An Embolic Deflection Device for Aortic Valve Interventions

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Objectives We describe initial human experience with a novel cerebral embolic protection device.

Background Cerebral emboli are the major cause of procedural stroke during percutaneous aortic valve interventions.

Methods With right radial artery access, the embolic protection device is advanced into the aortic arch. Once deployed a porous membrane shields the brachiocephalic trunk and the left carotid artery deflecting emboli away from the cerebral circulation. Embolic material is not contained or removed by the device. The device was used in 4 patients (mean age 90 years) with severe aortic stenosis undergoing aortic balloon valvuloplasty (n = 1) or transcatheter aortic valve implantation (n = 3).

Results Correct placement of the embolic protection device was achieved without difficulty in all patients. Continuous brachiocephalic and aortic pressure monitoring documented equal pressures without evidence of obstruction to cerebral perfusion. Additional procedural time due to the use of the device was 13 min (interquartile range: 12 to 16 min). There were no procedural complications. Pre-discharge cerebral magnetic resonance imaging found no new defects in any of 3 patients undergoing transcatheter aortic valve implantation and a new 5-mm acute cortical infarct in 1 asymptomatic patient after balloon valvuloplasty alone. No patient developed new neurological symptoms or clinical findings of stroke.

Conclusions Embolic protection during transcatheter aortic valve intervention seems feasible and might have the potential to reduce the risk of cerebral embolism and stroke. (J Am Coll Cardiol Intv 2010;3:1133–8) © 2010 by the American College of Cardiology Foundation
Transcatheter aortic valve interventions are associated with a risk of cerebral embolism and stroke. Atheroembolism might occur as a consequence of traumatic passage of wires and catheters around an atheromatous aortic arch (1). Calcific embolism might occur when the endothelial covering of a degenerated aortic valve is disrupted. Thromboembolism might occur during any interventional procedure. Aortic balloon valvuloplasty has been associated with a stroke rate of 1% to 4% (2–5). Transcatheter aortic valve implantation (TAVI) has been associated with a stroke rate of 1.9% to 4.2% (6,7).

Clinical stroke might represent one end of the spectrum of cerebral embolism. Recent studies suggest that subclinical cerebral embolic events are common (8–11). Cranial magnetic resonance imaging (cMRI) has demonstrated an incidence of new cerebral lesions in 22% of elderly high-risk patients undergoing diagnostic catheterization with crossing of the aortic valve (12), and recent studies found that 73% to 84% of patients undergoing TAVI had new cerebral lesions on cMRI (13,14). The clinical importance of asymptomatic new cMRI lesions is unknown but remains a concern (8,15–17).

Cerebral protection devices exist for carotid interventions (18) and might lead to a 60% reduction of brain embolism. Other devices are currently under investigation for surgical aortic valve replacement (19). We report our first-in-human experience with the Embrella Embolic Deflector (Embrella Cardiovascular, Inc., Wayne, Pennsylvania) device, which is designed to reduce the number of cerebral emboli in percutaneous aortic valve interventions.

**Methods**

**Patients.** The device was used in 4 patients with severe symptomatic aortic stenosis. All patients underwent balloon aortic valvuloplasty, and in 3 patients this was followed by TAVI. Pre- and post-procedural cMRI studies were performed. All patients were reviewed by a senior team of cardiologists and cardiac surgeons and had been declined for open aortic valve replacement due to age and comorbidities. Procedures were approved by the Department of Health and Welfare, Canada, and patients gave written informed consent for TAVI, balloon aortic valvuloplasty, and the use of the Embrella Embolic Deflector.

**Embrella Embolic Deflector.** The device is designed to cover the ostia of the brachiocephalic trunk (and its right carotid branch) and the left carotid artery originating directly from the transverse aorta, thereby deflecting emboli away from the cerebral circulation. Deflecting petals consist of a heparin-coated polyurethane membrane with 100-μm-sized pores. This membrane is mounted on a Nitinol frame, which itself is attached to a 110-cm-long, 0.035-inch (0.09 cm) Nitinol shaft (Fig. 1A). When deployed, the petals of the device extend over a length of 58 mm with a width of 25 mm. Three radiopaque markers help fluoroscopy-guided deployment: one at the outer point of each petal, and one on the distal shaft (Fig. 1B). The entire system can be delivered through a 6-F delivery sheath introduced from the right arm.

Patients were pre-treated with clopidogrel 600 mg and aspirin 325 mg at least 2 h before commencement of the procedure. In all patients, a standard 6-F sheath was placed in the right radial artery, after which heparin was given so as to achieve an activated clotting time above 300 ms. A 0.035-inch J-tipped guidewire was advanced to the aortic arch, over which was passed a 90-cm-long 6-F Shuttle SL sheath (Cook Medical, Stouffville, Ontario, Canada). After confirming integrity of the porous membrane of the device by visual inspection, the device was retracted into a loading tool, flushed,
and subsequently introduced into the sheath. With the tip of the sheath in the aortic arch, the device was slowly released under fluoroscopic guidance. Deployment of the 2 petals, each in the opposite direction (one toward the ascending aorta, the other toward the distal aortic arch), without deformation of the petals was assured (Fig. 2). The device was then retracted toward the sheath so that the distal marker on the sheath aligned with the radiopaque marker on the device shaft (Figs. 3A and 3B). In this position the device and sheath were pulled back to cover the ostia of the brachiocephalic trunk and the left common carotid artery, adjacent to the greater curvature of the aortic arch (Fig. 3C). Correct device position was confirmed if contrast injections through the delivery sheath led to temporary dye pooling over the brachiocephalic and left carotid ostia adjacent to the overlying device (Fig. 3C). Pressure was measured continuously from the side port of the delivery sheath (representing brachiocephalic pressure distal to the Embrella device) and from a pigtail in the ascending aorta (representing pressure proximal to the Embrella device) to ensure that cerebral perfusion was maintained at all time (Fig. 4).

Aortic valve intervention. Balloon valvuloplasty was performed with a balloon (Nucleus, NuMed, Inc., London, Ontario, Canada) with a nominal diameter equal to the echocardiographic diameter of the aortic annulus. The TAVI was performed in a standard manner with an Edwards-SAPIEN valve and Retroflex 3 delivery system (Edwards Lifescience, Inc., Irvine, California) (20). Percutaneous femoral access was used. A 14-F arterial sheath was used in the 1 patient undergoing valvuloplasty alone, a 24-F sheath (for the 26-mm Edwards-SAPIEN valve) was used in 2 patients, and a 22-F sheath (for the 23-mm Edwards-SAPIEN valve) was used in 1 patient. Percutaneous puncture with pre-closure of the femoral access site (ProGlide, Abbott Vascular, Abbott Park, Illinois) was routine. Rapid pacing during balloon valvuloplasty and TAVI was routine. General anesthesia with transesophageal echo-guidance was used in all TAVI procedures.

Statistics. All data are presented, given the small study population, as median and interquartile range (IQR). No group comparisons were performed.

Results

Baseline characteristics. Median age was 90 years (IQR: 87 to 92 years), 3 men and 1 woman. Risk factors for stroke
included peripheral vascular disease in 2, prior stroke in 3, hypertension in 3, and dyslipidemia in 2; none suffered diabetes or was a smoker, and none had severe ascending aorta calcification (21). Fluoroscopic calcification of the ascending aorta was graded mild in all, and fluoroscopic valvular calcification was graded 3+ (dense circumferential calcification) in 3 patients.

**Procedural outcome.** Correct placement of the Embrella Embolic Deflector with the deflecting petals covering the brachiocephalic and left carotid artery ostia was achieved in all 4 patients. The device seemed to be self-aligning within the transverse aorta and did not require manipulation beyond withdrawal to appose the outer curvature of the aortic arch. Contrast injection through the delivery sheath confirmed transient pooling in the arch vessels distal to the deflector. Radial and aortic monitoring showed no significant reduction in perfusion pressure and did not vary through the course of the procedure (Fig. 4).

Advancement of wires, pigtail catheters, valvuloplasty balloons, and the relatively bulky valve delivery system alongside the Embrella device was associated with minimal interaction without significant interference or dislodgement of the device (Fig. 5). In 1 case a wire and pigtail catheter seemed to pass behind the deflector. This was corrected by further withdrawing the deflector to improve apposition of the device. At the end of the valve procedures, the deflector was easily withdrawn into the delivery sheath and removed. Hemostasis was accomplished with a standard radial compression band. Device inspection showed no evidence of visible
damage or adherent thrombus or embolic material (Fig. 6). The total procedural time was 91.5 min (IQR: 83 to 97 min). Total time for insertion of the radial sheath, subsequent exchange for the Shuttle SL sheath and insertion, placement, and finally retrieval of the Embrella device was 13 min (IQR: 12 to 16 min). The Embrella deflector was deployed (“device in patient”) for a total of 42 min (IQR: 39 to 50 min).

Clinical outcome. Clinical assessment before hospital discharge did not reveal any new neurologic symptoms. No procedural complications occurred; in particular there were no complications related to insertion of the Embrella device. Pre-discharge cMRI showed a 5-mm acute cortical infarct in the right temporal lobe in the patient that underwent balloon aortic valvuloplasty alone. No patient undergoing TAVI had a new finding on pre-discharge cMRI.

Discussion

Our first-in-human experience demonstrates that cerebral embolic protection during transcatheter aortic valve interventions is feasible and can be accomplished without significantly interfering with or prolonging what is an already complex procedure.

The Embrella device has a number of advantageous features. It can be introduced easily from the radial artery with minimal interference with the course of the TAVI procedure. Protection during the entire course of a TAVI procedure is feasible. A single device provides protection for the right carotid and right vertebral branches of the brachiocephalic artery and the left carotid artery. In some patients, the device might also overlie the left subclavian ostium, providing protection for the left vertebral. Because the device is not positioned within the cerebral vessels, the risk of arterial spasm, injury, thrombosis, or transiently impaired cerebral perfusion seems minimal.

Cerebral emboli originating from the aortic valve and proximal aorta are likely the major mechanism of stroke in the setting of aortic valve intervention (12–14). Although stroke rates were relatively high in the early TAVI experience, the reported risk of stroke seems to be falling, perhaps due to the development of less traumatic valve delivery catheters (22,23), improved technique, and patient selection. Nevertheless, recent TAVI series continue to report a 1% to 4% risk of clinical stroke associated with significant morbidity and mortality (6,7,23).

Several lines of evidence suggest that reported stroke rates might underestimate the clinical importance of cerebral embolism. Early experience with transcranial Doppler and post-procedural cMRI (13,14) suggests that cerebral embolism is more the norm than the exception with TAVI, even in the absence of clinical deficits. Comparable experience with carotid stenting suggests microemboli play a role in memory loss and other neurocognitive syndromes (24,25).

Several studies suggest that cerebral protection during carotid interventions might reduce cerebral embolism and improve outcomes (18,26–28).

The current study documents use of the Embrella device in the setting of TAVI. However, other potential applications can be envisioned. Open heart or aortic surgery in the presence of aortic atheroma or intracardiac thrombus and mitral valvuloplasty or atrial appendage closure in the presence of left atrial thrombus might represent additional potential applications for cerebral protection.

Study limitations. Our experience can only be considered a proof of concept, given the small number of patients. Further studies will be required to document safety and efficacy. All our patients had type II aortic arch anatomy with the right subclavian and right carotid artery originating from the brachiocephalic trunk. The importance of variation in aortic arch anatomy is unknown, as is the applicability of this device in patients undergoing aortic valve interventions with different interventional devices and routes of access (e.g., transaxillary or transapical). The risk of device thrombosis in the presence of suboptimal anticoagulant and antiplatelet therapy and prolonged dwell time are unknown. An obvious concern is that this device does not trap emboli or allow for their removal. Instead emboli are deflected into the descending aorta. Although cerebral embolization might be reduced, embolization to the periphery, kidneys, and bowel might be correspondingly increased. Theoretically the clinical consequences are less with peripheral microembolism; however, this remains to be demonstrated.

Conclusions

The use of an aortic embolic deflector system seems feasible and is compatible with clinical aortic valvuloplasty and transcatheter valve implantation. The procedure seems safe with minimal additional time requirements. The Embrella...
Embolic Deflector is a promising device that might improve the outcomes of TAVI. Further studies are required to further assess safety and efficacy.

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REFERENCES


Key Words: cerebral embolism ■ cerebral protection ■ Embrella Embolic Deflector ■ percutaneous aortic valve replacement ■ stroke ■ TAVI.