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"*Tailor-made*" *Total Cerebral Protection during Transcatheter Aortic Valve Implantation*

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Abstract

Transcatheter aortic valve implantation (TAVI) is an alternative treatment to surgical aortic valve replacement for treating severe aortic stenosis. With the increased use of TAVI, the risk of cerebrovascular complications during the procedure has become an emerging problem. We evaluated the safety and feasibility of our total cerebral protection methods using embolic protection devices (EPDs) for carotid artery stenting. We collected the results of cases in which the clinical team determined that our protection method was necessary among patients undergoing TAVI from May to October 2019 in our medical center. We applied this method to patients who had a potentially high risk of cerebrovascular events during the procedure. The methods of protection were selected comprehensively based on the potential of collateralization of brain perfusion when some arteries were blocked with a balloon, accessibility of the brain arteries, and the ability to cover the brain arteries with devices. Five patients, aged 83.8 ± 1.8 years, were included in the study. Technical success was achieved in all five patients. No cases showed any new neurological symptoms after the procedures; however, head MRI on the day after showed new ischemic lesions in three of five cases (60%). In all cases, emboli were found in the collected filters. This report demonstrates protection of the entire perfusion area in each case using EPDs in patients at high risk of intraoperative embolism. The methods we used were feasible and can potentially reduce cerebrovascular events following TAVI.

Keywords: transcatheter aortic valve implantation, cerebrovascular complications, cerebral embolic protection devices, embolic protection devices

Introduction

Transcatheter aortic valve implantation (TAVI) is a minimally invasive procedure in which an artificial valve is carried from the femoral artery to the patient's heart through a catheter and placed inside the diseased aortic valve without open-heart surgery. TAVI is an alternative to surgical aortic valve replacement in patients with both severe symptomatic aortic stenosis and surgical risk.[1–6] The use of TAVI has increased rapidly and triggered a paradigm shift in this field. However, one emerging problem is the risk of cerebrovascular complications during the procedure. It has also been reported that among patients who received TAVI, those who had a stroke had a worse prognosis than those who did not have a stroke.[7] Several randomized and/or registration studies have revealed that the incidence of stroke after TAVI is 2–6%.[5,6,8] Moreover, new silent cerebral micro-emboli are observed with MRI in up to 94% of all patients after TAVI.[9–11]

Cerebral embolic protection devices (CEPDs) used during TAVI were developed to deflect or filter embolic material from the cerebral circulation while maintaining normal cerebral perfusion.[12–15] Two types of CEPDs are now available. The one is the deflecting embolic materials to descending aorta include the TriGuard (Keystone Heart, Herzliya,

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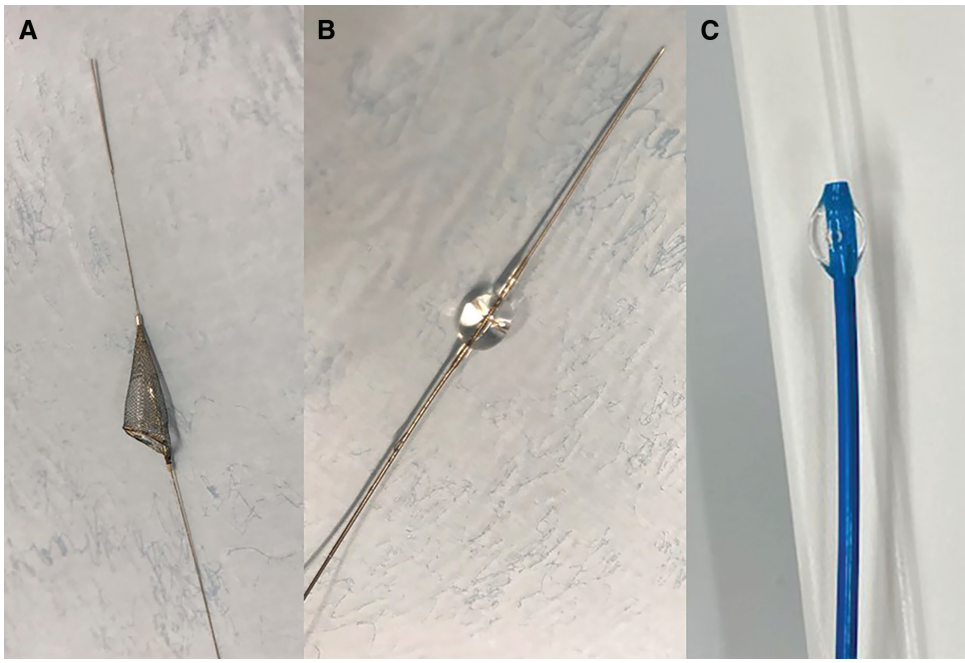


Fig. 1 Representative EPDs used for this study. (A) SpiderFX 6-mm system (Medtronic) for filter protection. (B) Carotid GUARDWIRE (Medtronic) for balloon protection. (C) 9Fr OPTIMO EPD (Tokai Medical Products) as the balloon guiding catheter.

Israel) and Embrella (Edwards Lifesciences, Irvine, CA, USA). They are positioned along the external curvature to protect the brachiocephalic artery, left common carotid, and left subclavian artery (only TriGuard) from embolism that occurred when performing TAVI. The other is the filter includes the Sentinel (Boston Scientific, Corp., Marlborough, MA, USA). The Sentinel with dual-filter system contains filters positioned in the brachiocephalic trunk and the left common carotid. The Sentinel is transferred via right radial artery and is positioned in the brachiocephalic trunk and the left common carotid as a filter. Some retrospective studies have shown that CEPDs reduce new brain lesions in the protected lobes of patients.[14,16] Hence, CEPDs have the potential to mitigate the risk of clinically evident cerebrovascular events.

Due to the delay of the introduction of CEPDs in Japan, there are few institutions to prevent cerebral emboli during TAVI even in patients with a high risk of embolisms, such as cases with severe calcification after aortic valve replacement and bicuspid valves.[17] We developed alternative methods of cerebral protection using embolic protection devices (EPDs) commonly used in carotid artery stenting (CAS). The use of EPDs is considered as an alternative until CEPDs become available in Japan (Fig. 1). After careful consideration of the access routes and collateral circulation, the methods were applied to protect the entire cerebral perfusion area in patients at high risk of embolism during TAVI, such as cases described above.

In this preliminary report, we evaluated the safety and feasibility of these protection methods and comment on the incidence of postprocedural lesions seen with diffusion-weighted imaging (DWI).

Materials and Methods

The study protocol was approved by the institutional review board of the Kokura Memorial Hospital Research Ethics Committee (Approval number: 20091401), and a waiver of consent was sought and obtained for this cohort study with no unique patient identifiers. The Clinical Research Review Committee of Kokura Memorial Hospital meets the requirements of the Certified Clinical Research Review Committee established by the Ministry of Health, Labor and Welfare in Japan. Reporting as an observational study guarantees the right to refuse in an opt-out format.

Patient selection

We collected the results of cases that our protection method was necessary among patients undergoing TAVI from May to October 2019. All the patients in this study were selected by the heart team. We informed the patients that the cerebral

embolism prevention procedure by using EPDs was off-label use and obtained their consent. The criteria for this protection were: the patients with artificial or bicuspid valve with severe calcification. The artificial valve is known to progress calcification faster and more severely than the native valve, and the bicuspid valve is reported to have a high risk for cerebral embolism.[17] Before treatment, all cases were discussed at our stroke and heart team meeting. In all cases, preoperative head and neck MRA and thoracoabdominal CTA were performed to evaluate the aorta and head and neck arteries. The methods of protection were selected comprehensively based on the potential of collateralization of brain perfusion when some arteries were blocked with a balloon, accessibility of the brain arteries, and the ability to cover the brain artery with the protection devices.

Assessment of vascular structure

We evaluated the presence of the anterior communicating artery, posterior communicating artery, and the vertebral artery on MRI (Fig. 2A). The diameters of the bilateral vertebral artery and brachiocephalic artery were measured. The vertebral artery diameters were measured at three points (proximal, medial, and distal) within 30 mm distal to the bilateral subclavian arteries on the coronal plane of the thoracoabdominal CTA, and the longest value was recorded. The brachiocephalic artery diameters were measured at three locations (proximal, medial, and distal) on the coronal plane of the thoracoabdominal CTA, and the longest value was recorded. To evaluate the shape of the aortic arch, the distance from the apex of the arch to the origin of the brachiocephalic artery was measured vertically. If the distance was within the diameter of the left common carotid artery, it was considered type 1; if it was one diameter but less than two diameters, it was type 2; and if it was two diameters or more, it was type 3 (Fig. 2B).[18]

Procedural technique

The deployment of EPDs and TAVI were performed under general anesthesia. Systemic heparinization to maintain an activated clotting time of 250 sec or more was done during the procedures. Because the right femoral artery was used as the approach route for TAVI, the remaining left femoral artery and the bilateral brachial arteries were used as the access route for the EPDs. Figure 1 shows the representative EPDs that we used in this study. For this reason, we had to protect four brain arteries from three access routes. We protected the left vertebral artery through the left brachial access route and the left carotid artery through the left femoral route. The main concern was protection of the right side. (1) If the diameter of the brachiocephalic artery was small enough to be covered with a balloon and adequate collateral flow could be achieved to the right brain through the anterior communicating artery or the right posterior communicating artery, temporary closure of the brachiocephalic artery with a balloon could protect the right brain without increasing the risk of low-perfusion ischemia. (2) If the diameter of the brachiocephalic artery was larger than the size of the balloon or poor collateralization of cerebral perfusion was warranted, the right carotid territory and right vertebral territory must be protected with filter device and balloon device separately. For this, the right common carotid artery required access from the right subclavian artery in a retrograde fashion or from left femoral approach in an anterograde fashion.

Placement of the EPDs was done by the stroke team, which was followed by valve replacement by the heart team. Postprocedural MRI and neurological evaluation were performed within 24 hours. All debris caught in the filter devices was evaluated.

Results

Of the 153 patients who underwent TAVI at our institution over the course of 6 months, we used EPDs to prevent embolisms in five patients (3.3%). All patients were male, and the average age was 83.8 (±1.8) years. Four patients had a history of surgical aortic valve replacement. Two patients had bicuspid valves (Table 1).

The devices used in each case are shown in Fig. 3, and the procedures for deployment of EPDs in all cases are described below.

Case 1

In this case, the diameter of the brachiocephalic artery was small enough (within 14 mm) to be temporarily occluded by a 9Fr CELLO Temporary Occlusion Balloon Catheter II (Fuji Systems Corporation, Tokyo, Japan). On MRA, we also confirmed the presence of the anterior communicating artery and bilateral vertebral arteries (Fig. 2A). The thoracoabdominal CTA image showed that the aortic arch[18] was type 3 (Fig. 2B). We placed the CELLO Temporary Occlusion Balloon Catheter II in the brachiocephalic artery via the right brachial artery. After inflation of the balloon within the brachiocephalic artery, angiography of the aorta showed that perfusion from the brachiocephalic artery was blocked (Fig. 2C). Also, angiography from the left internal carotid artery and the left

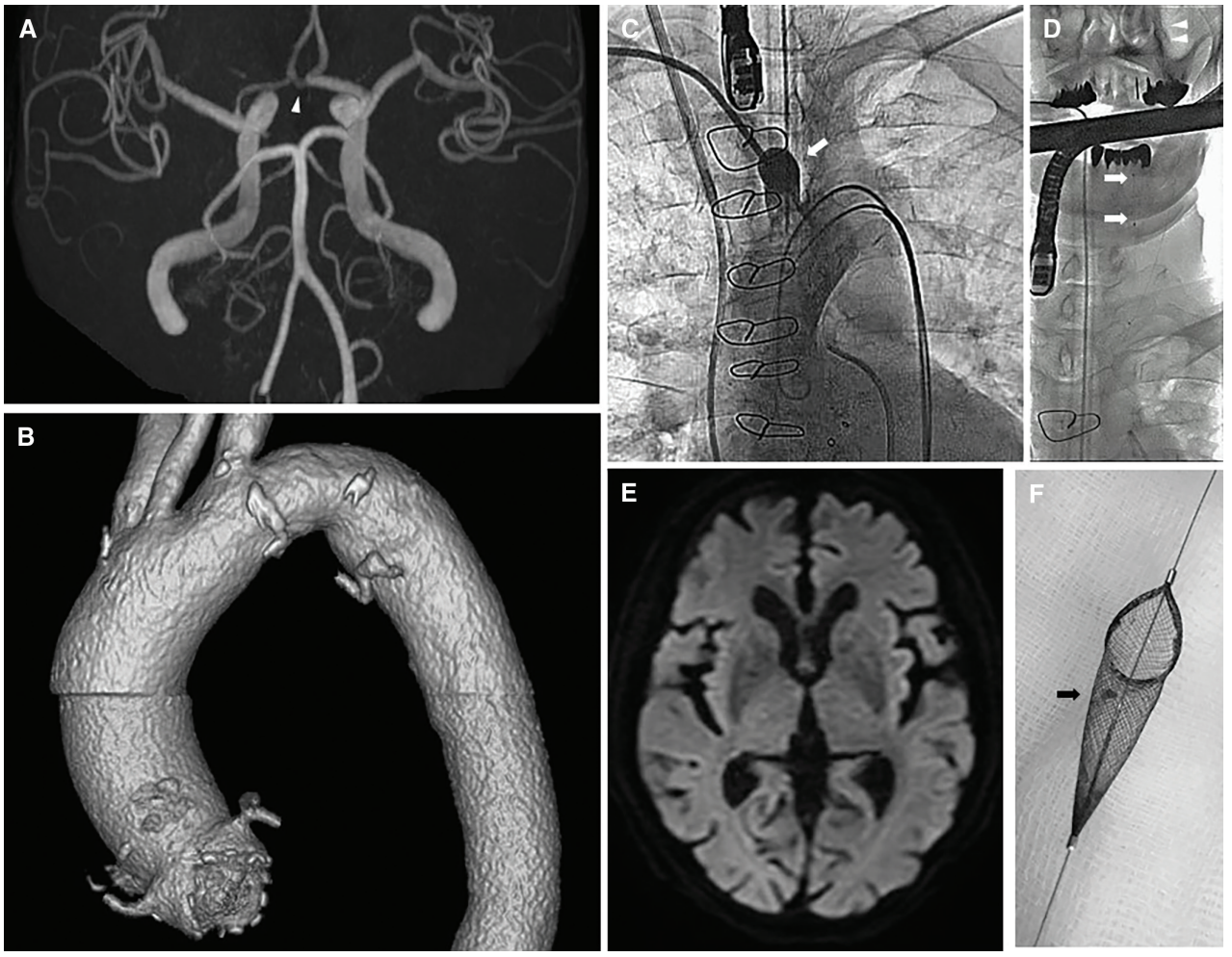


Fig. 2 Representative case: Case 1. The patient presented with exertional dyspnea and was diagnosed with recurrence of aortic valve stenosis 12 years after surgical valve replacement. Because the patient was at high risk of stroke during TAVI, we planned to perform total cerebral protection. (A) Preoperative head MRI showing the existence of the anterior communicating artery (white arrowhead) indicating that left-to-right blood flow could be expected when temporarily closing the brachiocephalic artery with a balloon. Existence of the bilateral vertebral arteries also indicates that the posterior circulation territory could be perfused through the left vertebral artery when the brachiocephalic artery is closed with a balloon. (B) A thoracoabdominal CTA image showing that the aortic arch is type 3,[18] and that the diameter of the brachiocephalic artery was small enough to be occluded by a 9Fr balloon guiding catheter (CELLO Temporary Occlusion Balloon Catheter II, Fuji Systems Corporation). (C) Frontal view of non-subtracted aortic angiography showing the inflated 9F CELLO Temporary Occlusion Balloon Catheter II blocking perfusion from the aorta to the brachiocephalic artery (white arrow). (D) Anteroposterior X-ray view showing the protection device placed in the left vertebral artery (Spider FX, Medtronic; double white arrows) via the left brachial artery. The left internal carotid artery was protected with a FilterWire EZ (Boston Scientific; double white arrowheads) navigated from the left femoral artery. (E) Diffusion-weighted MRI obtained the day after TAVI. No obvious new ischemic lesion was observed. (F) Embolic material was confirmed in the collected filter (black arrow).

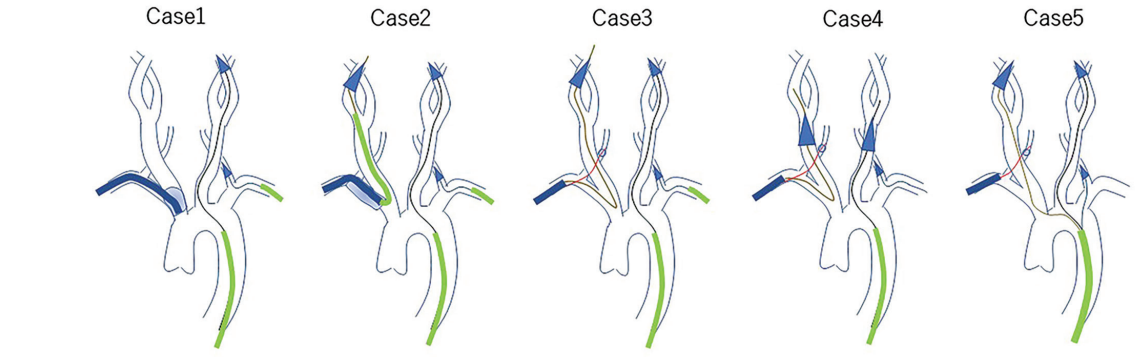
vertebral artery showed sufficient perfusion to the right hemisphere and reverse flow to the right vertebral artery. The left internal carotid artery was protected with a FilterWire EZ (Boston Scientific) that was placed through a guiding catheter via the left femoral route. The left vertebral artery was protected with a 5-mm Spider FX (Medtronic, Minneapolis, MN, USA) deployed via the left brachial route (Fig. 2D).

Case 2

In this case, the diameter of the brachiocephalic artery was within 14 mm; however, if we temporally occlude the brachiocephalic artery by the balloon of

Table 1 Clinical data and demographic characteristics of the patients

	Case 1	Case 2	Case 3	Case 4	Case 5
Patient characteristics and medical history					
Age	85	83	82	84	85
Sex	M	M	M	M	M
Hypertension	−	−	+	+	−
Diabetes mellitus	−	+	+	−	−
Previous stroke	−	−	−	−	+
Aortic valve replacement	+	−	+	+	+
Vascular structure and types of heart valves					
Anterior communicating artery	+	+	+	+	−
Posterior communicating artery (right/left)	−/−	−/+	−/−	−/−	−/−
Vertebral artery (right/left)	+/+	+/+	+/+	+/+	+/+
Internal carotid artery stenosis (right/left)	−/−	−/−	−/−	−/−	−/−
Vertebral artery stenosis (right/left)	−/−	−/−	=/=	−/−	−/−
Diameter of vertebral artery (mm; right/left)	3.75/4.71	3.98/4.44	4.67/4.50	4.89/4.79	2.71/4.24
Diameter of brachiocephalic artery (mm; right/left)	135	136	169	168	133
Aortic arch type	Type 3	Type 3	Type 1	Type 3	Type 1
Aortic valve	Tricuspid	Bicuspid	Bicuspid	Tricuspid	Tricuspid
Shaggy aorta: ascending aorta/aortic arch calcification	−	−	−	−	+



Rt.ICA	Balloon guiding catheter	Filter	Filter	Filter (Rt.CCA)	Filter
Rt.VA		Balloon guiding catheter	Occlusion balloon catheter	Occlusion balloon catheter	Occlusion balloon catheter
Lt.ICA	Filter	Filter	Filter	Filter (Lt.CCA)	Filter
Lt.VA	Filter	Filter	Filter	Filter	Filter

Fig. 3 Schema for protection during transcatheter aortic valve implantation. Schematic illustrations of the frontal aortogram showing the placement of the embolic protection devices in each case. They represent the position of the protection devices. The triangles indicate the filter protection devices, and the round shapes indicate balloons. The bold lines represent the catheters. CCA: common carotid artery, ICA: internal carotid artery, VA: vertebral artery.

the guiding catheter, perfusion in the right cerebral hemisphere must be insufficient due to the stenosis of the A1 segment of the right anterior cerebral artery. We planned that the right carotid artery would be protected using a filter protection device to keep the blood flow to the right cerebral hemisphere.

The balloon of a 9Fr OPTIMO EPD (Tokai Medical Products) induced via the right brachial artery was inflated in the right subclavian artery proximal to the orifice of the right vertebral artery to protect the right vertebral artery. We speculated that accessing the right carotid artery with filter devices through a guiding catheter would be difficult due to the tight angulation between the right subclavian artery and the right common carotid artery with severe atherosclerosis. To overcome these difficulties, a Simmonds type 5Fr catheter (SY3 125 cm, Gadelius Medical, Tokyo, Japan) was first used to obtain access to the right common carotid artery. A CHIKAI 14 was introduced into the right internal carotid artery through the 5Fr SY3. Then, an exchange was made to replace the 5Fr SY3 with a SpiderFX 6-mm system in the right internal carotid artery. The left internal carotid artery and left vertebral artery were protected, as in case 1.

Case 3

In this case, the diameter of the brachiocephalic artery was too large (at least 16 mm) to be protected with a 9Fr CELLO Temporary Occlusion Balloon Catheter II. Additionally, in the head MRA, the right anterior cerebral artery A1 segment was found to be hypoplastic, and a risk of low-perfusion ischemia was present due to temporary brachiocephalic artery occlusion by the balloon. For these reasons, we planned to place EPDs separately in both the internal carotid arteries and both vertebral arteries.

A 6Fr Destination 55 cm (Terumo, Tokyo, Japan) was placed in the right subclavian artery. As in case 2, we speculated that accessing the right carotid artery with filter devices through a guiding catheter would be difficult due to the tight angulation between the right subclavian artery and the right common carotid artery with severe atherosclerosis. We performed the same exchange maneuver to navigate a SpiderFX 6-mm system in the right internal carotid artery as presented in case 2. The right vertebral artery was protected with a Carotid GUARDWIRE (Medtronic) via the same 6Fr Destination. The left internal carotid artery and left vertebral artery were protected, as in case 1.

Case 4

In this case, because the potential ability of collateralization of the blood flow was the same as in case 3, we planned to place EPDs in each artery, as in case 3.

A 6 Fr Destination was placed in the right subclavian artery via the right brachial artery. A Simmonds type 5Fr SY3 was used to access the right common carotid artery through the Destination. As in cases 2 and 3, we tried the same exchange maneuver to navigate a SpiderFX 6-mm system in the right internal carotid artery but failed due to its tortuous anatomy. As a result, we put the SpiderFX-6mm system in the right common carotid artery. Also, because the navigation of a FilterWire EZ was hard to induce in the left internal carotid artery, the FilterWireEZ was deployed in the left common carotid artery. The left vertebral artery was protected, as in case 1.

Case 5

In this case, the diameter of the brachiocephalic artery was small enough (within 14 mm) to be temporarily occluded by a 9Fr CELLO Temporary Occlusion Balloon Catheter II. However, the anterior communicating artery and the posterior communicating artery were not confirmed on MRA, indicating low potential of collateral flow when we temporarily occluded the brachiocephalic artery with a balloon. For these reasons, we planned to place filter-type EPDs in the right carotid artery. After the experiences in the initial cases, we had difficulty with retrograde access from the right subclavian artery to the right common carotid artery, and we were also concerned that during the retrograde access the turning of the catheter tip of the Simmonds type 5Fr SY3 near the aortic valve would be mandatory and that this maneuver could increase the embolic risk, especially for patients with aortic valve stenosis. Therefore, an anterograde approach to the right carotid artery was planned through the same guiding catheter used to protect the left carotid artery, via the left femoral access route. The approach seemed feasible with the shape of the aortic arch. In addition, the left vertebral artery could be protected through the same guiding catheter if a 7Fr guiding sheath was used. The right vertebral artery was protected via the right brachial artery.

A 7Fr Flexor Shuttle Guide Sheath (COOK Medical, Bloomington, IN, USA) was inserted through the left femoral artery and placed in the descending aorta. From the 7Fr Flexor Shuttle Guiding Sheath, a 6-mm SpiderFX was deployed in the right internal carotid artery, a FilterWire EZ was deployed in the left internal carotid artery, and a 5-mm SpiderFX was deployed in the left vertebral artery. The right vertebral artery was protected with a Carotid Guardwire.

Postoperative course and pathology

Technical success was achieved in all five patients. For all cases, a postoperative MRI was performed

within 24 hr (Fig. 2E). No cases showed any new neurological symptoms. However, the head MRI on the day after the procedure showed new ischemic lesions in three of the five cases (60%; cases 2, 4, and 5). All ischemic lesions were small and were distributed in multiple vascular areas.

The filters caught debris in all patients (Fig. 2F). Histopathological findings included fibrous lesions and calcified pieces of tissue that contained some thrombi.

Discussion

In this report, we describe our initial experiences with our total brain protection methods using EPDs originally designed for CAS in patients who had a potentially high risk of cerebrovascular events during TAVI, such as cases with severe calcification after aortic valve replacement and bicuspid valves. In Japan, the introduction of CEPDs has been delayed, and it is difficult to provide generalized protection against cerebral embolism during TAVI. Variations in the protection methods were applied to each patient, mainly due to the anatomical differences in their vessels. All protection methods achieved technical success; however, asymptomatic acute cerebral infarctions were detected with MRI-DWI in three of the five patients.

Post-TAVI symptomatic cerebral infarction at our institution was 2.7% (from October 2013 to May 2019, 724 patients underwent TAVI and 20 had symptomatic cerebral infarction). This was the same as the reported incidence of post-TAVI symptomatic stroke of 2%–6%.[5,6,8] Reliable prevention of cerebral ischemia (stroke, transient ischemic attack, and silent ischemic lesions) is a key factor in the success of TAVI.[7,12] CEPDs used during TAVI are mesh filters used to prevent embolic material from entering the carotid arteries, either by deflecting or capturing emboli, and in theory, they could be used to prevent stroke after TAVI. The devices differ in pore size, location of deployment, and chemical composition. The Embrella Embolic Deflector (Edwards Lifesciences, Irvine, CA) includes two heparin-coated membranes with 100-μm pores. The Sentinel (Boston Scientific) is a dual filter with 140-μm pores. The two filters are placed into the brachiocephalic artery and the left common carotid artery. On the other hand, the TriGuard (Keystone Heart, Caesarea, Israel) is a nitinol-coated device with 250- to 130-μm pores that covers the left subclavian artery in addition to the brachiocephalic and left common carotid arteries.

After the introduction of CEPDs, several randomized studies and/or registries started using MRI to detect new silent cerebral ischemic lesions following TAVI. Although the use of CEPDs may theoretically reduce the occurrence of cerebral embolic lesions, it has not been associated with a reduced rate of new lesions as assessed with MRI. A recent meta-analysis including eight studies (of which five were randomized control studies) involving 1285 patients demonstrated that the use of CEPDs is not associated with the number of DWI lesions. The overall incidence of new lesions was 88%: 86% in patients with the use of CEPDs and 91% in patients without CEPDs.[19] In the study, the use of CEPDs was associated with a significantly smaller ischemic volume per lesion and a smaller total volume of lesions.

Although many factors lead to the ineffectiveness of CEPDs in decreasing new ischemic lesions, the effectiveness of the protection itself depends on the position and stability of the device. The Embrella and Sentinel do not protect the left vertebral artery, which accounts for up to 20% of total brain perfusion. In a study that observed the distribution of new ischemic lesions post-TAVI, 90% of the infarct volume was involved in the posterior circulation.[20] This implies the importance of protecting the left vertebral artery during TAVI. In a single-arm study, the Sentinel was deployed in the brachiocephalic trunk and left common carotid artery with an additional single filter in the left vertebral artery.[21] In the future, when CEPD is introduced, indications such as using EPDs for the left vertebral artery will be considered. In contrast to those two devices, the TriGuard covers the left subclavian artery to protect the left vertebral artery.[15,22,23] However, the use of TriGuard also did not show a decrease in the number of postprocedural new cerebral DWI lesions in a prospective, single-arm feasibility pilot study.[22] One of the reasons for this ineffectiveness could be the instability of devices, which was evident from the reports of irreversible dislocation of the devices. In the DEFLECT I study, which investigated the performance of the TriGuard device, the success rate of total protection was 80% among 37 patients.[23] This could be caused by the interaction between the TriGuard device and either the dilatation balloon or the valve delivery system.

In our series of total cerebral protection with EPDs, we found new DWI lesions in 60% of the patients. Due to the small number of cases in this report, we could not show a significant difference in cerebral infarction compared with the conventional TAVI. However, our protection system achieved the lower end of the range.[9–11] In terms of coverage by the devices, we were successful in setting up the total cerebral protection system with consideration of the anatomical features of each patient. In terms of the stability of protection, we experienced dislodgement of the protection devices in case 5. However, in

contrast to the TriGuard system, we could re-deploy the protection system easily. The concern with such a manipulation is an increase in the risk of embolic stroke. When manipulating multiple protection devices in the large pore guiding catheter, attention is needed not to interact with the other wires, which could easily result in dislodgement of the devices.

Knowledge of the cerebral circulation is essential for deciding the method of protection. We believe the cooperation and discussions between the stroke team and the heart team were key factors in the success of our "tailor-made" methods of protection. Moreover, the stroke team was familiar with EPDs, which were originally developed for protection during CAS. This multidisciplinary approach could lead to good outcomes of TAVI.

According to previous reports, the rate of immediate conversion to sternotomy was 2.1–3.2% during TAVI.[24,25] Annular rupture, device embolization, and pericardial tamponade were the most common reasons for conversion.[25] EPDs were prepared in the arteries to be protected before performing TAVI. Even if complications occur during TAVI, it was considered that the time loss is relatively short just by collecting the device.

One of the drawbacks of this protection method is the necessity to puncture the bilateral brachial arteries. These access routes can reduce the number of devices in the guiding catheter from the femoral artery, and as a result, can avoid interactions between multiple wires. However, brachial artery access was associated with a 10% complication rate and an increased risk of complications associated with increasing sheath size.[26] The development of smaller devices may mitigate the risk. Besides, this method takes a long time to prepare. It takes about 60–120 min to protect from the complication of procedures. Improved procedures and the introduction of new devices such as CEPD may significantly reduce preparation time.

This study has some limitations. The main limitation was the small number of patients, although it was designed as a feasibility pilot study. A second limitation was that the protection methods included off-label use of devices. However, the flexibility of protection devices can broaden the availability of protection methods.

Conclusions

This report demonstrates the protection of the entire perfusion area in each case using EPDs for CAS in patients with artificial or bicuspid valves with severe calcification at high risk of intraoperative embolism. Our methods are feasible and can potentially reduce cerebrovascular events following TAVI.

Conflicts of Interest Disclosure

All the authors have no conflict of interest.

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