Transcarotid Approach for Transcatheter Aortic Valve Replacement With the Sapien 3 Prosthesis
A Multicenter French Registry

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ABSTRACT

OBJECTIVES This study sought to describe the procedural and clinical outcomes of patients undergoing transcarotid (TC) transcatheter aortic valve replacement (TAVR) with the Edwards Sapien 3 device.

BACKGROUND The TC approach for TAVR holds the potential to become the optimal alternative to the transfemoral gold standard. Limited data exist regarding safety and efficacy of TC-TAVR using the Edwards Sapien 3 device.

METHODS The French Transcarotid TAVR prospective multicenter registry included patients between 2014 and 2018. Consecutive patients treated in 1 of the 13 participating centers ineligible for transfemoral TAVR were screened for TC-TAVR. Clinical and echocardiographic data were prospectively collected. Perioperative and 30-day outcomes were reported according to the updated Valve Academic Research Consortium (VARC-2).

RESULTS A total of 314 patients were included with a median (interquartile range) age of 83 (78 to 88) years, 63% were males, Society of Thoracic Surgeons mortality risk score 5.8% (4% to 8.3%). Most patients presented with peripheral artery disease (64%). TC-TAVR was performed under general anesthesia in 91% of cases, mostly using the left carotid artery (73.6%) with a procedural success of 97%. Three annulus ruptures were reported, all resulting in patient death. At 30 days, rates of major bleeding, new permanent pacemaker, and stroke or transient ischemic attack were 4.1%, 16%, and 1.6%, respectively. The 30-day mortality was 3.2%.

CONCLUSIONS TC-TAVR using the Edwards Sapien 3 device was safe and effective in this prospective multicenter registry. The TC approach might be considered, in selected patients, as the first-line alternative approach for TAVR whenever the transfemoral access is prohibited. Sapien 3 device was safe and effective in our multicenter cohort. (J Am Coll Cardiol Intv 2019;12:413–9) © 2019 Published by Elsevier on behalf of the American College of Cardiology Foundation.

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The transcatheter (TC) approach for transcatheter aortic valve replacement (TAVR) has been developed as an alternative to the transfemoral gold standard whenever the latter is precluded. Significant peripheral vascular disease or significant descending aortic disease are some of the anatomic challenges that render the iliofemoral pathway unfeasible. Despite an apparent increase over time in the proportion of patients eligible for the transfemoral approach, alternative accesses still represent up to 15% of patients undergoing TAVR in contemporary registries, with 3.4% of patients treated with the TC approach in the recent FRANCE TAVI registry. The TC access has the potential to alleviate some drawbacks of the other nonfemoral approaches (transapical, subclavian, direct aortic, transcaval), given its minimally invasive feature. Previous reports asserting the safety of the TC approach for TAVR focused on the Medtronic CoreValve device (Minneapolis, Minnesota) with 3.4% of patients treated with the TC access, the latter was the approach used for TAVR with the Edwards Sapien 3 device.

**METHODS**

**PATIENT SELECTION.** The French Transcarotid TAVR registry is a collaborative initiative developed by interventional cardiologists and cardiac surgeons performing TC-TAVR. This voluntary database prospectively collected consecutive patient data from 13 French participating centers (Lille University Hospital, Lille; Brabois University Hospital, Vandoeuvre les Nancy, Nancy; Angers University Hospital, Angers; Bordeaux University Hospital; Chirurgie Cardioïque et Vasculaire, Infirmière Protestante, Lyon; Marie Lannelongue Hospital, Plessis-Robinson; Institut Mutualiste Montsouris, Paris; Rennes University Hospital, Rennes; Hôpital Européen Georges Pompidou, Paris; Robert Debré University Hospital, Reims; Montpellier University Hospital, Montpellier; Centre Hospitalo-Universitaire de Nîmes; Centre Hospitalo-Universitaire de Perpignan) between January 2014 and April 2018, including patient demographics, clinical and procedural characteristics, and outcomes.

Patients experiencing severe symptomatic aortic stenosis were considered for TAVR by the institutional heart team whenever deemed to be at high or prohibitive surgical risk. Multimodal vascular imaging was performed in all patients to choose the optimal approach for TAVR. Nonfemoral approach was considered when patient anatomy precluded the transfemoral access: oblitative lower limb arterial disease with severe stenosis, small-caliber iliofemoral vasculature (i.e., diameter <6 mm), heavily calcified vessels, tortuosity, or significant descending aortic disease. Peripheral artery disease was defined as history of peripheral arterial surgery or angioplasty, or stenosis ≥50% of the iliofemoral axis. Consecutive patients treated with the Sapien 3 transcatheter heart valve (THV) through the TC approach were included in this registry. All patients provided written informed consent for the intervention.

**PRE-PROCEDURAL SCREENING.** Vascular anatomy was assessed in all patients eligible for TAVR. Preoperative multislice computed tomography (MSCT) was used to confirm suitable supra-aortic anatomy. The dimensions of carotid, subclavian, and vertebral arteries were carefully assessed, and Doppler ultrasonography complemented MSCT whenever necessary. Careful assessment of the ipsilateral common carotid artery investigated the presence of minimal luminal diameter ≥6 mm without significant (i.e., ≥50%) stenosis or plaque at high risk of embolization, and the absence of subclavian, vertebral, and contralateral carotid stenosis or occlusion, or congenital variants of the aortic arch (e.g., Bovine arch), which are contraindications for the TC approach. Cerebral magnetic resonance angiography screening, if necessary supplemented by a transcranial Doppler ultrasound, was performed to evaluate the circle of Willis and collateral cerebral blood flow to identify patients with the potential for cerebral hypoperfusion. The circle of Willis provides compensation for the reduced blood flow through the ipsilateral carotid during clamping and obstruction by the delivery catheter. Thus, absence of severe stenosis or occlusion of the contralateral carotid or vertebral arteries were verified. All magnetic resonance angiography and transcranial Doppler ultrasound images were interpreted by neurovascular radiologists to inspect adequate collateral cerebral blood flow and evaluate the risk of cerebral hypoperfusion. In all the patients deemed eligible to the TC access, the latter was the approach used for TAVR.

**PROCEDURES.** All procedures were performed as previously described. For primary access both common carotid arteries were eligible, whereas the left side was favored because it provides superior coaxial alignment between the aortic root and the THV during deployment. General anesthesia and local...
were performed before hospital discharge. Cardiography and carotid Doppler ultrasonography while short clamping proximally and distally to the transversal fashion with PROLENE sutures 5 arterial access was then surgically repaired in a aortogram before carotid sheath removal. The carotid sheath and the catheter during intravascular navigation. Intravenous heparin was administered to maintain an activated clotting time $\geq 250$ s. A J-tipped soft guidewire was used to guide the JR4 catheter (pigtail or AL1 catheters could have been used, according to crossing difficulties) and then exchanged with a straight-tip guidewire to cross the aortic valve. When the crossing was achieved, the catheter was pushed into the left ventricle, before exchanging the straight guidewire for a stiff guidewire (SAFARI pre-shaped TAVI guidewire 0.035-inch $\times$ 300 cm, Boston Scientific Marlborough, Massachusetts; or Amplatz extra stiff 0.035-inch guidewire, Cook, Inc., Bloomington, Indiana). Pre- and post-dilatation were left to the discretion of the surgeons. After the Edwards-Sapien 3 prosthesis was loaded, the Certitude delivery system, used in all patients, was inserted through the radial or femoral arteries. Temporary pacing wire was inserted through the femoral vein. A 6-F catheter secondary arterial access was inserted through the radial or femoral arteries. Intraoperatively, cerebral perfusion was continually monitored using cerebral oximetry with near infrared spectroscopy (Equanox 7600, Nonin Medical Inc., North Plymouth, Minnesota).

After vertical 2- to 3-cm incision 1 or 2 fingers above the left clavicle, the common carotid artery was carefully dissected to avoid lesion of the vagus nerve. A complementary small incision 1 cm above the previous one was possible to increase stability for the sheath and the catheter during intravascular navigation. Intravenous heparin was administered to maintain an activated clotting time $\geq 250$ s. A J-tipped soft guidewire was used to guide the JR4 catheter (pigtail or AL1 catheters could have been used, according to crossing difficulties) and then exchanged with a straight-tip guidewire to cross the aortic valve. When the crossing was achieved, the catheter was pushed into the left ventricle, before exchanging the straight guidewire for a stiff guidewire (SAFARI pre-shaped TAVI guidewire 0.035-inch $\times$ 300 cm, Boston Scientific Marlborough, Massachusetts; or Amplatz extra stiff 0.035-inch guidewire, Cook, Inc., Bloomington, Indiana). Pre- and post-dilatation were left to the discretion of the surgeons. After the Edwards-Sapien 3 prosthesis was loaded, the Certitude delivery system, used in all patients, was inserted through the primary carotid artery and carefully advanced into the ascending aorta. THV implantation was performed under rapid pacing. Absence of significant periprosthetic regurgitation was checked on aortogram before carotid sheath removal. The carotid arterial access was then surgically repaired in a transversal fashion with PROLENE sutures 5-0 or 6-0, while short clamping proximally and distally to the vascular access. Post-operative transthoracic echocardiography and carotid Doppler ultrasonography were performed before hospital discharge.

**CLINICAL ENDPOINTS.** Procedural success was defined as a successful implantation of a single THV, in the appropriate aortic position and without aortic rupture. The 30-day clinical endpoints are reported according to the updated Valve Academic Research Consortium (VARC-2) (15). All cerebrovascular events were recorded. Whenever stroke and transient ischemic attack (TIA) were suspected, patients underwent examination by a senior neurologist and underwent diagnostic neuroimaging whenever indicated according to the neurologist. Stroke and TIA were defined in accordance with the definition of a central nervous system type 1 and type 3a event, respectively, as defined by the Academic Research Consortium (16).

**STATISTICAL ANALYSIS.** Continuous variables are presented as median (interquartile range), and categorical variables are presented as frequencies and percentages. The 30-day survival curve was modeled using the Kaplan-Meier method. Analyses were performed using SPSS 23 software (IBM SPSS Statistics for Windows version 23.0, IBM Corp., Armonk, New York).

**RESULTS**

Of the 6,680 patients who underwent TAVR at the 13 participating centers during the study period, a total
of 314 patients (4.7%) were included in this multi-center cohort with a median (interquartile range) age of 83 (78 to 88) years, two-thirds of them were males, with intermediate to high surgical risk (Society of Thoracic Surgeons mortality risk score, 5.8% [4% to 8.3%]), and most of them were severely dyspneic with a New York Heart Association functional class III or IV in two-thirds of the patients. One-third of the patients had atrial fibrillation, two-thirds had moderate to severe chronic renal failure, and most of the patients presented with peripheral artery disease (64%). TC-TAVR was performed under general anesthesia in 91% of cases in this cohort, mostly through the left carotid (73.6% of cases), and procedural success was achieved in 97% of procedures (Table 1).

**Mortality.** Procedure failures (3%) accounted for 3 patients who required a valve-in-valve procedure for persistent severe angiographic aortic regurgitation, 3 annulus ruptures, all of which were fatal: 2 patients died during the procedure, the third patient died on day 3; 2 patients had conversion to open surgery because of an impossible carotid crossing caused by excessive tortuosity; finally, 1 patient had left-ventricle perforation by the stiff guidewire. The 30-day mortality was 3.2% (n = 10) (Figure 1).

**Morbidity.** Major bleeding was observed in 13 patients (4.1%), whereas major bleeding was related to the carotid access in only 1 patient who presented a cervical hematoma treated medically, but who needed a transfusion of 2 U of red blood cells. Three patients (1%) experienced a tamponade. Five patients (1.6%) presented a major vascular complication, 2 of which concerned the carotid access. Two patients (0.6%) experienced pre-operative coronary obstruction leading to an ST-segment elevation acute myocardial infarction, resulting in patient death in 1 of them 6 days after the procedure.

At 30 days 16.2% of patients required a permanent pacemaker. A total of 5.1% of patients had moderate to severe paravalvular leak on the control transthoracic echocardiogram. Furthermore, the median post-implant echocardiographic mean gradient was 11 (8 to 13) mm Hg. The median hospital stay was 7 days (5 to 10).

**Cerebrovascular events.** Five patients (1.6%) presented a stroke or TIA: 3 strokes occurred within 24 h after the implantation (1 ipsilateral and 2
contralateral to the carotid access) and 2 patients presented a TIA 10 and 12 days after the procedure (both contralateral to the carotid access). Of the patients who experienced perioperative stroke/TIA, only 1 had a history of atrial fibrillation and none had a history of prior stroke or TIA (Table 2).

**DISCUSSION**

This descriptive study reports the largest contemporary cohort to date of TC TAVR and demonstrates the safety and efficacy of the TC approach for TAVR with the Edwards Sapien 3 THV.

The Certitude delivery system is usually used to deliver the Sapien 3 THV transapically; it is compatible with the low-profile 18-F catheter Certitude sheath for the 23- and 26-mm valve and the 21-F catheter Certitude sheath for the 29-mm valve (outer diameter, 25-F catheter). It has an integrated pusher to streamline the procedure and an articulation feature to facilitate the coaxial positioning. In this cohort the Certitude delivery system was used to implant the THV through both the left and right carotid artery. Major vascular complications have been reported to be inversely correlated with reduced delivery profile (17), although in this cohort we have not witnessed such a relationship for the TC approach because all major vascular complications occurred with 23- or 26-mm Sapien 3 devices, possibly due to the surgical nature of the access that allows direct repair of the access after THV delivery. Furthermore, major bleeding was observed in 4% of patients in this cohort, which is lower than previous data with transfemoral TAVR of the Sapien 3 THV (18).

Stroke is a major concern for the TC approach. This study found a low (1.6%) rate of stroke or TIA at 30 days, which is lower than observed in the PARTNER 2 trial (5.5%) that included predominantly transfemorally treated patients (19) but comparable with previous observational data with the Medtronic CoreValve (2.2%) (10). Extensive pre-operative evaluation of the cerebrovascular anatomy with MSCT, magnetic resonance angiography, and Doppler in patients eligible for the TC approach might have selected patients at lower risk of cerebrovascular events. Another explanation might be the dislodgement of atherosclerotic plaques by the delivery system by friction during transfemoral TAVR, which is reduced during TC-TAVR because the latter allows easier alignment with the aortic annulus. Despite initial reluctance toward this approach because of the proximity to the brain, several reports, including the presented study, reported reassuring data regarding neurologic outcomes, which contributed to the acceptance and expansion of this approach (3,9,10). This might be explained by the more extensive experience with the carotid approach among cardiovascular surgeons, a less invasive surgery than with the transapical approach that requires thoracotomy or the transaortic approach that requires sternotomy, and less challenging than the transcaval approach. A recent report from the CoreValve US Pivotal Trial and Continued Access Study substudy analysis provided reassuring data regarding the transaxillary approach, further suggesting that nontransthoracic alternative approaches should be favored (20,21).

The 30-day mortality rate remains acceptable with the TC approach in this study (3.2%), comparable with the PARTNER 2 trial intermediate surgical risk cohort (mean Society of Thoracic Surgeons score, 5.8%) and lower than previous observational reports with the TC access in higher risk patients (6% to 7%) (9,10). The incidence of annulus ruptures in this study is comparable with the incidence reported in the published data (1%). However, it is worth noting that the existing published data supports the hypothesis that balloon-expandable valves are at higher risk of annulus rupture and appropriate preventive measures should be observed (22). Two conversions to open surgery were observed in this registry and were caused by excessively tortuous carotid anatomy. This observation emphasizes that excessive tortuosity of the carotid artery should be considered as a contraindication to the TC approach. Also, the TC access should only be attempted after careful evaluation of its feasibility on pre-operative MSCT. The rate of 30-day moderate to severe perivalvular leak in this cohort (5.1%) is comparable with other recent studies that reported the rates to be between 3% and 10% after TAVR (2,3,19,22). Further research is warranted to investigate if superior coaxial alignment provided with the TC approach could yield lower risk of prosthetic regurgitation than the transfemoral approach. Furthermore, the median duration of hospital stay was 7 (5 to 10) days. This is shorter than the median 9 days from non-transfemoral TAVR to discharge reported in the FRANCE TAVI registry (3). The observed new pacemaker rate was 16%, which is slightly higher than previous reports (24); this may be caused by variations in indications among participating centers, or oversizing practice. Indeed, the rate of new pacemakers varied between 7% and 33%.
STUDY LIMITATIONS. This prospective observational study is subject to bias. Only patients treated with the Sapien 3 device were included in the presented study. Outcomes of this study represent those of tertiary high-volume TAVR centers used to the TC approach, thus should be interpreted with caution. Registry data can also be subject to underreporting of complication rates (25). Furthermore, follow-up was stopped in this study at 30 days and a more extended follow-up might provide further insight regarding long-term outcomes.

CONCLUSIONS

The TC approach for TAVR using the Sapien 3 THV was safe and effective in this multicenter French registry. The TC approach could be considered as a safe alternative approach for TAVR when the transfemoral access is prohibited.

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REFERENCES

1. Hayashida K, Lefèvre T, Chevalier B, et al. Transfemoral aortic valve implantation new criteria to predict vascular complications. J Am Coll Cardiol Intv 2011;4:851-8.
2. Grover FL, Vemulapalli S, Carroll JD, et al. 2016 Annual report of the Society of Thoracic Surgeons/ American College of Cardiology Transcatheter Valve Therapy Registry. J Am Coll Cardiol 2017; 69:1215-30.
3. Auffret V, Lefèvre T, Van Belle E, et al. Temporal trends in transcatheter aortic valve replacement in France: FRANCE 2 to FRANCE TAVI. J Am Coll Cardiol 2017;70:42-55.
4. Overtchouk P, Modine T. Alternate access for TAVI: stay clear of the chest. Interv Cardiol Rev 2018;13:145-50.
5. Greenbaum AB, Babalarios VC, Chen MY, et al. Transcaval access and closure for transcatheter aortic valve replacement: a prospective investigation. J Am Coll Cardiol 2017; 69:511-21.
6. Ciucu C, Tarantini G, Latib A, et al. Trans-subclavian versus transapical access for transcatheter aortic valve implantation: multicenter study. Catheter Cardiovasc Interv Off J Soc Card Angiogr Interv 2016;87:332-8.
7. Bauernschnitt R, Schreiber C, Bleiziffer S, et al. Transcatheter aortic valve implantation through the ascending aorta: an alternative option for no-access patients. Heart Surg Forum 2009;12: E63-4.
8. Blackstone EH, Suri RM, Rajeswaran J, et al. Propensity-matched comparisons of clinical outcomes after transapical or transfemoral transcatheter aortic valve replacement: a placement of aortic transcatheter valves (PARTNER)-1 trial substudy. Circulation 2015;131:1989-2000.
9. Mlyotse D, Sudre A, Teiger E, et al. Transcatheter transcarotid aortic valve replacement: feasibility and safety. J Am Coll Cardiol Intv 2016;9:472-80.
10. Debry N, Delbeye C, Azmoun A, et al. Transcarotid transcatheter aortic valve replacement: general or local anesthesia. J Am Coll Cardiol Intv 2016;9:2123-20.
11. Folliguet T, Laurent N, Bertram M, et al. Transcarotid transcatheter aortic valve implantation: multicentre experience in France. Eur J Cardio-Thorac Surg Off J Eur Assoc Cardio-Thorac Surg 2018;53:157-61.
12. Modine T, Sudre A, Delbeye C, et al. Transcutaneous aortic valve implantation using the left carotid access: feasibility and early clinical outcomes. Ann Thorac Surg 2012;93:1489-94.
13. Modine T, Lemesle G, Azzouzi R, Sudre A. Aortic valve implantation with the CoreValve ReValving System via left carotid artery access: first case report. J Thorac Cardiovasc Surg 2010; 140:928-9.
14. Overtchouk P, Aouelmat I, Coïn C, Fattouch K, Modine T. Transcatheter approach for TAVI: an optimal alternative to the transfemoral gold standard. Ann Cardiothorac Surg 2017;6:555-7.
15. Kappetein AP, Head SJ, Généreux P, et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. J Thorac Cardiovasc Surg 2013;145:6-23.
16. Lansky AJ, Messé SR, Brickman AM, et al. Proposed standardized neurological endpoints for cardiovascular clinical trials. J Am Coll Cardiol 2017;69:679-91.
17. Barbanti M, Binder RK, Melanie F, et al. Impact of low-profile sheaths on vascular complications during transfemoral transcatheter aortic valve replacement. EuroIntervention J [Internet]. December 27, 2013. Available at: https://www.ncbi.nlm.nih.gov/pubmed/24366240.
18. Kodali S, Thourani VH, White J, et al. Early clinical and echocardiographic outcomes after SAPIEN 3 transcatheter aortic valve replacement in inoperable, high-risk and intermediate-risk patients with aortic stenosis. Eur Heart J 2016;37: 2252-62.

PERSPECTIVES

WHAT IS KNOWN? Previous reports suggested that transcarotid transcatheter aortic valve replacement using self-expandable devices was a safe alternative when transfemoral approach was precluded.

WHAT IS NEW? Procedural success and 30-day mortality of the transcarotid approach are comparable with those of transfemoral approach reported in randomized trials using the Sapien 3 device, whereas cerebrovascular and major bleeding events were similar to those reported with the self-expandable devices despite design differences of transcatheter heart valves and delivery systems.

WHAT IS NEXT? Further research is warranted to provide direct comparative evaluation of the transcarotid approach to the transfemoral and other alternative approaches, such as transsubclavian, transapical, transaortic, and transaortic. Also, data on safety of transcarotid transcatheter aortic valve replacement in low-risk patients and all comers would allow operators to consider this approach regardless of the risk profile.
19. Leon MB, Smith CR, Mack MJ, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. N Engl J Med 2016;374:1609–20.

20. Gleason TG, Schindler JT, Hagberg RC, et al. Subclavian/axillary access for self-expanding transcatheter aortic valve replacement renders equivalent outcomes as transfemoral. Ann Thorac Surg 2018;105:477–83.

21. Schäfer U, Deuschl F, Schofer N, et al. Safety and efficacy of the percutaneous transaxillary access for transcatheter aortic valve implantation using various transcatheter heart valves in 100 consecutive patients. Int J Cardiol 2017;232:247–54.

22. Coughlan J, Kiernan T, Mylotte D, et al. Annular rupture during transcatheter aortic valve implantation: predictors, management and outcomes. Interv Cardiol Rev 2018;13:140.

23. Reardon MJ, Van Mieghem NM, Popma JJ, et al. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. N Engl J Med 2017;376:1321–31.

24. van Rosendael PJ, Delgado V, Bax JJ. Pacemaker implantation rate after transcatheter aortic valve implantation with early and new-generation devices: a systematic review. Eur Heart J 2018;39:2003–13.

25. Messé SR, Acker MA, Kasner SE, et al. Stroke after aortic valve surgery: results from a prospective cohort. Circulation 2014;129:2253–61.

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