



Temporal Trends in Transcatheter Aortic Valve Replacement in France

FRANCE 2 to FRANCE TAVI

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ABSTRACT

BACKGROUND Transcatheter aortic valve replacement (TAVR) is standard therapy for patients with severe aortic stenosis who are at high surgical risk. However, national data regarding procedural characteristics and clinical outcomes over time are limited.

OBJECTIVES The aim of this study was to assess nationwide performance trends and clinical outcomes of TAVR during a 6-year period.

METHODS TAVRs performed in 48 centers across France between January 2013 and December 2015 were prospectively included in the FRANCE TAVI (French Transcatheter Aortic Valve Implantation) registry. Findings were further compared with those reported from the FRANCE 2 (French Aortic National CoreValve and Edwards 2) registry, which captured all TAVRs performed from January 2010 to January 2012 across 34 centers.

RESULTS A total of 12,804 patients from FRANCE TAVI and 4,165 patients from FRANCE 2 were included in this analysis. The median age of patients was 84.6 years, and 49.7% were men. FRANCE TAVI participants were older but at lower surgical risk (median logistic European System for Cardiac Operative Risk Evaluation [EuroSCORE]: 15.0% vs. 18.4%; $p < 0.001$). More than 80% of patients in FRANCE TAVI underwent transfemoral TAVR. Transesophageal echocardiography guidance decreased from 60.7% to 32.3% of cases, whereas more recent procedures were increasingly performed in hybrid operating rooms (15.8% vs. 35.7%). Rates of Valve Academic Research Consortium-defined device success increased from 95.3% in FRANCE 2 to 96.8% in FRANCE TAVI ($p < 0.001$). In-hospital and 30-day mortality rates were 4.4% and 5.4%, respectively, in FRANCE TAVI compared with 8.2% and 10.1%, respectively, in FRANCE 2 ($p < 0.001$ for both). Stroke and potentially life-threatening complications, such as annulus rupture or aortic dissection, remained stable over time, whereas rates of cardiac tamponade and pacemaker implantation significantly increased.

CONCLUSIONS The FRANCE TAVI registry provided reassuring data regarding trends in TAVR performance in an all-comers population on a national scale. Nonetheless, given that TAVR indications are likely to expand to patients at lower surgical risk, concerns remain regarding potentially life-threatening complications and pacemaker implantation. (Registry of Aortic Valve Bioprotheses Established by Catheter [FRANCE TAVI]; [NCT01777828](https://clinicaltrials.gov/ct2/show/study/NCT01777828)) (J Am Coll Cardiol 2017;70:42-55)
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Over the past decade, transcatheter aortic valve replacement (TAVR) has evolved from an emerging technique to mainstream therapy for patients with severe aortic stenosis who are deemed to have a prohibitive (1,2) or high (2–4) surgical risk. Growing experience and refined transcatheter devices allowed a shift toward simplified procedures as well as the performance of TAVR in lower-surgical risk patients (5,6). The publication of the PARTNER 2 (Placement of Aortic Transcatheter Valves 2) randomized trial (7) will likely accentuate this trend and result in an exponential increase in TAVR performance. Several registries provided valuable insights into the dissemination and outcomes of TAVR on a national basis (8–13). However, data relating to the evolution of patients and procedural characteristics, and outcomes over time on a nationwide scale, remain scarce (13–15). Moreover, most of these registries did not include data reflecting contemporary practice trends.

Following the end of the inclusion period of the FRANCE 2 (French Aortic National CoreValve and Edwards 2) registry (8) in January 2012, another national TAVR monitoring program, the FRANCE TAVI (French Transcatheter Aortic Valve Implantation) registry, was designed and launched in January 2013. In the present study, we report the characteristics and short-term outcomes of patients included in this registry. Furthermore, we provide a comparison with the FRANCE 2 registry patients to ascertain national patterns of changing procedural characteristics and clinical outcomes of TAVR recipients in France during a 6-year period.

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METHODS

Launched in January 2013, FRANCE TAVI is an initiative of GACI, the French Society of Cardiology's

ABBREVIATIONS AND ACRONYMS

ACC = American College of Cardiology

ESV = Edwards SAPIEN valve

EuroSCORE = European System for Cardiac Operative Risk Evaluation

FRANCE 2 = French Aortic National CoreValve and Edwards 2 registry

MCV = Medtronic CoreValve

PPI = permanent pacemaker implantation

STS = The Society of Thoracic Surgeons

TAVR = transcatheter aortic valve replacement

TVT = transcatheter valve therapy

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