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Cerebral Embolism Following Transcatheter Aortic Valve Implantation

Comparison of Transfemoral and Transapical Approaches

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Objectives The objective of this study was to compare the incidence of cerebral embolism (CE) as evaluated by diffusion-weighted magnetic resonance imaging (DW-MRI) following transapical (TA) transcatheter aortic valve implantation (TAVI) versus transfemoral (TF) TAVI.

Background The TA-TAVI approach avoids both the manipulation of large catheters in the aortic arch/ascending aorta and the retrograde crossing of the aortic valve, and this avoidance might lead to a lower rate of CE.

Methods This was a prospective multicenter study including 60 patients who underwent cerebral DW-MRI the day before and within the 6 days following TAVI (TF approach: 29 patients; TA approach: 31 patients). Neurologic and cognitive function assessments were performed at DW-MRI time points.

Results The TAVI procedure was performed with the Edwards valve and was successful in all cases but one (98%). A total of 41 patients (68%) had 251 new cerebral ischemic lesions at the DW-MRI performed 4 ± 1 days after the procedure, 19 patients in the TF group (66%) and 22 patients in the TA group (71%; $p = 0.78$). Most patients (76%) with new ischemic lesions had multiple lesions (median number of lesions per patient: 3, range 1 to 31). There were no differences in lesion number and size between the TF and TA groups. No baseline or procedural factors were found to be predictors of new ischemic lesions. The occurrence of CE was not associated with a measurable impairment in cognitive function, but 2 patients (3.3%) had a clinically apparent stroke within the 24 h following the procedure (1 patient in each group).

Conclusions TAVI is associated with a high rate of silent cerebral ischemic lesions as evaluated by DW-MRI, with no differences between the TF and TA approaches. These results provide important novel insight into the mechanisms of CE associated with TAVI and support the need for further research to both reduce the incidence of CE during these procedures and better determine their clinical relevance. (J Am Coll Cardiol 2011;57:18–28) © 2011 by the American College of Cardiology Foundation

Transcatheter aortic valve implantation (TAVI) has become an alternative treatment for those patients with symptomatic severe aortic stenosis considered at very high or prohibitive surgical risk (1). Transfemoral (TF) TAVI is the most commonly used approach, and it involves advancing a large catheter (18- to 24-F) containing the valve through the aortic arch and retrogradely crossing a severely diseased native aortic valve, both well-known potential risk factors for cerebral embolism (2–5). The risk of cerebral embolism during TF-TAVI might be even higher if we take into consideration that the population undergoing TAVI nowadays consists of very old patients with a high prevalence of atherosclerotic disease (6,7). Kahlert et al. (8) and Ghanem et al. (9) have recently shown that TF-TAVI was associated with >70% incidence of new cerebral lesions following the procedure as evaluated by diffusion-weighted magnetic res-

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onance imaging (DW-MRI). Transapical (TA) TAVI has become an alternative to the TF approach in patients with nonappropriate (i.e., too small, diseased, and/or severely calcified) iliofemoral arteries (1). The TA approach consists of directly puncturing the ventricular apex through a small left lateral thoracotomy and then advancing the new valve through a catheter inserted through the ventricular apex and located at the mid portion of the left ventricular cavity. It has been hypothesized that by avoiding both the manipulation of large catheters in the ascending aorta/aortic arch and the retrograde crossing of the native aortic valve, TA-TAVI might be associated with a lower rate of cerebral embolism. Also, comparing the incidence of cerebral ischemia of TA and TF approaches might provide important new insights regarding the mechanisms of cerebral embolism associated with TAVI procedures. However, no data exist on the incidence of cerebral embolism associated with TA-TAVI as evaluated by DW-MRI. The objectives of this prospective multicenter study were to: 1) compare TA-TAVI versus TF-TAVI with respect to the incidence of cerebral embolism as evaluated by DW-MRI; and 2) determine the predictive factors associated with cerebral embolism during the TAVI procedures.

Abbreviations and Acronyms

CT = computed tomography
DW = diffusion weighted
MMSE = Mini Mental State Examination
MRI = magnetic resonance imaging
NIHSS = National Institutes of Health Stroke Scale
TA = transapical
TAVI = transcatheter aortic valve implantation
TEE = transesophageal echocardiography
TF = transfemoral

Methods

Patients. Patients who underwent TAVI under the Canadian compassionate clinical use program at the Quebec Heart & Lung Institute, Quebec City, Quebec, Canada (January 2008 to February 2010) and St. Paul's Hospital, Vancouver, British Columbia, Canada (August 2008 to December 2009) were screened for inclusion in the study. Patients with the diagnosis of symptomatic severe aortic stenosis considered nonoperable or very high surgical risk candidates were evaluated by a multidisciplinary team composed of interventional cardiologists and cardiac surgeons to determine TAVI eligibility. Depending on the size, disease, and degree of calcification of iliofemoral arteries as evaluated by aorto-iliofemoral angiography and/or computed tomography (CT), the patients were selected for the TF or TA approach (10). Patients were excluded if they had any contraindication to undergo an MRI study or if they were unable to have an MRI performed within 24 h prior to TAVI. The protocol was approved by the local ethics committee of each center, and all patients provided written informed consent to participate in the study.

Transesophageal echocardiography (TEE) and CT. All patients underwent TEE before and/or during the TAVI procedure, and the presence of aortic plaques ≥4 mm in the ascending aorta/aortic arch was recorded. In patients who underwent thoracic CT without contrast injection before the procedure, the CT images of the aortic valve were analyzed offline in the cardiac CT core lab of the Quebec Heart & Lung Institute by experienced technicians blinded to clinical data and supervised by a cardiologist (E.L.). Briefly, a prospective echocardiogram (ECG)-gated scan protocol was performed during a single breath hold at end-diastole (70% to 80% RR interval) to cover the entire cardiac silhouette in the axial plane (64 × 0.6 mm collimation, reconstruction increment 1.5 mm, rotation time 0.33 s) by noncontrast multidetector CT (Somatom Definition, Siemens AG, Erlangen, Germany). Three-dimensional multiplanar reconstruction was performed to examine the aortic valve in-plane (2-mm slice thickness, 2 to 5 slices per valve for full coverage) and precisely measure leaflet calcifications defined as pixels >130 Hounsfield units (TeraRecon, San Mateo, California). Aortic valve leaflet calcium volumes (mm^3) were determined using the modified Simpson technique (11,12).

TAVI procedures. The TAVI procedures have been extensively detailed in previous studies (10). All procedures were performed with the Edwards valve (Edwards SAPIEN or SAPIEN XT, Edwards Lifesciences Inc., Irvine, California), which consists of a trileaflet pericardial bovine valve mounted in a stainless steel (Edwards SAPIEN) or cobalt-chromium (SAPIEN XT) stent that is deployed by a balloon expandable mechanism. The valve was available in 23- and 26-mm sizes. Both TF and TA procedures were performed under general anesthesia, with similar anesthesia-ventilation techniques throughout the entire study period, without cardiopulmonary bypass. Balloon aortic valvuloplasty was systematically performed before valve implantation. In the TF approach, the native aortic valve was crossed with a standard straight soft-tip guidewire that was subsequently exchanged for a stiff guidewire. The balloon-mounted valve was advanced through a 22-F (23-mm valve) or 24-F (26-mm valve) sheath with the Retroflex delivery catheter (Edwards Lifesciences). After the native aortic valve was crossed, the new valve was positioned using fluoroscopic, angiographic, and TEE guidance and subsequently expanded under rapid pacing (180 to 220 beats/min). The number of rapid pacing runs per procedure was recorded. The TA approach consisted of a direct puncturing of the ventricular apex through a small left lateral thoracotomy and then advancing a 26-F sheath through the ventricular apex up to the mid ventricular cavity. The aortic valve was crossed with a soft J tip guidewire that was subsequently exchanged for a stiff J tip guidewire, which was advanced to the descending aorta. Following valvuloplasty, the Edwards valve was advanced antegradely through the 26-F catheter up to the native aortic valve, and then valve positioning and deployment followed similar steps as the retrograde TF approach. In all TA cases, catheter retrieval and ventricular

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