Embrella embolic deflection device for cerebral protection during transcatheter aortic valve replacement

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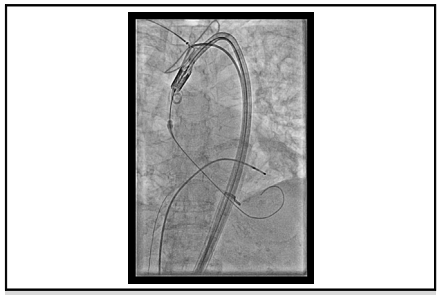
ABSTRACT

Aims: To compare the extent of cerebral ischemic injury after transcatheter aortic valve replacement (TAVR) with the use of an Embrella Embolic Deflector System versus unprotected TAVR.

Methods: Fifteen patients with severe symptomatic aortic stenosis underwent TAVR with use of the Embrella Embolic Deflector System for cerebral protection. Cerebral diffusion-weighted magnetic resonance imaging (DWI) was performed in all patients at day 4 after the procedure and images were retrospectively compared to 37 patients who had previously undergone TAVR without a protection device (TAVR-only group).

Results: Successful placement of the Embrella device was achieved in all patients. DWI revealed an increase in the number of ischemic lesions in the Embrella group compared with the TAVR-only group (9.0 vs 5.0, $P = .044$). The use of the Embrella device was however associated with a significant reduction in single-lesion volume: 9.7 μL [5.8, 18.4] versus 17.8 μL [9.5, 38.7] ($P < .001$). Moreover, total infarct volumes of more than 1000 μL were only seen in the TAVR-only group. More lesions occurred in the right side of the brain in the Embrella group, whereas in the TAVR-only group lesions were distributed equally between left and right. One patient in the TAVR-only group suffered from a transient ischemic attack. Postoperative evaluation was clinically uneventful in the Embrella group.

Conclusions: The use of the Embrella device during TAVR increased the number of cerebral ischemic lesions on postprocedural brain imaging. This increase in number was however accompanied by a significant reduction in single-lesion volume and the absence of large total infarct volumes. (J Thorac Cardiovasc Surg 2015;149:799-805)



Embrella Embolic Deflector System for brain protection during transcatheter aortic valve replacement.

Central Message

We evaluated the benefit of the Embrella Embolic Deflector System for cerebral protection during TAVR. The use of this device during TAVR increased the number of cerebral ischemic lesions on postprocedural brain imaging, although it significantly reduced lesion volume as compared to procedures performed without cerebral protection.

Author Perspective

TAVR is associated with a high incidence of new cerebral ischemic lesions. The use of an EPD may reduce the frequency of TAVR-related embolic events. The current study shows that the use of Embrella device for brain protection during TAVR is associated with a higher number of postprocedural cerebral DWI lesions. This increase in number is, however, accompanied by a significant reduction in lesion volume, the absence of large lesions, and a trend toward lower total infarct volume as compared to procedures without EPD usage. This reduction in infarct volumes may lower the risk of future neurocognitive impairment and needs further investigation.

See Editorial Commentary pages 806-7.

Supplemental material is available online.

Transcatheter aortic valve replacement (TAVR) is an accepted treatment option for inoperable or high-risk patients with severe aortic stenosis. Although good procedural success and favorable clinical outcomes have been reported,[1,2] issues remain regarding the relatively high complication rate. One of the most important drawbacks of TAVR is the risk of intraprocedural cerebral embolization causing brain injury. In high-risk surgical candidates, TAVR is associated with an approximately 2-fold increased incidence of stroke or transient ischemic attack (TIA) (5.5% vs 2.4%, $P = .04$) at 30 days as compared with surgical aortic valve replacement.[3] Moreover, new foci of restricted cerebral perfusion on diffusion-weighted magnetic resonance imaging (DWI) are reported in 58% to 91% of patients undergoing TAVR.[4-8] The clinical impact of these new, usually asymptomatic DWI lesions is still uncertain. However, epidemiologic studies have reported an association between asymptomatic cerebral

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Received for publication March 6, 2014; revisions received April 25, 2014; accepted for publication May 9, 2014; available ahead of print Nov 15, 2014.

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0022-5223/$36.00

http://dx.doi.org/10.1016/j.jtcvs.2014.05.097

Abbreviations and Acronyms

CABG = coronary artery bypass grafting
DWI = diffusion-weighted magnetic resonance imaging
EPD = embolic protection device
FLAIR = fluid-attenuated inversion recovery
IQR = interquartile range
MRI = magnetic resonance imaging
MSCT = multislice computed tomography
PCI = percutaneous coronary intervention
SD = standard deviation
TAVR = transcatheter aortic valve replacement
TE = echo time
TIA = transient ischemic attack
TR = repetition time

infarctions and frailty, decline in cognitive and physical functions, early development of dementia, and an increased risk of subsequent stroke.[9,10] In order to reduce the risk of these potentially devastating adverse events and in the light of progressive movement of TAVR toward younger lower-risk patients, significant research has focused on identifying the risk factors of TAVR-related cerebral embolization and methods for reducing the risk of cerebral ischemic injury. Embolic protection devices (EPDs) have already demonstrated their benefit in carotid artery interventions.[11] This would suggest that the application of a similar concept for brain protection could minimize the embolic burden during TAVR as well.

We report our experience with the Embrella Embolic Deflector System (Edwards Lifesciences Ltd, Irvine, Calif), an umbrella-like device, designed for percutaneous delivery to the aortic arch, for prevention of cerebral ischemic injury caused by emboli originating in the heart and aorta. Proof-of-concept was shown in a first-in-human study with 4 patients.[12] We aimed to evaluate the effectiveness of the Embrella device in diminishing the number of post-TAVR cerebral infarcts on DWI, in patients undergoing TAVR with the use of this protection device compared with TAVR procedures without the use of an EPD.

METHODS

Patients

Between September 2012 and July 2013, a total of 58 patients with symptomatic severe aortic stenosis underwent transfemoral TAVR in our institution. During this period, brain magnetic resonance imaging (MRI) had been performed routinely as part of post-TAVR standard care at our center in all patients without contraindications for MRI. From May 2013 onwards, the Embrella Embolic Deflector System was used during TAVR in 15 consecutive patients, without implementing eligibility requirements. These patients were retrospectively compared to the all 37 patients who had undergone TAVR in the previously mentioned period of time, without the use of an EPD and who underwent a postprocedural brain MRI (TAVR-only group). All patients were formally discussed in the heart team and considered inoperable or at high risk for surgical aortic valve replacement because of age, high logistic EuroSCORE, porcelain aorta, malignancy, frailty, or severe comorbidities. As the Embrella device is CE-marked in May 2010, commercially available and used in clinical practice in our series, and as cerebral DWI is part of postprocedural standard care at our center, institutional approval of waiver of informed consent was obtained.

Device and Procedure

The Embrella Embolic Deflector System is an umbrella-like device that consists of 2 polyurethane membranes mounted on a nitinol frame (Figure 1, *A*). This device is designed to deflect rather than to capture embolic particles. The polyurethane membrane has 100-μm pores to ensure proper blood circulation downstream of the device. The device can be folded, sheathed and loaded into a 6F long delivery sheath. It is attached to a 0.035-inch nitinol delivery cable and can be introduced in the horizontal segment of the aortic arch through either right radial, ulnar, or brachial arteries. Subsequently, the device consisting of 2 petals is released from the sheath, is pulled back, and is positioned at the outer curvature of the aortic arch, such that the petals cover the left carotid and the innominate arteries (Figure 1, *B*). In some patients, it will further cover (sometimes only partially) the left subclavian artery.

Before beginning the TAVR procedure, apposition of the filter frame in the aortic arch was confirmed with angiography to ensure protection of the cerebral vascular circulation.

Sitting at the outer curvature of the aortic arch, the device does not interfere with the TAVR procedure, and in particular there is no interference with the large valve delivery system (Figure 1, *C*). Once the procedure is terminated, the device is resheathed using the 6F delivery sheath.

TAVR was performed in all cases via the transfemoral approach with the Medtronic CoreValve system (CoreValve Revalving Technology, Medtronic, Minneapolis, Minn) or Edwards SAPIEN XT valve prosthesis (Edwards Lifesciences). Regardless of the prosthesis type, balloon aortic valvuloplasty was performed under rapid pacing to predilate the native aortic valve. The valve prostheses were subsequently deployed under rapid pacing (Edwards: 180 beats/min) or slow pacing (CoreValve: 120-140 beats/min).

Magnetic Resonance Imaging

Magnetic resonance imaging was performed within 4 days after TAVR, using a 3-Tesla system (Philips Medical Systems, Best, The Netherlands).

The imaging protocol included a diffusion-weighted single-shot spin echo echoplanar sequence (diffusion gradient *b* values of 0 and 1000 s/mm^2, repetition time [TR]: 3307 milliseconds, echo time [TE]: 68 milliseconds, 26 slices with a slice thickness of 4 mm, field of view: 230 mm, matrix: 256 $\times$ 205) and a turbo fluid-attenuated inversion recovery (FLAIR; TR/TE = 11,000/125 milliseconds). The acquisition time for the DWI sequences was 69 seconds.

All MRIs were assessed by 2 skilled observers blinded to neurologic status and procedure. Diffuse alterations in the DWI were not regarded as embolic types of lesions. Number of ischemic lesions, overall single-lesion volume, mean lesion volume per patient, total ischemic volume per patient, and location and vascular territories of all focal diffusion abnormalities (bright lesions on DWI) were documented.

Endpoints and Definitions

The primary endpoint was the number of new ischemic lesions on cerebral DWI. Our secondary endpoints included technical success, defined as successful delivery and retrieval of the Embrella Embolic Defector System, volume and distribution of postprocedural DWI lesions, and clinical outcomes including post-TAVR rates of TIA and stroke and periprocedural cerebrovascular events. According to the VARC-2 criteria, stroke is defined as an acute episode of focal or global neurologic dysfunction caused by the brain, spinal cord, or retinal vascular injury as a result of hemorrhage or infarction.[13] According to the same criteria, TIA is defined as a transient episode (<24 hours) of focal neurologic dysfunction caused by the brain, spinal cord, or retinal ischemia, without acute infarction. Silent brain