

Novel TAVI Systems

First-in-human experience with the Medtronic CoreValve Evolut R

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EuroIntervention. 2014;9:1260-3.

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 $7.1 \pm 4.1\%$, 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.

Keywords: aortic stenosis, carotid vascular access, transcatheter aortic valve replacement

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). 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.

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 transcatheter aortic valve replacement (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 ($\geq 50\%$) 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 transcatheter aortic valve replacement. A common carotid artery minimal luminal diameter threshold of ≥ 7.0 mm was considered appropriate for transcatheter aortic valve replacement 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 transcatheter aortic valve replacement.

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 selected for all TAVR devices. The left side provides superior coaxial alignment between the aortic root and the THV during deployment, and affords simpler cardiac catheterization and operating room configuration. All patients received a loading dose of aspirin (300 mg) and clopidogrel (300 mg), prophylactic antibiotics, and had central venous access for insertion of a temporary pacing wire. Control angiography during the procedure necessitated insertion of a 6-F vascular access sheath via the radial or femoral arteries. Intra-operatively, cerebral perfusion was continually monitored using cerebral oximetry with near-infrared spectrometry (Equanox 7600, Nonin Medical Inc., North Plymouth, Minnesota). The proximal left common carotid artery was exposed via a small incision 2 cm above the left clavicle (**Figure 1**).

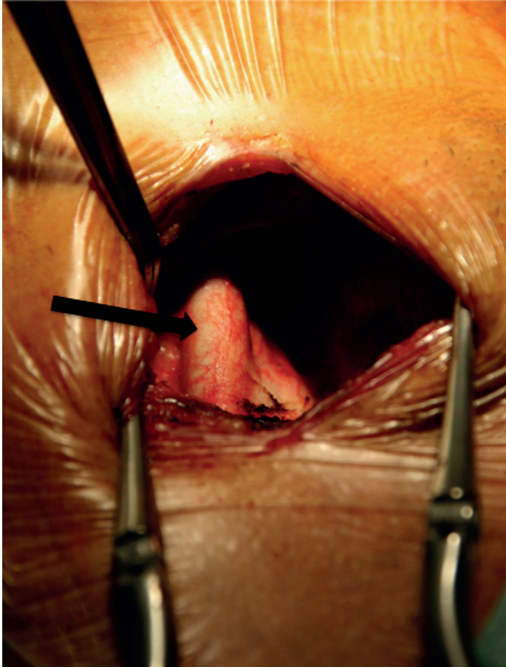


FIGURE 1 Exposure of the Left Common Carotid Artery
Exposure of the left common carotid artery (**black arrow**) for transcatheter aortic valve replacement.

The carotid artery was carefully dissected to avoid injury to the vagus nerve, which was retracted from the immediate surgical field. Vascular clamps were used to achieve proximal and distal control of the carotid artery, and percutaneous access was then achieved by insertion of a 5-F vascular access sheath. The stenotic aortic valve was then crossed in the usual fashion, using a straight-tip guide wire and a Judkin's right or Amplatz left 1 diagnostic catheter. A pre-shaped Amplatz Super stiff guide wire was then positioned in the apex of the left ventricle, and a 14-F sheath was inserted for the purposes of performing balloon aortic valvuloplasty. Thereafter, sequential dilation of the carotid artery was performed in selected cases with 16- and 18-F dilators, and an 18-F vascular access sheath (CoreValve cases, Cook Medical, Bloomington, Indiana) or the Edwards e-sheath (Edwards Lifesciences, Irvine, California) were then carefully advanced into the ascending aorta (**Figure 2**).

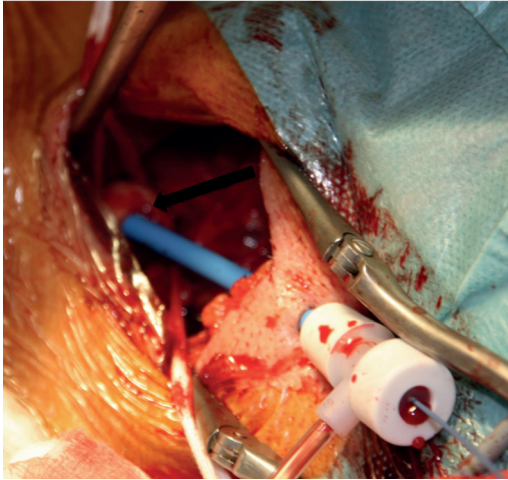


FIGURE 2 Insertion of the Vascular Access Sheath

The 14-F vascular access sheath in situ in the left common carotid artery (**black arrow**). Note the vascular access sheath is stabilized through a 1-cm incision cranial to the carotid dissection field.

Intravenous heparin was administered to maintain an activated clotting time ≥ 250 s. Standard TAVR implantation techniques were followed as previously described (9,13). After valve deployment, the 18-F sheath was carefully retracted, and vascular clamps were used to minimize blood loss while the arterial access site was surgically repaired using 6/0 Prolene suture (**Figure 3**). A control angiogram was performed to assess artery patency, and patients were then transferred to the intensive care unit for overnight monitoring.

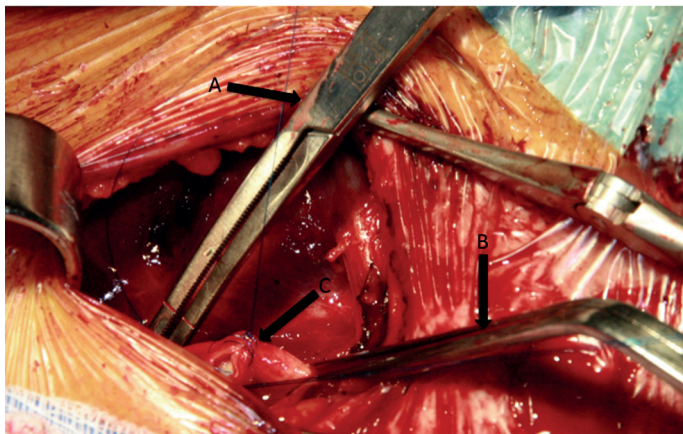


FIGURE 3 Vascular Closure

Proximal (**A**) and distal (**B**) vascular clamps are used to control access site bleeding during surgical closure of the left common carotid arteriotomy (**C**).

Clinical endpoints and follow-up.

Procedural, 30-day, and 1-year major clinical endpoints were defined according to the updated Valve Academic Research Consortium criteria (14). Stroke was of particular interest, and was defined as an acute episode of a focal or global neurological deficit and a change in the level of consciousness; hemiplegia, hemiparesis, numbness, or unilateral sensory loss; aphasia or dysphasia; hemianopia; amaurosis fugax; or other neurological signs or symptoms consistent with stroke (14). Stroke diagnosis required input from a stroke physician and/or diagnostic neuroimaging. Nonfocal global encephalopathy was not defined as stroke without neuroimaging evidence of cerebral infarction (14). The duration of symptoms and/or the demonstration of an ischemic or hemorrhagic lesion on neuroimaging further defined stroke (≥ 24 h; positive imaging) or transient ischemic attack (TIA) (< 24 h; negative imaging). Stroke was further classified as ischemic, hemorrhagic, or undetermined. Finally, stroke was categorized as disabling or nondisabling, the former being determined by a modified Rankin score of 2 or more at 90 days and an increase in at least 1 modified Rankin score category from an individual's pre-stroke baseline (15).

Statistical analysis.

Continuous variables are presented as mean \pm SD or median and range, and repeated measures were compared using a paired Student *t* test. Categorical variables are presented as frequencies and percentages. The 1-year rate of death is shown using a Kaplan-Meier curve. Analyses were performed using SPSS version 20.0 (IBM Corp., Armonk, New York).

RESULTS

A total of 96 elderly patients underwent transcatheter TAVR across 3 participating sites between April 2009 and December 2013. The mean age and Society of Thoracic Surgeons predicted risk of mortality score of the transcatheter TAVR patients was 79.4 ± 9.2 years and $7.1 \pm 4.1\%$, respectively (**Table 1**). Most patients (92.7%) described New York Heart Association functional class III or IV, and one-fifth had previously had cardiac surgery.

TABLE 1 Baseline Characteristics of Transcatheter Aortic Valve Replacement Patients (N = 96)

Age, yrs	79.4 ± 9.2
Female	38 (39.6)
Logistic EuroScore	21.7 ± 12.9
EuroScore II	7.2 ± 5.8
STS PROM	7.1 ± 4.1
NYHA functional class III or IV	89 (92.7)
Diabetes mellitus	31 (32.3)
Coronary artery disease	54 (56.3)
Prior myocardial infarction	16 (16.7)
Prior coronary artery bypass grafting	18 (18.8)
Prior stroke or TIA	10 (10.4)
Atrial fibrillation	39 (40.6)
Prior cardiac surgery	21 (21.9)
Permanent pacemaker	13 (13.5)
Pulmonary hypertension*	11 (11.5)
Peripheral arterial disease prohibiting TAVR	96 (100)
Aortic valve area, mm ²	0.8 ± 0.3
Aortic valve mean gradient, mm Hg	45.7 ± 13.7
Left ventricular ejection fraction, %	50.5 ± 16.7

Values are mean ± SD or n (%).

* Pulmonary artery systolic pressure >60 mm Hg.

NYHA = New York Heart Association; STS PROM = Society of Thoracic Surgeons predicted risk of mortality; TAVR = transcatheter aortic valve replacement; TIA = transient ischemic attack.

Successful carotid artery vascular access was achieved in all patients. The majority of cases were performed under general anesthesia (98.9%) using the left common carotid artery (88.5%) (**Table 2**). The Medtronic CoreValve and Edwards SAPIEN THV were implanted in 89 (92.7%) and 7 (7.3%) patients, respectively. Procedural complications included: THV embolization (n = 3, 3.1%), implantation of a second THV (n = 3, 3.1%), and cardiac tamponade due to left ventricular wire perforation (n = 4; 4.2%). There were 4 (4.2%) cases of both major bleeding and major vascular complications; none involved the carotid vascular access site (**Table 3**). Conversion to SAVR was not performed in any case. Post-implantation hemodynamics demonstrated a significant reduction in transvalvular mean gradient from 45.7 ± 13.7 mm Hg to 5.7 ± 3.9 mm Hg ($p < 0.0001$) and an increase in effective orifice area from 0.8 ± 0.3 cm² to 1.9 ± 0.4 cm² ($p < 0.0001$). More than mild post-implantation aortic regurgitation was observed in 20 (21.5%) patients.

TABLE 2 Procedural Characteristics of Transcatheter TAVR Patients (N = 96)

General anesthesia	95 (98.9)
Left carotid vascular access	85 (88.5)
Pre-implant balloon valvuloplasty	93 (96.9)
Pre-implant valvuloplasty balloon size, mm	23.4 ± 1.9
Post-implant valvuloplasty	9 (9.4)
Medtronic CoreValve	89 (92.7)
Edwards SAPIEN	7 (7.3)
23 mm	2 (2.1)
26 mm	25 (26.0)
29 mm	53 (55.2)
31 mm	16 (16.7)
THV embolization	3 (3.1)
Procedural valve-in-valve	3 (3.1)
Tamponade	4 (4.2)
Conversion to SAVR	0 (0.0)
Mean gradient, mm Hg	5.7 ± 3.9
Estimated orifice area, cm ²	1.9 ± 0.4
Aortic regurgitation*	
Grade 0	31 (33.3)
Grade 1	42 (45.2)
Grade 2	17 (18.3)
Grade 3	3 (3.1)
Grade 4	0 (0.0)

Values are n (%) or mean ± SD.

* Data available in 93 patients.

SAVR = surgical aortic valve replacement; TAVR = transcatheter aortic valve replacement; THV = transcatheter heart valve.

There were 3 (3.1%) procedural deaths: 1 case of left main coronary artery occlusion, and 2 patients who experienced cardiac tamponade. At 30 days, there were an additional 3 deaths (aspiration pneumonia and multiorgan failure; spontaneous ventricular fibrillation; and gastrointestinal hemorrhage), resulting in a 30-day mortality rate of 6.3%. The median duration of hospital stay was 11 days (inter-quartile range: 9 to 15 days). Long-term follow-up was available in all patients: median follow-up 360 days (interquartile range: 265 to 606 days). The 1-year mortality rate was 16.7% (**Figure 4**).

TABLE 3 Clinical Outcomes of Transcatheter Aortic Valve Replacement Patients (N = 96)

Mortality		
Procedural		3 (3.1)
30-day		6 (6.3)
1-year		16 (16.7)
Bleeding		
Minor		34 (37.4)
Major		4 (4.2)
Life-threatening		4 (4.2)
Vascular complications		
Minor		4 (4.2)
Major		4 (4.2)
Myocardial infarction		1 (1.0)
Acute kidney injury (grade 3)		7 (7.3)
New pacemaker*		22 (26.5)
Hospital stay, days		11 (9–15)
Composite endpoints		
Device success		86 (89.9)
Early safety		89 (92.7)
Clinical efficacy		89 (92.7)

Values are n (%) or median (interquartile range).

* A total of 22 of 83 patients required new pacemaker.

TAVR = transcatheter aortic valve replacement.

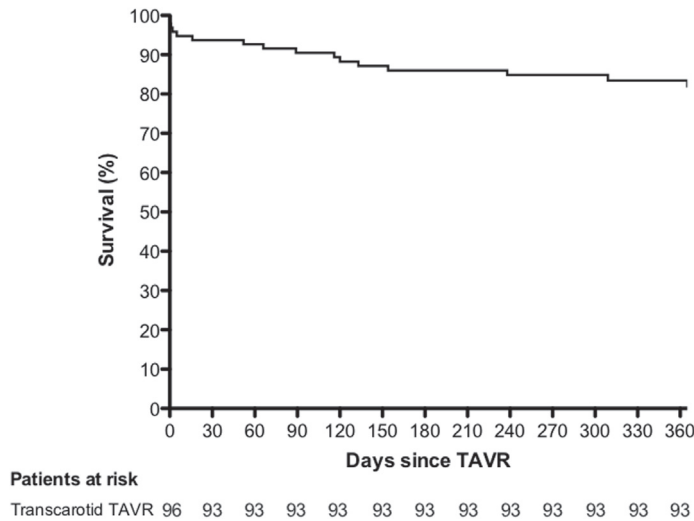


FIGURE 4 1-Year Mortality After Transcatheter TAVR

Kaplan-Meier survival curve of patients undergoing transcatheter transcatheter aortic valve replacement (TAVR).

There were 3 (3.1%) cases of Valve Academic Research Consortium–defined in-hospital stroke ($n = 0$) or TIA ($n = 3$) (**Table 4**). All patients underwent computed tomographic or magnetic resonance neuroimaging and were assessed by a consultant neurologist. Two TIAs were noted immediately post-operatively and 1 on post-operative day 1. These events were localized as ipsilateral ($n = 1$) or contralateral ($n = 2$) to the carotid vascular access site. Clinical features of the events included hemiparesis ($n = 2$) and aphasia ($n = 1$); however, neuroimaging did not show new ischemic lesions in any case. Pre-operatively, all patients were prescribed dual antiplatelet therapy, and all received intraprocedural heparin. Two additional cases of transient nonfocal global encephalopathy with normal neuroimaging were not defined as stroke/TIA. At 30 days, a further 3 TIAs were observed (1 ipsilateral, 2 contralateral), thus yielding an overall event rate of (6.3%). In-hospital atrial fibrillation occurred in each of these additional cases, and the events occurred despite treatment with aspirin and oral anticoagulation. Clinical localization relative to the carotid vascular access site was ipsilateral in 1 case and contralateral in 2 cases. Neuroimaging did not demonstrate any new ischemic lesions in any of these patients. Two further neurological events were noted during long-term follow-up: an ischemic stroke causing aphasia and visual field defect on day 51, and a hemorrhagic stroke on day 409.

TABLE 4 Stroke and TIA in Transcarotid TAVR Patients (N = 96)

In-hospital stroke or TIA	3 (3.1)
TIA	3 (3.1)
Stroke	0 (0)
Ipsilateral localization	1 (33)
Hemorrhagic stroke	0 (0)
In-hospital atrial fibrillation	1 (33)
CHA ₂ DS ₂ -VASc score*	3.8 ± 0.8
Aortic valve pre-dilation	3 (100)
THV post-dilation	1 (33)
30-day stroke or TIA	6 (6.3)
TIA	6 (100)
Stroke	0 (0)
Ipsilateral localization	2 (33)
Hemorrhagic stroke	0 (0)
In-hospital atrial fibrillation	4 (67)
Discharge anticoagulation	4 (67)
Discharge dual antiplatelet therapy	2 (33)

Values are n (%).

* CHA₂DS₂-VASc (congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, stroke/transient ischemic attack, vascular disease, age 65–74 years, sex category) score (24).

TIA = transient ischemic attack; other abbreviations as in **Table 2**.

DISCUSSION

This study provides information on the largest cohort of patients undergoing transcarotid vascular access for TAVR. The salient findings from this study are: transcarotid TAVR is technically feasible in appropriately selected patients; carotid vascular access site complications are rare; and the 30-day rate of stroke or TIA was 6.3%, although all of these ischemic events were transient in nature.

Initially approved TAVR systems in the United States required vascular access sheaths with 18- to 24-F inner diameter. Such large-bore catheters are problematic for the 25% to 30% of patients with peripheral arterial disease and, in particular, for elderly females with small iliofemoral anatomy (3,16). The sheath to femoral artery ratio is considered to be the most powerful predictor of TAVR-related vascular complications (3), and using this measurement almost one-quarter of TAVR candidates require an alternate vascular access route (1,2). A variety of alternative access solutions have been described (4–6), each with specific advantages and disadvantages. Most recently, transcaval TAVR has produced encouraging short-term outcomes (7). It is likely that the proportion of patients undergoing TAVR using alternate vascular access routes will fall due to advances in transcatheter technology (some current devices

are now 14- to 16-F) (17,18); however, these technologies are not yet available worldwide, and patients with severe peripheral arterial disease will remain a considerable challenge for transfemoral access regardless of sheath size.

Transcarotid TAVR with a self-expanding prosthesis was first performed in Lille in 2009 (9). The technique has subsequently been adopted by several European and U.S. centers (9,13,19,20) and has been performed with both self- and balloon-expandable prostheses (13). The surgical approach to the carotid artery is relatively uncomplicated due to its superficial location, and operative experience with the carotid arteries is widely available among cardiovascular surgeons. For the purposes of TAVR, the left common carotid is preferentially chosen, as it allows superior coaxial alignment of the THV with the aortic annulus (**Figure 5**). We prefer to perform transcarotid TAVR under general anesthesia, although regional anesthesia has been successfully performed (19). Important procedural differences from other access routes include routine sequential dilation of the artery (10- to 16-F dilators) and insertion of the 18-F sheath at the time of THV deployment (after balloon valvuloplasty). In the current series, we did not experience major vascular complications or major bleeding related to the vascular access site. There were no access-related deaths.

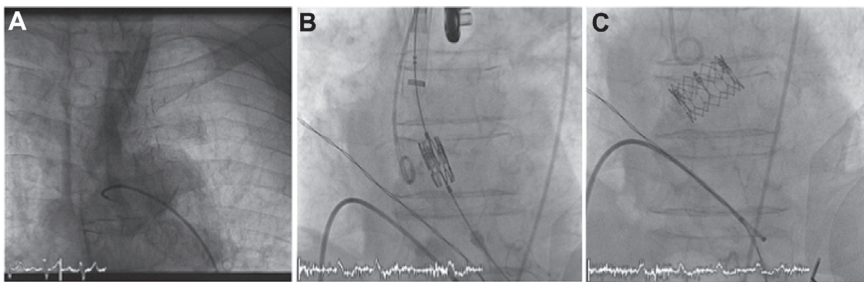


FIGURE 5 Transcarotid TAVR

Transcarotid transcatheter aortic valve replacement (TAVR). (A) Selective angiography of the left common carotid artery, (B) positioning, and (C) deployment of a 29-mm Edwards Sapien XT valve.

At 30 days, 6 patients (6.3%) had evidence of transient cerebral ischemia. Significantly, none of these events met the criteria for stroke, and neuroimaging did not demonstrate new ischemic lesions in any case. These data compare favorably with stroke rates reported in other alternate access series, where the rate of stroke is higher than that observed in transfemoral cohorts (18,21). Webb et al. (18) reported a 30-day stroke rate of 5.6% among patients undergoing contemporary transaortic or transapical TAVR with the SAPIEN 3 valve (Edwards Lifesciences), whereas a stroke rate of 4.3% was described for alternate-access CoreValve implantation in the Advance registry (21). It is intriguing that 4 of 6 TIAs were clinically located contralateral to the site of vascular access. This suggests that there may be several potential stroke mechanisms during transcarotid TAVR: 1) embolization of carotid artery plaque due to arterial puncture and instrumentation; 2) access site trauma providing a nidus for thrombosis

with subsequent embolization; 3) inadequate collateral perfusion through the circle of Willis; and 4) embolization of debris during balloon valvuloplasty or THV implantation. The low rate of stroke observed in this study may be attributed to careful patient selection (common carotid artery minimal lumen diameter ≥ 7.0 mm), mandatory pre-treatment with dual antiplatelet agents, and adequate intraoperative anticoagulation (activated clotting time >250 s). We also limited the duration of antegrade ischemia by placing the large bore introducer sheath only when necessary. Nevertheless, there remains the potential to further reduce the risk of cerebral ischemia by limiting THV post-dilation (22), using embolic protection devices (23), and by further refining the anatomical selection criteria for transcatheter TAVR. A total of 4 of 6 episodes of TIA were located to the right cerebral hemisphere in patients that underwent TAVR using the left common carotid artery. Although we believe this observation is due to the play of chance, we must acknowledge that there is a possibility that embolization from the aortic valve may preferentially access the cerebral vasculature via the right common carotid artery, and therefore, using the right common carotid artery for transcatheter TAVR could be associated with a reduced risk of stroke. More study is required into the mechanism of stroke with this technique.

The observed 30-day mortality rate (6.3%) was relatively high compared with contemporary series. However, this patient cohort was unsuitable for transfemoral TAVR, and thus the mean Society of Thoracic Surgeons predicted risk of mortality score of 7.1% may underestimate the true risk features of this group. Furthermore, this series includes all patients undergoing transcatheter TAVR since 2009, and the complication rates probably reflect our learning curve with TAVR and this technique using first-generation TAVR devices.

Ultimately, we believe that transcatheter TAVR should be considered as an alternative to transapical, transaortic, transcaval, or trans-subclavian procedures. Because there exists limited comparative data between alternate access routes, a patient-centric individualized approach to vascular access should be undertaken by the institutional Heart Team. Transcatheter TAVR may have particular benefits over procedures requiring thoracotomy or sternotomy in patients with advanced lung disease or prior sternotomy, where recovery from surgery could be protracted. Similarly, transcatheter TAVR is technically less challenging than the transcaval approach. Longer-term follow-up is, however, required to demonstrate the efficacy of this approach.

Study limitations.

The study findings should be interpreted in light of the study design. This prospective study included a small number of patients at selected high-volume TAVR centers, and the results demand cautious interpretation. It is possible that the true rate of neurological events has been underestimated, as systematic evaluation by a neurologist was not performed prior to and following TAVR. We were, however, very focused on neurological outcomes, and there was a low threshold for neurologist evaluation and/or neuroimaging.

CONCLUSIONS

Transcarotid vascular access for TAVR is feasible and is associated with encouraging short- and medium-term clinical outcomes. Prospective studies with longer-term follow-up are required to ascertain if transcarotid TAVR yields equivalent safety and efficacy to other nonfemoral vascular access routes.

PERSPECTIVES

WHAT IS KNOWN? A significant proportion of patients undergoing TAVR are not suitable for transfemoral vascular access. In such cases, a range of vascular alternate access routes have been described, including the transapical, transaortic, trans-subclavian, and transcaval approaches. Transcarotid vascular access has been previously described and may be a minimally invasive and more straightforward technique compared with the aforementioned approaches; however, little information is available describing the performance and outcomes associated with this strategy.

WHAT IS NEW? This study describes the largest cohort of patients undergoing transcarotid TAVR to date. It demonstrates that carotid vascular access for the purposes of TAVR is feasible and safe. This approach safely facilitated the implantation of both self- and balloon-expandable THVs. Importantly, no patient in this series experienced a stroke; however, a 30-day rate of TIA of 6.3% was observed.

WHAT IS NEXT? The results of this study suggest that transcarotid TAVR should be considered a reasonable vascular access route in patients who are not suitable for a transfemoral approach. Indeed, this technique may have specific advantages over the more invasive transapical or transaortic strategies in certain patient cohorts. Larger series with extended follow-up are required to definitively prove the safety and efficacy of this technique.

ABBREVIATIONS AND ACRONYMS

MRA = magnetic resonance angiography
 TAVR = transcatheter aortic valve replacement
 THV = transcatheter heart valve

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