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Transcarotid Transcatheter Aortic Valve Replacement

Feasibility and Safety

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ABSTRACT

OBJECTIVES The purpose of this study was to assess the feasibility and safety of transcarotid transcatheter aortic valve replacement (TAVR).

BACKGROUND Many candidates for TAVR have challenging vascular anatomy that precludes transfemoral access. Transcarotid arterial access may be an option for such patients.

METHODS The French Transcarotid TAVR Registry is a voluntary database that prospectively collected patient demographics, procedural characteristics, and clinical outcomes among patients undergoing transcarotid TAVR. Outcomes are reported according to the updated Valve Academic Research Consortium criteria.

RESULTS Among 96 patients undergoing transcarotid TAVR at 3 French sites (2009 to 2013), the mean age and Society of Thoracic Surgeons predicted risk of mortality were 79.4 ± 9.2 years and 7.1 ± 4.1%, respectively. Successful carotid artery access was achieved in all patients. The Medtronic CoreValve (Medtronic, Inc., Minneapolis, Minnesota) (n = 89; 92.7%) and Edwards SAPIEN valves (Edwards Lifesciences, Irvine, California) (n = 7; 7.3%) were used. Procedural complications included: valve embolization (3.1%), requirement for a second valve (3.1%), and tamponade (4.2%). There were no major bleeds or major vascular complications related to the access site. There were 3 (3.1%) procedural deaths and 6 (6.3%) deaths at 30 days. The 1-year mortality rate was 16.7%. There were 3 (3.1%) cases of Valve Academic Research Consortium–defined in-hospital stroke (n = 0) or transient ischemic attack (TIA) (n = 3). None of these patients achieved the criteria for stroke and none manifested new ischemic lesions on cerebral computed tomography or magnetic resonance imaging. At 30 days, a further 3 TIAs were observed, giving an overall stroke/TIA rate of 6.3%.

CONCLUSIONS Transcarotid vascular access for TAVR is feasible and is associated with encouraging short- and medium-term clinical outcomes. Prospective studies are required to ascertain if transcarotid TAVR yields equivalent results to other nonfemoral vascular access routes. (J Am Coll Cardiol Intv 2016;9:472–80)

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Substantive peripheral vascular disease and small-caliber iliofemoral vasculature renders transfemoral transcatheter aortic valve replacement (TAVR) challenging or impossible in up to one-quarter of TAVR candidates (1-3). In such cases, a variety of alternate vascular access routes have been described: transapical (4), transaxillary (5), direct aortic (6), and transcaval (7). Each of these alternative strategies may be undesirable in certain clinical and anatomical situations, and each may be associated with adverse clinical consequences, including greater invasiveness, post-procedural pain, delayed mobility and patient discharge, and perhaps, increased mortality in the case of the transapical route (8).

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Transcarotid vascular access for the purposes of TAVR has been suggested as an access route with the potential to mitigate some of the disadvantages of other nonfemoral approaches (9). Manipulation of the carotid arteries and insertion of large-bore sheaths for the delivery of transcatheter heart valves (THVs), however, could potentially increase the risk of stroke. Importantly, there remain few published data describing the safety and efficacy of this approach.

We sought to address this knowledge gap by describing the procedural and clinical outcomes of a large cohort of consecutive patients undergoing transcarotid TAVR.

METHODS

PATIENTS. The French Transcarotid TAVR registry is a collaborative initiative developed by interventional cardiologists and cardiac surgeons performing transcarotid TAVR. This voluntary database has prospectively collected consecutive patient data from 3 participating centers (Hôpital Cardiologique, Lille; Hôpital Louis Pradel, Lyon; and Hôpital Henri Mondor, Paris) since April 2009, including patient demographics, clinical and procedural characteristics, and clinical outcomes.

At each participating institution, patients with severe aortic stenosis considered by the institutional Heart Team to be at high or excessive surgical risk were considered for TAVR. In all cases, multimodal vascular access assessment was performed to determine the optimal vascular access route for TAVR. Nonfemoral vascular access was considered in patients with iliofemoral or descending aortic anatomy at high risk for vascular complications who would potentially benefit from TAVR. In April 2009, the first transcarotid TAVR was performed using the Medtronic CoreValve (Medtronic, Inc., Minneapolis, Minnesota) in a patient without traditional vascular access options (9). Subsequently, experience with this technique has increased, and in some centers, transcarotid vascular access has become the default access of choice when transfemoral TAVR is not possible (10). All patients provided written informed consent for the intervention.

ABBREVIATIONS AND ACRONYMS

MRA = magnetic resonance angiography

TAVR = transcatheter aortic valve replacement

THV = transcatheter heart valve

PRE-PROCEDURAL SCREENING. TAVR candidates underwent anatomic assessment with contrast angiography or, more recently, multislice computed tomography. Patients with small-caliber (≤6 mm), heavily calcified, severely tortuous, or stenotic iliofemoral anatomy or those with significant descending aortic pathology were considered to be candidates for transcarotid TAVR. The dimensions of the carotid, subclavian, and vertebral arteries were carefully assessed using multislice computed tomography and Doppler ultrasonography. Patients with evidence of significant (≥50%) common or internal carotid artery stenosis, with plaque considered to be at high risk of embolization, or with congenital variants of the aortic arch (e.g., Bovine arch) were not considered for transcarotid TAVR. A common carotid artery minimal luminal diameter threshold of ≥7.0 mm was considered appropriate for transcarotid vascular access. Prior ipsilateral carotid artery intervention, contralateral carotid artery occlusion, or stenosis/occlusion of the vertebral arteries were also considered to be contraindications to transcarotid TAVR.

The arterial circle of Willis serves as a potential collateral pathway that maintains cerebral perfusion in cases of diminished afferent blood supply through the internal carotid arteries. Cerebral magnetic resonance angiography (MRA) can accurately delineate the components of the circle of Willis and determine the adequacy of collateral blood flow (11,12). In all cases, screening cerebral MRA was performed and interpreted by neuroimaging specialists to evaluate collateral cerebral blood flow, and patients with suspected inadequate collateral flow were excluded. In cases with equivocal cerebral MRA, transcranial echo Doppler was also performed in an attempt to further identify patients with the potential for cerebral hypoperfusion.

PROCEDURES. The participating institutions adopted a standardized procedural technique, in which the left common carotid artery was preferentially