blood flow from the VA by blocking the SA in patients with VA stenosis to prevent a potential debris embolism into the posterior circulation during the procedure. Two balloons were used to control the flow: one was just part of the balloon-expandable stent, and the other was an additional angioplasty balloon. The balloons at the SA and VA were defined as the SA balloon and VA balloon, respectively.

Current EPDs for carotid angioplasty stenting could be used for SA or VA stenting. EPD use had the following advantages over BEPT: (1) no flow clamping and (2) sufficient access in patients with VA stenosis. For VA stenting, however, the major concern for EPD use was the potential difficulty in filter retrieval because the lesion was typically at the origin of the VA, requiring the stent to be placed beyond the VA origin; hence, the stent protruded into the SA. Additionally, EPD retrieval difficulty could increase the risk of VA spasms. For flow clamping, in patients with SA occlusion, the VA had reverse flow at baseline; as a result, VA balloon occlusion did not reduce cerebral inflow; instead, it stopped reflux from the VA and enhanced cerebral perfusion. This occurrence is also observed in patients with VA stenosis, as long as the contralateral VA provided enough compensation. Even if the contralateral VA had concurrent severe stenosis or occlusion, short-term SA balloon clamping could be tolerable in patients with elevated systemic blood pressure under general anesthesia and healthy posterior intracranial communication. In addition, in patients with SA occlusion, the clamping VA balloon could offer a clear marker for the distal orientation of the SA stent, particularly in patients with tortuous LSA [Supplementary Figure 1, <http://links.lww.com/CM9/B145>].

The balloons' inflation and deflation sequence of BEPT worked as the clamping and declamping during carotid endarterectomy. In patients with symptomatic VA stenosis, the symptoms usually came from either an embolism due to an unstable plaque or cerebral hypoperfusion owing to concurrent contralateral VA stenosis. Accordingly, the target VA frequently still had an upward inflow rather than reflux. Therefore, inflation of the SA balloon to create reverse blood flow of the VA was always the first step. Then, the VA was cannulated, predilated (if necessary), and stented. While the SA balloon was kept inflated, the VA balloon was deflated for a few seconds and then inflated again. In the end, the SA and VA balloons

were deflated successively. In this way, potential debris were flushed away to the brachial artery throughout the procedure [Figure 1].

In patients with SA occlusion, once the SA lesion was successfully passed, the brachial artery was punctured, and a 4-Fr sheath was placed. The VA balloon was inflated prior to predilation of the SA lesion and remained inflated. Then, a balloon-expandable stent was deployed at the SA while its balloon was kept inflated. The VA balloon was deflated for a second and then inflated again. Finally, the SA and VA balloons were deflated successively [Figure 1].

Based on preliminary experience, BEPT appears to be useful for the endovascular treatment of symptomatic VA stenosis or SA occlusion to prevent posterior circulation embolisms. A longer-term study involving larger numbers of patients is required to verify the safety and efficacy of this method.

### Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published, and appropriate efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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### Conflicts of interest

None.

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