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EDITORIAL COMMENT

TAVR in Patients With Left Ventricular Thrombus

The Search for a More "Complete" Understanding*

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The presence of left ventricular (LV) thrombus has widely been considered an absolute contraindication for transcatheter aortic valve replacement (TAVR) (1). When valve replacement cannot be delayed, cerebral embolic protection devices have been utilized to mitigate stroke risk (2,3). The most widely studied devices offer incomplete cerebral embolic protection, covering the brachiocephalic trunk and left common carotid but leaving the left vertebral artery unprotected. Recently, the safety and feasibility of complete cerebral embolic protection during TAVR has been described (4,5). In this issue of *JACC: Case Reports*, it is in this context that Mierke et al. (6) highlight the first published case of complete cerebral artery protection during TAVR in a patient with an LV thrombus.

The patient described is a 56-year-old man with New York Heart Association functional class IV heart failure who presented with acute decompensation due to aortic stenosis and was found to have a large apical thrombus (46 × 36 mm) on transthoracic echocardiography. Following heart team discussion, the decision was made to perform TAVR with complete cerebral embolic protection. A SENTINEL Cerebral Protection System (Boston Scientific, Marlborough, Massachusetts) was placed at the brachiocephalic trunk and the left common carotid artery, and a FILTERWIRE EZ Embolic Protection System (Boston Scientific) was placed in the left vertebral artery. A 29-mm SAPIEN 3 bioprosthetic aortic valve (Edwards Lifesciences, Irvine, California) was implanted without complications. On follow-up, the patient had significant improvement in functional status and no cerebral or systemic embolic events.

We congratulate the authors on this challenging case. The procedural adeptness demonstrated by the team resulted in significant improvement in this patient's quality of life without imparting excess morbidity. In order to understand the implications of this novel reporting, a brief review of cerebral embolic protection during TAVR is warranted.

The proposed need for cerebral embolic protection during TAVR stems from 2 important discoveries: 1) cerebrovascular events after TAVR have a negative prognostic implication on functional status and survival; and 2) many patients develop silent cerebral lesions on magnetic resonance imaging following TAVR in the absence of clinical findings (7,8). Addressing this unmet need, several cerebral embolic protection devices were developed (Claret SENTINEL [Boston Scientific], TriGuard HDH [Keystone Heart, Tampa, Florida]) and investigated in randomized control trials (the CLEAN-TAVI trial in 2014, the DEFLECT-III trial in 2015, the MISTRAL-C trial in 2015, and the SENTINEL trial in 2017) (9–13). The devices in these early trials offered incomplete cerebral embolic protection, leaving the left vertebral artery unprotected or, as in the case of the TriGuard device,

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diverted emboli from the brain toward other organs. In 2018, Van Gils et al. (4) highlighted the safety and feasibility of complete cerebral embolic protection during TAVR in an 11-patient case series. In the Van Gils et al. (4) study, a standard dual-filter SENTINEL device was utilized to protect the brachiocephalic trunk and the left common carotid and a WIRION single-filter unit (Allium Medical, Caesarea, Israel) was deployed in the left vertebral artery via the left radial artery. More recently, Latib et al. (5) reported promising outcomes in a first-in-human case series of 20 patients undergoing TAVR with the Emblok embolic protection system (Innovative Cardiovascular Solutions, Grand Rapids, Michigan). The Emblok system provides complete cerebral and systemic embolic protection via positioning in the aortic arch and covers all 3 epiaortic vessels.

In addition to complete cerebral embolic protection, Mierke et al. (6) utilized intraprocedural imaging, valve selection, and procedural technique to mitigate stroke risk for their patient. Intraprocedurally, transesophageal echocardiography was used to check wire positioning and distance away from the LV thrombus. The SAPIEN valve and delivery system were chosen because they allow for implantation without wire contact against the LV apex. This is in contrast to the Medtronic CoreValve (Medtronic, Minneapolis, Minnesota) and Boston Scientific ACURATE and LOTUS valves, which require wire apposition against the apex during implantation. Last, procedural techniques that independently increase stroke risk such as balloon valvuloplasty with pre-dilation, rapid pacing, and device recapture and repositioning were minimized or avoided altogether.

Mierke et al. (6) have also shed light on several important questions that require further investigation moving forward. First, the optimal anticoagulation strategy for patients with LV thrombus requiring TAVR remains unclear. Researchers must focus on identifying the most efficacious modalities, levels, and durations of anticoagulation during the preoperative, intraprocedural, and postoperative stages for optimal thrombus dissolution. Second, with embolic protection device selection rapidly evolving, it remains unclear whether certain devices or protection strategies are superior to others. Indeed, the approach in this case report would not have protected the patient from mesenteric or limb ischemia. Total body embolic protection devices are in the infancy of development, but early outcomes and feasibility data have been promising. Finally, it remains yet to be seen whether or not embolic protection devices will become a permanent component of the TAVR procedural zeitgeist moving forward. The uptake of embolic protection devices by operators may remain low due to not only to the complicated technical skill required to deploy them, but also the low reimbursement tied to their utilization. In the absence of strong clinical trial-driven evidence showing benefit with these devices, such barriers to utilization may remain difficult to overcome.

This case simultaneously highlights the challenging decisions clinicians face on a daily basis and also the remarkable growth that transcatheter interventions and interventionalists have experienced over the last decade. Although the presence of an LV thrombus was previously deemed an absolute contraindication to TAVR, advances in transcatheter valve technology, procedural skill, and embolic protection devices have allowed for valve replacement to be carried out safely in these critically ill patients when necessary. A complete grasp of thromboembolic risk mitigation during TAVR remains years away; however, this case by Mierke et al. (6) serves as an important piece in the grander puzzle of understanding.

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