Protecting the aorta during transcatheter aortic valve replacement: Have we found the answer?

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See related article on pages 799-805.

Neurologic injury ranging from transient cognitive dysfunction to catastrophic permanent stroke constitutes the single main morbidity of cardiac surgery and largely affects modern transcatheter aortic valve replacement (TAVR).¹⁻³ Today, the incidence of cerebrovascular events after TAVR ranges from 3% to 7%.⁴ In the current report, Samim and colleagues⁵ have explored one of the novel embolic protection devices (EPDs) aimed at reducing these extremely pervasive complications that often carry surmountable challenges to the patient in terms of a reduction in functional status and quality of life, and the healthcare provider in the form of increased hospital stay and need for rehabilitation.

In this small series, the authors used an embolic deflection device (Embrella; Edwards Lifesciences Corporation, Irvine, Calif) in the aortic arch to minimize cerebral embolization during transfemoral TAVR. They found that the 15 consecutive patients in the intervention group exhibited a significantly higher number of new ischemic cerebral lesions in postoperative diffusion-weighted magnetic resonance imaging when compared retrospectively with 37 patients who underwent TAVR without any EPD in the same institution (a median of 9.0 lesions [4.0-12.0] in the Embrella group and 5.0 lesions [2.0-7.0] in the TAVR-only group, $P = .044$).

The authors are to be commended for the safe use of the EPD because implementation was successful in all cases, no vascular complications were observed, and the use of EPD did not interfere with the primary TAVR procedure. However, the patient series is small and carries an inherent selection bias because no inclusion/exclusion criteria

were defined, and within the small cohort 2 different transcatheter valves are used, potentially leading to inconsistency of operational variables. Although the results can be ruled as inconclusive, this pioneering work provides many contemporary topics for discussion on the arena of cerebral protection in modern cardiac interventions.

Cerebral injury in association with cardiac surgery is well documented, but still poorly understood. During traditional cardiac surgery using cardiopulmonary bypass, the bulk of damage is attributed to emboli dislodged from the ascending aorta on placement of and removal of the aortic crossclamp.^{6,7} Although these surgical manipulations are avoided in TAVR, temporary circulatory disruptions during balloon valvuloplasty or rapid ventricular pacing can lead to periods of suboptimal cerebral perfusion and ischemia.⁸ Moreover, balloon valvuloplasty and deployment of the transcatheter valve can expose valvular calcium deposits, tissue factor, and thrombin reserves from the diseased native valve into the circulation, triggering coagulation cascades leading to increased thrombogenicity.⁹ Although EPDs may be beneficial for athermanous debris, they do not address circulating tissue factors. To some, the introduction and deployment of an EPD into the aortic arch can seem counterintuitive; the operator is adding an intervention that requires a large sheath to be manipulated within one of the potentially most emboli-rich area of human vasculature.

EPDs can be categorized in 2 broad categories: (1) deflectors, which redirect emboli to the lower half of the body; and (2) retrieval devices, which capture and collect emboli for removal. Among the deflector devices, the Embrella Embolic Deflector (evaluated in the current study) and the TriGuard (Keystone Heart, Ltd, Caesarea, Israel) have the largest clinical experience to date. Both devices use a nitinol frame that is positioned across the origin of the great vessels in the aortic arch. The Embrella is inserted via the right radial or brachial approach, and the TriGuard is delivered via the femoral artery. In the current study with the Embrella device, although the system appeared to block the biggest particles from entering the cerebral circulation (reflected in reduced single lesion volume in the intervention group), the total number of lesions increased particularly on the right side of the brain, which may correspond to the placement of the EPD via the brachiocephalic artery.

The retrieval EPD system with the most clinical experience to date is the Montage Dual Filter (Claret Medical, Inc, Santa Rosa, Calif). The system uses right upper-extremity access to place 2 conical filters in the

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Disclosures: VHT is on the Advisory Board of St Jude Medical Inc, Edwards Lifesciences Corporation, Boston Scientific, and Abbott Medical and has performed research for Medtronic Inc, Edwards Lifesciences Corporation, St Jude Medical Inc, Direct Flow Medical Inc, and Sorin Medical. All other authors have nothing to disclose with regard to commercial support.

Received for publication Dec 3, 2014; accepted for publication Dec 3, 2014; available ahead of print Jan 13, 2015.

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J Thorac Cardiovasc Surg 2015;149:806-688
0022-5223/\$36.00

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<http://dx.doi.org/10.1016/j.jtcvs.2014.12.006>

brachiocephalic and left common carotid arteries. At the completion of the procedure, the filters are withdrawn and captured debris is removed. A first-in-man series of 40 patients was reported in 2012 showing that macroscopic debris was removed from 54% of patients treated; 1 minor stroke (at 30 days) and 2 major strokes (at 4 hours, at 27 days) were observed.¹⁰ Another retrieval system that has been shown to be safe and feasible for transaortic TAVR uses the new generation of the EMBOL-X intra-aortic filter (Edwards Lifesciences Corporation), with a large clinical trial forthcoming.¹¹ Although manipulation of the ascending aorta is required, the arch is avoided in this approach.

The multifactorial etiology of cerebral injury and the invasive manipulation required to place the devices may be the biggest challenges and areas requiring further study for the prevention of stroke during TAVR.

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