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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 Bioprostheses Established by Catheter [FRANCE TAVI]; 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.

SEE PAGE 56

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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working group of interventional cardiology, with the participation of the French Society of Thoracic and Cardiovascular Surgery. Device manufacturers partly funded the registry but had no role in data collection or analysis or in manuscript preparation.

Designed as an all-comers registry, it prospectively includes data on all patients who underwent TAVR for severe aortic stenosis in 48 of 50 active TAVR centers in France and who volunteered to participate. FRANCE TAVI was designed in continuity with the FRANCE 2 registry (8) to provide further data on baseline characteristics of patients as well as procedural aspects and clinical outcomes of TAVR recipients on a national scale. A shortened version of the case report form from FRANCE 2 was used for FRANCE TAVI, but definitions remained identical between the 2 registries except for major bleeding and vascular complications (Online Appendix).

The decision to perform TAVR and the choices of approach and device used were made on the basis of assessment by a multidisciplinary heart team at each participating center, as previously described (8). Procedures and post-procedural management were performed in accordance with each site's routine protocol. A 30-day follow-up was recommended in the case report form and was performed either on site or by telephone contact with the patient and the patient's physician depending on each site's protocol. Patients included in the registry provided written informed consent for the procedure and for anonymous processing of their data. The registry was approved by the Institutional Review Board of the French Ministry of Higher Education and Research and by the National Commission for Data Protection and Liberties. FRANCE TAVI is supported by the French Society of Cardiology.

The FRANCE TAVI dataset was collected using a dedicated web-based interface from the French Society of Cardiology. All data, including in-hospital complications and follow-up, were site reported according to the definitions within the national dataset (Online Appendix). The database was managed by the French Society of Cardiology, which implemented regular data quality checks, including range checks and assessments of internal consistency. In cases of missing, extreme, or inconsistent values, centers were contacted and asked to verify and modify records as appropriate.

STUDY GROUP AND ENDPOINTS. For the purposes of this analysis, a FRANCE TAVI database encompassing all patients included from January 2, 2013, to

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*The key personnel, institutions, and organizations participating in the FRANCE TAVI Registry are listed in the Online Appendix.

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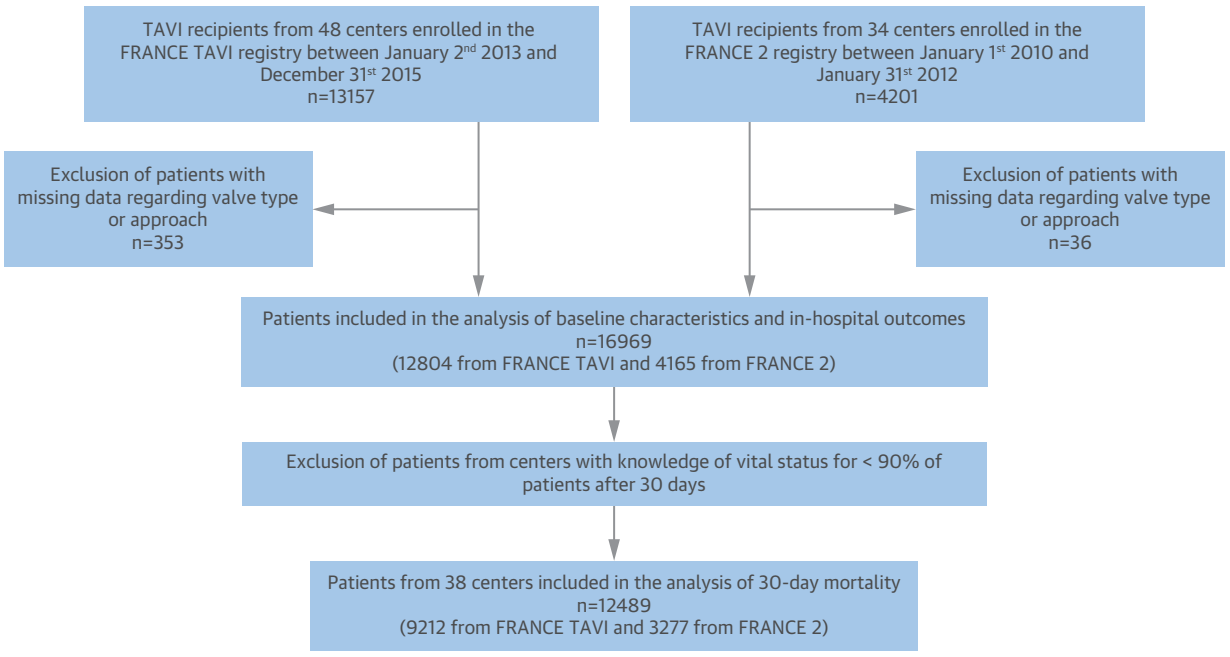
FIGURE 1 Study Flow Chart



Few patients in the FRANCE 2 (French Aortic National CoreValve and Edwards 2) and FRANCE TAVI (French Transcatheter Aortic Valve Implantation) registries were excluded for the initial analysis of baseline characteristics and hospital outcomes. TAVI = transcatheter aortic valve implantation.

December 31, 2015, was locked. To evaluate longitudinal changes in patients' characteristics, TAVR performance, and clinical outcomes over time, we used the data from FRANCE 2, which consecutively included all patients who underwent TAVR in France from January 2010 to January 31, 2012. Detailed methodology and definitions used in this registry have been published elsewhere (8). In both databases, patients with missing data on valve type or approach (n = 389) were excluded from the analysis (**Figure 1**). Baseline characteristics and in-hospital outcomes for these patients are documented in Online Table 1.

The primary endpoint of the study was in-hospital all-cause mortality reported in the full cohort. Secondary endpoints were in-hospital complications in the full cohort and 30-day all-cause mortality reported among centers in which vital status after 30 days was known for at least 90% of patients, to ensure the comparability of follow-up completeness between registries. Baseline characteristics and in-hospital outcomes of patients with versus without reported 30-day follow-up are presented in Online Table 2.

In cases of discrepancies in definitions of patients' characteristics or outcomes between the 2 registries, no formal statistical comparison was made between the 2 groups of patients, and data of the FRANCE TAVI group were reported separately.

STATISTICAL ANALYSIS. Because data came from multiple recruitment centers, 2-level analyses were used to assess whether patients' characteristics, procedural data, and outcomes were different according to registry (FRANCE 2 or FRANCE TAVI) or year of inclusion, by taking into account the effects of potential common context of patients (first level) recruited in different centers (second level). For these 2 levels of analyses, patients' characteristics or outcomes were used as predicted variables, and registry or year of inclusion was an explanatory variable. Depending on the predicted variable's type, different models were used: a 2-level linear model for continuous data; a 2-level logistic model for dichotomous data; and a 2-level multinomial logit model for polytomous data. Analyses according to year of inclusion were limited to centers that participated in both registries, and the ordinal effect of year of inclusion was tested by inserting the variable in its continuous form in the relevant model. Statistical analyses were performed using Stata Statistical Software release 10 (StataCorp, LLC, College Station, Texas). Given that

TABLE 1 Baseline Characteristics

	FRANCE 2 (n = 4,165)	FRANCE TAVI (n = 12,804)	p Value
Clinical characteristics			
Age, yrs	82.8 ± 7.1	83.4 ± 7.2	0.001
Median	84.3 (79.3–87.8)	84.7 (80.4–88.1)	
Male	2,111/4,165 (50.7)	6,314/12,804 (49.3)	0.065
Body mass index, kg/m^2	26.0 ± 5.0 4,156	26.5 ± 5.3 12,623	<0.001
Logistic EuroSCORE, %	21.7 ± 14.2 4,045	17.9 ± 12.3 12,341	<0.001*
Median	18.4 (11.4–28.5)	15.0 (9.5–23.0)	
<10	797 (19.7)	3,244 (26.3)	
10–19	1,415 (35.0)	4,894 (39.7)	
20–39	1,400 (34.6)	3,469 (28.1)	
≥40	433 (10.7)	734 (5.9)	
NYHA functional class III or IV	3,124/4,157 (75.2)	8,269/12,241 (67.6)	<0.001
≥2 APE within previous year	484/4,142 (11.7)	1,715/1,2038 (14.3)	<0.001
Clinical history			
Coronary artery disease†	1,851/4,149 (44.6)	5,093/11,961 (42.6)	0.117
Previous myocardial infarction <90 days	51/4,158 (1.2)	238/12,622 (1.9)	0.018
Previous CABG	730/4,149 (17.6)	1,441/12,684 (11.4)	<0.001
Previous SAVR	69/4,149 (1.7)	559/12,659 (4.4)	<0.001
Previous permanent pacemaker	597/4,145 (14.4)	1,807/12,655 (14.3)	0.769
Atrial fibrillation	1,070/4,108 (26.1)	2,763/11,119 (24.9)	<0.001
Previous stroke/TIA	411/4,149 (9.9)	1,395/12,631 (11.0)	0.074
Diabetes mellitus	1,045/4,149 (25.2)	3,271/12,617 (25.9)	0.314
Peripheral vascular disease	1,139/4,158 (27.4)	2,853/12,629 (22.6)	<0.001
Chronic pulmonary disease	1,009/4,149 (24.3)	2,551/12,641 (20.2)	<0.001
Serum creatinine ≥200 μmol/l	354/4,158 (8.5)	635/12,178 (5.2)	<0.001
Renal dialysis	104/4,149 (2.5)	235/12,443 (1.9)	0.025
Life expectancy <1 yr	96/4,149 (2.3)	356/12,261 (2.9)	<0.001
Echocardiographic findings			
Ejection fraction, %	53.2 ± 14.2 4,104	55.2 ± 13.6 12,378	<0.001
Median	55 (45–65)	60 (45–65)	
<50%	1,382 (33.7)	3,400/12,378 (27.5)	<0.001
Aortic valve area, cm^2	0.67 ± 0.18 3,911	0.69 ± 0.26 11,569	<0.001
Aortic annulus, mm	22.2 ± 2.2 3,828	23.6 ± 2.7 11,340	<0.001
Aortic mean gradient, mm Hg	48.1 ± 16.5 4,047	47.2 ± 15.9 12,340	0.001
Moderate or severe AR	735/3,931 (18.7)	2,118/10,118 (20.9)	0.065
Moderate or severe MR	850/3,940 (21.6)	2,369/10,498 (22.6)	0.792
Severe PH (sPAP >60 mm Hg)	419/3,221 (13.0)	1,280/9,715 (13.2)	0.924

Values are mean ± SD, median (IQR), n/N (%), n, or n (%). *Test performed using log-transformed variable. †Presence of at least 1 significant lesion (≥50%) on the pre-procedural coronary angiogram.

APE = acute pulmonary edema; AR = aortic regurgitation; CABG = coronary artery bypass graft; EuroSCORE = European System for Cardiac Operative Risk Evaluation; FRANCE 2 = French Aortic National CoreValve and Edwards 2 registry; FRANCE TAVI = French Transcatheter Aortic Valve Implantation registry; IQR = interquartile range; MR = mitral regurgitation; NYHA = New York Heart Association; PH = pulmonary hypertension; SAVR = surgical aortic valve replacement; sPAP = systolic pulmonary artery pressure; TIA = transient ischemic attack.

few patients were included in the FRANCE 2 registry during January 2012 (n = 221), TAVR cases performed in 2011 and 2012 within this registry were grouped together for the purpose of descriptive analysis. All tests were 2-sided at the 0.05 significance level.

RESULTS

This analysis included a total of 12,804 patients entered into FRANCE TAVI from January 2013 to December 2015 and 4,165 patients enrolled in the FRANCE 2 registry from January 2010 to January 2012 (Figure 1). Baseline characteristics of the study group are summarized in Table 1.

The median age of these patients was 84.6 years (interquartile range [IQR]: 80.1 to 88.0 years), and 49.7% were men. Overall, FRANCE TAVI participants were older, had lower surgical risk as estimated by the logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE 1), and were less likely to present with coexisting conditions or severe symptoms. The rate of patients with a previous surgical aortic valve replacement markedly increased from 1.7% in FRANCE 2 to 4.4% in FRANCE TAVI (p < 0.001). Regarding echocardiographic findings, FRANCE TAVI participants had a larger aortic annulus and lower rates of impaired left ventricular function.

Table 2 shows linear trends in baseline characteristics over time among centers that participated in both registries (31 centers; n = 13,745). The percentage of octogenarians increased from 69.8% in 2010 to 76.9% in 2014 to 2015, whereas the logistic EuroSCORE gradually decreased over time, with only 28.8% of patients with a score ≥20% in 2015 compared with 51.1% in 2010. The median logistic EuroSCORE decreased from 20.3% (IQR: 12.1% to 30.8%) to 13.6% (IQR: 9.0% to 21.0%) over the study period. This trend was consistently observed whether the valve used was the Edwards SAPIEN valve (ESV; Edwards Lifesciences, Irvine, California) or the Medtronic CoreValve (MCV; Medtronic, Minneapolis, Minnesota) or whether the valve was delivered transfemorally; increasing age was observed only within transfemoral TAVR and MCV recipients (Online Tables 3 to 5). Interestingly, "valve-in-valve" procedures accounted for almost 10% of MCV recipients in 2015.

Within FRANCE TAVI, clinical characteristics of ESV and MCV recipients were mainly comparable (Online Table 6). In contrast, patients who underwent transfemoral and nontransfemoral procedures had major differences in baseline characteristics (Online Table 7).

PROCEDURAL CHARACTERISTICS. Although ESV and MCV were used exclusively in FRANCE 2, other devices (Lotus, Boston Scientific, Natick, Massachusetts; Direct Flow Medical, Santa Rosa, California; Centera, Edwards Lifesciences; Portico, St. Jude Medical, St. Paul, Minnesota; and JenaValve, Irvine,

TABLE 2 Baseline Characteristics per Year of Inclusion Within Centers Involved in Both Registries

	FRANCE 2		FRANCE TAVI			
	2010 (n = 1,378)	2011/2012 (n = 2,385)	2013 (n = 2,512)	2014 (n = 3,177)	2015 (n = 4,293)	p Value for Trend
Clinical characteristics						
Age, yrs	82.4 ± 7.3 1,378	82.9 ± 7.2 2,385	83.1 ± 7.5 2,512	83.2 ± 7.3 3,177	83.0 ± 7.3 4,293	0.01
Median	83.8 (78.6–87.6)	84.4 (79.7–87.8)	84.5 (80.2–87.9)	84.5 (80.1–88.2)	84.3 (80.2–87.8)	
Male	705/1,378 (51.2)	1,207/2,385 (50.6)	1,226/2,512 (48.8)	1,551/3,177 (48.8)	2,122/4,293 (49.4)	0.126
Body mass index, kg/m^2	26.0 ± 5.1 1,372	26.1 ± 5.0 2,382	26.5 ± 5.2 2,483	26.5 ± 5.3 3,151	26.6 ± 5.2 4,194	<0.001
Logistic EuroSCORE, %	23.2 ± 14.7 1,325	20.5 ± 14.0 2,318	18.7 ± 12.5 2,410	17.7 ± 12.1 3,059	16.7 ± 11.6 4,131	<0.001*
Median	20.3 (12.1–30.8)	16.7 (10.4–27.1)	15.3 (10.0–24.0)	15.0 (9.5–23.0)	13.6 (9.0–21.0)	
<10	232 (17.5)	527 (22.7)	564 (23.4)	804 (26.3)	1,234 (29.9)	
10–19	416 (31.4)	862 (37.2)	949 (39.4)	1,221 (39.9)	1,709 (41.4)	
20–39	505 (38.1)	705 (30.4)	718 (29.8)	869 (28.4)	1,005 (24.3)	
≥40	172 (13.0)	224 (9.7)	179 (7.4)	165 (5.4)	183 (4.4)	
NYHA functional class III or IV	1,040/1,378 (75.6)	1,750/2,381 (73.5)	1,706/2,460 (69.4)	2,047/3,074 (66.6)	2,546/4,041 (63.0)	<0.001
≥2 APE within previous year	191/1,374 (13.9)	261/2,367 (11.0)	322/2,424 (13.3)	386/3,025 (12.8)	516/4,066 (12.7)	0.137
Clinical history						
Coronary artery disease†	593/1,375 (43.1)	1,078/2,372 (45.5)	976/2,340 (41.7)	1,281/3,006 (42.6)	1,646/3,858 (42.7)	0.338
Previous myocardial infarction <90 days	17/1,377 (1.2)	32/2,379 (1.4)	54/2,476 (2.2)	46/3,145 (1.5)	62/4,207 (1.5)	0.555
Previous CABG	275/1,375 (20.0)	374/2,372 (15.8)	314/2,499 (12.6)	345/3,164 (10.9)	416/4,211 (9.9)	<0.001
Previous SAVR	22/1,375 (1.6)	41/2,372 (1.7)	78/2,498 (3.1)	146/3,158 (4.6)	214/4,199 (5.1)	<0.001
Previous permanent pacemaker	205/1,371 (15.0)	342/2,372 (14.4)	382/2,487 (15.4)	452/3,157 (14.3)	554/4,212 (13.2)	0.076
Atrial fibrillation	378/1,356 (27.9)	605/2,352 (25.7)	583/2,273 (25.7)	676/2,865 (23.6)	771/3,406 (22.6)	<0.001
Previous stroke/TIA	139/1,375 (10.1)	231/2,372 (9.7)	276/2,490 (11.1)	371/3,151 (11.8)	428/4,211 (10.2)	0.590
Diabetes mellitus	375/1,375 (27.3)	588/2,372 (24.8)	640/2,487 (25.7)	798/3,144 (25.4)	1,097/4,208 (26.1)	0.949
Peripheral vascular disease	436/1,377 (31.7)	580/2,379 (24.4)	531/2,495 (21.3)	655/3,161 (20.7)	887/4,212 (21.1)	<0.001
Chronic pulmonary disease	359/1,375 (26.1)	572/2,372 (24.1)	561/2,499 (22.5)	618/3,156 (19.6)	631/4,210 (15.0)	<0.001
Serum creatinine ≥200 μmol/l	148/1,377 (10.8)	161/2,379 (6.8)	131/2,443 (5.4)	180/3,054 (5.9)	188/4,014 (4.7)	<0.001
Renal dialysis	44/1,375 (3.2)	51/2,372 (2.2)	56/2,481 (2.3)	67/3,127 (2.1)	61/4,072 (1.5)	<0.001
Life expectancy <1 yr	50/1,375 (3.6)	44/2,372 (1.9)	104/2,409 (4.3)	80/3,043 (2.6)	144/4,036 (3.6)	0.146
Echocardiographic findings						
Ejection fraction, %	52.4 ± 14.5 1,359	53.5 ± 14.1 2,347	54.3 ± 13.8 2,439	54.6 ± 13.5 3,099	55.6 ± 13.2 4,109	<0.001
Median	55 (40–64)	55 (45–65)	57 (45–65)	59 (45–65)	60 (49–65)	
<50%	490 (36.1)	773 (32.9)	755 (31.0)	857 (27.7)	1,046 (25.5)	<0.001
Aortic valve area, cm^2	0.66 ± 0.18 1,300	0.67 ± 0.18 2,221	0.68 ± 0.24 2,319	0.69 ± 0.23 2,877	0.71 ± 0.25 3,766	<0.001
Aortic annulus, mm	22.0 ± 2.1 1,268	22.3 ± 2.2 2,177	23.4 ± 2.7 2,230	23.4 ± 2.6 2,797	23.7 ± 2.7 3,726	<0.001
Aortic mean gradient, mm Hg	47.8 ± 16.6 1,348	48.2 ± 16.4 2,305	47.3 ± 15.9 2,444	47.1 ± 15.6 3,078	47.1 ± 15.9 4,059	0.003
Moderate or severe AR	234/1,289 (18.2)	446/2,247 (19.9)	401/1,867 (21.5)	572/2,725 (21.0)	734/3,227 (22.8)	0.051
Moderate or severe MR	300/1,296 (23.1)	497/2,253 (22.1)	468/2,139 (21.9)	594/2,757 (21.6)	773/3,264 (23.7)	0.992
Severe PH (sPAP >60 mm Hg)	157/1,079 (14.5)	223/1,818 (12.3)	268/1,964 (13.7)	319/2,485 (12.8)	360/3,015 (11.9)	0.109

Values are mean ± SD, n, median (IQR), n/N (%), or n (%). *Test performed using log-transformed variable. †Presence of at least 1 significant lesion (≥50%) on the pre-procedural coronary angiogram.
Abbreviations as in Table 1.

California) were available but seldom used in FRANCE TAVI (Table 3). There was a slight but significant decrease in ESV implantations, which nevertheless represented ~65% of TAVR procedures overall.

Transfemoral access increased in FRANCE TAVI compared with FRANCE 2, whereas there was a dramatic decrease in the use of transapical access in ESV recipients, from 27.9% in 2010 to 4.7% in 2015 among centers that participated in both registries ($p < 0.001$). However, nonfemoral approaches were still used in 17.2% of cases in FRANCE TAVI because of an increase in alternative approaches, especially direct aortic access in 698 patients (5.5%) and transcarotid access in 435 patients (3.4%).

TABLE 3 Procedural Characteristics

	FRANCE 2 (n = 4,165)	FRANCE TAVI (n = 12,804)	p Value
Location			
Catheterization laboratory	3,006/4,164 (72.2)	7,573/12,746 (59.4)	ref
Operating room	460/4,164 (11.0)	625/12,746 (4.9)	<0.001
Hybrid room	698/4,164 (15.8)	4,548/12,746 (35.7)	<0.001
General anesthesia	2,862/4,164 (68.7)	6,531/12,645 (51.7)	<0.001
TEE guidance	2,527/4,164 (60.7)	3,672/11,373 (32.3)	<0.001
Approach			
Transfemoral	3,058 (73.4)	10,602 (82.8)	ref
Transapical	732 (17.6)	541 (4.2)	<0.001
Subclavian	241 (5.8)	385 (3.0)	<0.001
Others	134 (3.2)	1,276 (10.0)	<0.001
Valve type			
Edwards SAPIEN*	2,759 (66.2)	8,232 (64.3)	ref
Medtronic CoreValve	1,406 (33.8)	4,465 (34.9)	<0.001
Others	0 (0.0)	107 (0.8)	–
Need for a second valve	94 (2.3)	236 (1.8)	0.155
Conversion to surgery	49 (1.2)	65/12,557 (0.5)	<0.001
Device success	3,970 (95.3)	12,139/12,544 (96.8)	<0.001

Values are n/N (%) or n (%). *Including all iterations (SAPIEN, SAPIEN XT, SAPIEN 3).
TEE = transesophageal echocardiography; other abbreviations as in Table 1.

Most procedures were performed in catheterization laboratories, although there was a significant decrease in their usage rate in favor of hybrid operating rooms from FRANCE 2 to FRANCE TAVI (Table 3). During the study period, a gradual shift toward simplified procedures was observed. In centers participating in both registries, general anesthesia and transesophageal guidance decreased from 70.3% to 47.2% and from 64.1% to 26.7%, respectively (Table 4).

Although there was no significant change in the need for a second valve in FRANCE TAVI (1.8 vs. 2.3%; p = 0.16) (Tables 3 and 4), device success significantly increased (96.8 vs. 95.3%; p < 0.001). Within FRANCE TAVI, the use of MCV, compared with ESV implantation, was associated with a lower rate of transfemoral approach use (80.7 vs. 83.8%; p < 0.001), a higher risk of need for a second valve (3.6% vs. 0.9%; p < 0.001), and a lower rate of procedural success (94.4% vs. 98.1%; p < 0.001). Procedural success was comparable between transfemoral and nontransfemoral approaches (96.7% vs. 97.1%; p = 0.20).

IN-HOSPITAL AND 30-DAY OUTCOMES. In-hospital deaths primarily had cardiovascular causes; the in-hospital mortality rate decreased gradually over time and was significantly lower in FRANCE TAVI than in FRANCE 2 (4.4% vs. 8.1%; p < 0.001) (Tables 5 and 6). By 2015, in-hospital mortality rates of 2.4%, 3.4%, 2.4%, and 4.2% were achieved in ESV, MCV, transfemoral, and nontransfemoral TAVR recipients, respectively, who were treated in centers participating in both registries, thus resulting in an overall in-hospital mortality rate of 2.7%. In-hospital outcomes according to valve type and approach within the FRANCE TAVI group are summarized in Online Tables 8 and 9.

The rate of patients discharged by day 5 post-TAVR increased from 11.9% to 24.7% from FRANCE 2 to FRANCE TAVI (p < 0.001). Infrequent complications (annulus rupture, aortic dissection, valve migration) did not significantly decrease over time, and rates of cardiac tamponade significantly increased (Table 5). Stroke rates were low and comparable (2.0% in FRANCE 2 and 2.0% in FRANCE TAVI; p = 0.82). Importantly, permanent pacemaker implantation (PPI) increased from 12.6% in FRANCE 2 to 17.5% in FRANCE TAVI (p < 0.001) because of a marked increase in ESV recipients (from 8.4% in 2010 to 15.1% in 2015 among centers participating in both registries). Within FRANCE TAVI, the rates of major bleeding and vascular complications requiring surgical or percutaneous interventions were 8.9% and 7.7%, respectively.

Among patients with an immediate pre-discharge echocardiogram, the rate of moderate or severe aortic regurgitation was significantly lower in FRANCE TAVI compared with FRANCE 2 (10.2% vs. 15.7%; p < 0.001), mainly because of ESV recipients, who had a 7.4% rate of moderate to severe aortic regurgitation compared with 15.1% among MCV recipients (p < 0.001) (Online Table 8).

A total of 12,489 patients from 38 centers that documented vital status for ≥90% of their TAVR patients were included in the 30-day mortality analysis (Table 5). Among these patients, 99.5% of the 3,277 patients from FRANCE 2 and 97.4% of the 9,212 patients from FRANCE TAVI had a known 30-day vital status. Mortality rates were 10.1% versus 5.4% among patients from FRANCE 2 and FRANCE TAVI, respectively (p < 0.001).

IMPACT OF TAVR ADOPTION. To evaluate the impact of centers starting their TAVR program following the inclusion period of FRANCE 2, we compared, within the FRANCE TAVI group, patients enrolled at centers that participated in both registries with patients enrolled at centers that participated in the FRANCE TAVI registry only (Online Tables 10 to 12). The latter patients were older, with a nonsignificantly higher surgical risk. These patients treated at centers that participated only in the FRANCE TAVI registry also were more likely to have undergone transfemoral access (89.6% vs. 80.9%; p < 0.001), with a

TABLE 4 Procedural Characteristics per Year of Inclusion Within Centers Involved in Both Registries

	FRANCE 2		FRANCE TAVI			
	2010 (n = 1,378)	2011/2012 (n = 2,385)	2013 (n = 2,512)	2014 (n = 3,177)	2015 (n = 4,293)	p Value for Trend
Location						
Catheterization laboratory	993 (72.1)	1,692 (70.9)	1,641/2,511 (65.4)	1,998/3,172 (63.0)	2,339/4,267 (54.8)	ref
Operating room	154 (11.2)	302 (12.7)	141/2,511 (5.6)	1,16/3,172 (3.7)	307/4,267 (7.2)	0.026
Hybrid room	231 (16.8)	391 (16.4)	729/2,511 (29.0)	1,058/3,172 (33.3)	1,621/4,267 (38.0)	<0.001
General anesthesia	968 (70.3)	1,497/2,384 (62.8)	1,364/2,504 (54.5)	1,839/3,162 (58.2)	1,991/4,222 (47.2)	<0.001
TEE guidance	883 (64.1)	1,281/2,384 (53.7)	866/2,322 (37.3)	1,041/2,937 (35.4)	964/3,616 (26.7)	<0.001
Approach						
Transfemoral	1,036 (75.2)	1,712 (71.8)	1,976 (78.7)	2,534 (79.8)	3,563 (83.0)	ref
Transapical	265 (19.2)	390 (16.3)	178 (7.1)	144 (4.5)	166 (3.9)	<0.001
Subclavian	70 (5.1)	164 (6.9)	120 (4.8)	101 (3.2)	114 (2.7)	<0.001
Others	7 (0.5)	119 (5.0)	238 (9.5)	398 (12.5)	450 (10.5)	<0.001
Valve type						
Edwards SAPIEN*	958 (69.5)	1,533 (64.3)	1,466 (58.4)	1,868 (58.8)	3,015 (70.2)	ref
Medtronic CoreValve	420 (30.5)	852 (35.7)	1,027 (40.9)	1,270 (40.0)	1,230 (28.7)	0.004
Others	0 (0.0)	0/2,376 (0.0)	19 (0.7)	39 (1.2)	48 (1.1)	–
Need for a second valve	28 (2.0)	55 (2.3)	58 (2.3)	72 (2.3)	56 (1.3)	0.012
Conversion to surgery	18 (1.3)	26 (1.1)	21/2,501 (0.8)	19/3,151 (0.6)	15/4,162 (0.4)	<0.001
Device success	1,315 (95.4)	2,275 (95.4)	2,332/2,441 (95.5)	2,995/3,106 (96.4)	4,158/4,248 (97.9)	<0.001

Values are n (%) or n/N (%). *Including all iterations (SAPIEN, SAPIEN XT, SAPIEN 3).
Abbreviations as in Tables 1 and 3.

numerically higher use of ESVs (66.7% vs. 63.6%; p = 0.77) and conscious sedation (51.5% vs. 47.5%; p = 0.33). Procedural success, however, was comparable between groups (96.5% vs. 96.8%; p = 0.55), and there was no difference in in-hospital mortality rates (5.0% vs. 4.2%; p = 0.14).

DISCUSSION

The present analysis is the first report of the second national French TAVR monitoring program, with a systematic comparison with its predecessor for evaluating TAVR performance trends across France during a 6-year period (**Central Illustration**). The chief findings of our analysis are as follows: 1) significant changes in baseline characteristics of patients occurred with an important decrease in estimated surgical risk over time, thus reflecting lower rates of comorbidities within FRANCE TAVI despite the inclusion of older patients; 2) >80% of patients benefited from the "transfemoral first" policy adopted by centers, whereas transapical access declined significantly in favor of alternative procedural access; 3) approximately 50% and 70% of procedures were performed using conscious sedation and without transesophageal guidance, respectively, with sustained procedural success; 4) in-hospital and 30-day mortality rates were significantly lower in FRANCE TAVI (4.4% and 5.4%, respectively); 5) infrequent but life-threatening complications did not decline over time, with a significant increase in cardiac tamponade rates; and 6) PPI rates markedly increased, especially within ESV recipients.

Unlike previous reports of large multicenter registries (13,14), we demonstrated highly significant changes in baseline characteristics and risk profile of TAVR recipients across France. The improved patient risk profile at baseline (evidenced by a steep decrease in the logistic EuroSCORE) was perhaps the most striking change. Several reasons could explain this trend. First, the favorable outcomes and sustained midterm hemodynamic performances demonstrated in high-risk patients with both ESV and MCV (16,17) could have encouraged the performance of TAVR in lower-risk patients. Second, operators may have been influenced by the current trends in published reports that highlight predictors of early and late death post-TAVR, as well as factors associated with procedural futility (14,16-19). Indeed, rates of coexisting conditions, such as chronic pulmonary disease, peripheral vascular disease, chronic kidney disease, or left ventricular dysfunction that have been independently linked to an increased mortality rate (12,14,16,18-20), were all lower in FRANCE TAVI. Despite a lack of specificity in the TAVR setting, a logistic EuroSCORE ≥40% is a well-known predictor of higher early and late death (14), and it was uncommon (6%) in FRANCE TAVI. The logistic EuroSCORE, albeit less

TABLE 5 Outcomes

	FRANCE 2 (n = 4,165)	FRANCE TAVI (n = 12,804)	p Value
In-hospital outcomes			
Time from implantation to discharge			<0.001*
Median, days	9 (7–13) 4,086	8 (6–11) 12,672	
1–5	484 (11.9)	3,132 (24.7)	
6–9	1,758 (43.0)	5,744 (45.3)	
≥10	1,844 (45.1)	3,796 (30.0)	
Complications			
Death			<0.001
From all-cause	339 (8.1)	562 (4.4)	
Cause of death			
CV death	210/339 (62.0)	370/562 (66.0)	ref
Non-CV death	112/339 (33.0)	160/562 (28.3)	0.205
Unknown	17/339 (5.0)	32/562 (5.7)	0.798
Annulus rupture	14 (0.3)	52/12,557 (0.4)	0.643
Aortic dissection	10 (0.2)	46/12,557 (0.4)	0.234
Valve migration	56 (1.3)	139/12,557 (1.1)	0.202
Tamponade	56 (1.3)	256/12,557 (2.0)	0.004
Stroke	83 (2.0)	249/12,557 (2.0)	0.824
STEMI	34 (0.8)	27/12,557 (0.2)	<0.001
Permanent pacemaker implantation†	446/3,548 (12.6)	1,870/10,681 (17.5)	<0.001
Pulmonary embolism	5 (0.1)	18/12,557 (0.1)	0.669
Renal failure	195 (4.7)	480/12,557 (3.8)	0.049
Renal dialysis	54 (1.3)	86/12,557 (0.7)	<0.001
Echocardiographic findings			
Aortic valve area, cm^2	1.81 ± 0.50 2,175	1.76 ± 0.56 4,724	<0.001
Aortic mean gradient, mm Hg	10.6 ± 5.4 3,481	10.3 ± 6.3 10,684	0.224
Moderate or severe AR	565/3,611 (15.7)	1,119/11,007 (10.2)	<0.001
Moderate or severe MR	550/3,426 (15.8)	1,519/9,544 (15.9)	0.379
Vital status after 30 days‡			
Dead	330/3,277 (10.1)	493/9,212 (5.4)	<0.001
Alive	2,932/3,277 (89.4)	8,480/9,212 (92.1)	ref
Unknown	15/3,277 (0.5)	2,39/9,212 (2.6)	<0.001
Cause of death			
CV death	193/330 (58.5)	310/493 (62.9)	ref
Non-CV death	108/330 (32.7)	147/493 (29.8)	0.396
Unknown	29/304 (8.8)	36/493 (7.3)	0.393

Values are median (IQR), n, n (%), n/N (%), or mean ± SD. *Test performed using log-transformed variable. †Numbers are given for patients without prior permanent pacemaker. ‡In a subgroup of 12,489 subjects from 38 centers with sufficient follow-up data (centers in which vital status after 30 days was known for at least 90% of the patients). Among these centers, vital status follow-up was complete for 99.5% of the FRANCE 2 patients and 97.4% of the FRANCE TAVI patients, thus leading to rates of 0.5% and 2.6% of unknown 30-day vital status, respectively.

CV = cardiovascular; STEMI = ST-segment elevation myocardial infarction; other abbreviations as in Table 1.

accurate than the Society of Thoracic Surgeons (STS) scoring system among TAVR recipients, is the most established score in Europe for evaluating operative risk (21). This score is calculated on the basis of death from all cardiac surgical procedures; however, its development cohort mainly included patients undergoing coronary artery bypass grafting. It consists of an online EuroSCORE calculator that includes 17 baseline and procedural variables, which provide a 30-day predicted mortality rate with a cutoff of >20% representing high-risk patients. Similar to the STS score, it imperfectly captures some comorbidities, such as frailty, cirrhosis, porcelain aorta, or hostile chest. Interestingly, the STS score and the logistic EuroSCORE provide similar estimated mortality rates for low-risk patients, whereas the logistic EuroSCORE tends consistently to overestimate the operative risk among high-risk patients (21). Third, early nonrandomized reports demonstrating TAVR results comparable to those of surgical aortic valve replacement and superior to those observed in high-risk patients among lower-surgical risk groups also likely contributed to these patterns in procedural evolution (22,23). Finally, the aging of TAVR recipients could reflect the reluctance of some heart teams to perform operations in octogenarians, even patients with minimal comorbidities; thus the teams adopted a TAVR policy for these patients. Although differing commissioning structures may play a significant role in differences in the evolution of baseline characteristics observed over time from 1 national registry to another (13,14), the inclusion of patients treated in 2015 whose changes were even more pronounced likely accentuated discrepancies between the present report and previous reports from other national registries.

The evolution toward a more simplified TAVR procedure is another major finding of the present report. Although the contribution of approach per se has been debated, transfemoral access seems to have mortality and morbidity benefits that justify its use as a first-line strategy (24). The increasing availability of smaller delivery systems enabled this approach to be used increasingly over time, ultimately in >80% of FRANCE TAVI patients overall. Conversely, we observed a dramatic decline in transapical access, with rates much lower than the ~25% to 30% reported in previous registries (9,10,14). However, such a trend was also reported by the STS/American College of Cardiology (ACC) transcatheter valve therapy (TVT) registry for procedures performed in 2014 within the United States (13). Future reports should focus on outcomes of newer alternative approaches (e.g., direct aortic, transcarotid).

Local anesthesia provided good clinical outcomes compared with general anesthesia in a propensity-matched analysis of the FRANCE 2 registry (25). Concerns also emerged regarding a higher rate of significant paravalvular leak associated with this technique, which does not allow periprocedural transesophageal guidance. However, despite the widespread use of local anesthesia in FRANCE TAVI, device success was greater, and moderate or severe

TABLE 6 Outcomes per Year of Inclusion Within Centers Involved in Both Registries

	FRANCE 2		FRANCE TAVI			
	2010 (n = 1,378)	2011/2012 (n = 2,385)	2013 (n = 2,512)	2014 (n = 3,177)	2015 (n = 4,293)	p Value for Trend
In-hospital outcomes						
Time from implantation to discharge						<0.001*
Median, days	9 (7–13) 1,358	9 (7–13) 2,328	8 (6–12) 2,502	8 (6–11) 3,166	7 (5–10) 4,245	
1–5	135 (9.9)	298 (12.8)	553 (22.1)	684 (21.6)	1,193 (28.1)	
6–9	556 (41.0)	998 (42.9)	1,056 (42.2)	1,416 (44.7)	1,927 (45.4)	
≥10	667 (49.1)	1,032 (44.3)	893 (35.7)	1,066 (33.7)	1,125 (26.5)	
Complications						
Death						
From all-cause	119 (8.6)	186 (7.8)	150 (6.0)	156 (4.9)	115 (2.7)	<0.001
Cause of death						
CV death	68/119 (57.1)	119/186 (64.0)	102/150 (68.0)	96/156 (61.5)	71/115 (61.7)	ref
Non-CV death	41/119 (34.5)	61/186 (32.8)	40/150 (26.7)	57/156 (36.5)	28/115 (24.4)	0.413
Unknown	10/119 (8.4)	6/186 (3.2)	8/150 (5.3)	3/156 (1.9)	16/115 (13.9)	0.236
Annulus rupture	4 (0.3)	9 (0.4)	13/2,501 (0.5)	14/3,151 (0.4)	9/4,162 (0.2)	0.404
Aortic dissection	3 (0.2)	6 (0.3)	15/2,501 (0.6)	11/3,151 (0.4)	7/4,162 (0.2)	0.437
Valve migration	19 (1.4)	31 (1.3)	34/2,501 (1.4)	36/3,151 (1.1)	44/4,162 (1.1)	0.204
Tamponade	22 (1.6)	23 (1.0)	51/2,501 (2.0)	60/3,151 (1.9)	79/4,162 (1.9)	0.027
Stroke	24 (1.7)	57 (2.4)	57/2,501 (2.3)	66/3,151 (2.1)	66/4,162 (1.6)	0.149
STEMI	8 (0.6)	24 (1.0)	12/2,501 (0.5)	5/3,151 (0.2)	5/4,162 (0.1)	<0.001
Permanent pacemaker implantation†	158/1,166 (13.6)	268/2,030 (13.2)	342/2,096 (16.3)	505/2,684 (18.8)	659/3,587 (18.4)	<0.001
Pulmonary embolism	2 (0.2)	2 (0.1)	2/2,501 (0.1)	4/3,151 (0.1)	8/4,162 (0.2)	0.336
Renal failure	74 (5.4)	102 (4.3)	142/2,501 (5.7)	129/3,151 (4.1)	141/4,162 (3.4)	<0.001
Renal dialysis	23 (1.7)	26 (1.1)	21/2,501 (0.8)	32/3,151 (1.0)	17/4,162 (0.4)	<0.001
Echocardiographic findings						
Aortic valve area, cm^2	1.76 ± 0.50 697	1.82 ± 0.52 1,270	1.73 ± 0.55 1,014	1.74 ± 0.57 1,187	1.67 ± 0.50 1,409	<0.001
Aortic mean gradient, mm Hg	10.9 ± 5.8 1,169	10.5 ± 5.3 2,002	9.7 ± 6.9 2,188	9.8 ± 5.7 2,649	11.5 ± 6.7 3,426	<0.001
Moderate or severe AR	203/1,202 (16.9)	330/2,071 (15.9)	301/2,259 (13.3)	333/2,749 (12.1)	306/3,505 (8.7)	<0.001
Moderate or severe MR	190/1,154 (16.5)	323/1,990 (16.2)	324/1,975 (16.4)	382/2,451 (15.6)	480/2,931 (16.4)	0.392
Vital status after 30 days‡						
Dead	105/1,021 (10.3)	182/1,854 (9.8)	148/2,043 (7.2)	143/2,462 (6.0)	114/3,411 (3.3)	<0.001
Alive	912/1,021 (89.3)	1663/1,854 (89.7)	1,877/2,043 (91.9)	2,283/2,462 (92.7)	3,130/3,411 (91.8)	ref
Unknown	4/1,021 (0.4)	9/1,854 (0.5)	18/2,043 (0.9)	36/2,462 (1.5)	167/3,411 (4.9)	<0.001
Cause of death						
CV death	58/105 (55.2)	107/182 (58.8)	97/148 (65.6)	82/143 (57.3)	68/114 (59.7)	ref
Non-CV death	36/105 (34.3)	58/182 (31.9)	40/148 (27.0)	53/143 (37.1)	33/114 (28.9)	0.868
Unknown	11/105 (10.5)	17/182 (9.3)	11/148 (7.4)	8/143 (5.6)	13/114 (11.4)	0.777

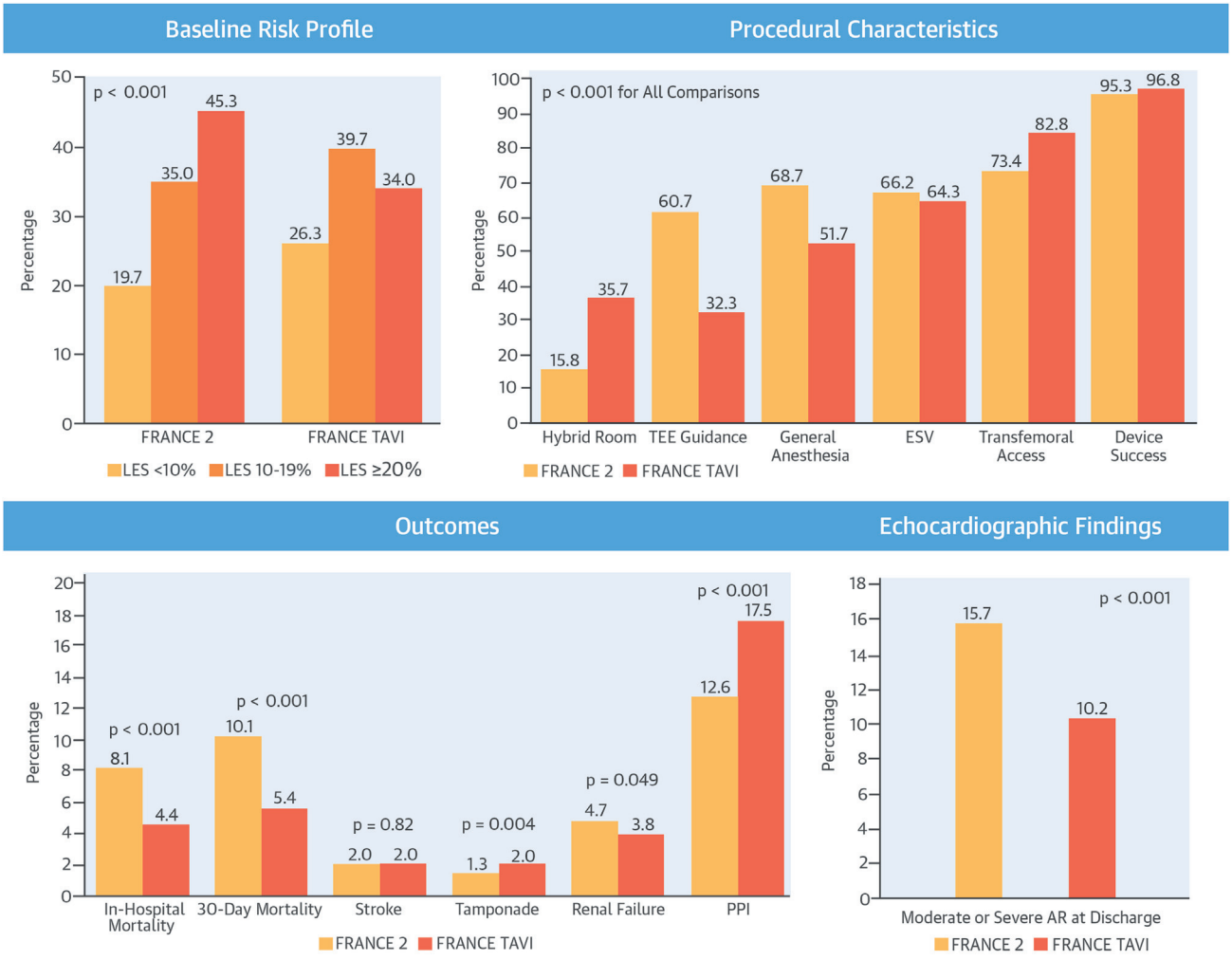
Values are median (IQR), n, n (%), n/N (%), or mean ± SD. *Test performed using log-transformed variable. †Number are given for patients without prior permanent pacemaker. ‡In a subgroup of 10,791 subjects from 24 centers with sufficient follow-up data (centers in which vital status after 30 days was known for at least 90% of the patients). Among these centers, vital status follow-up was complete for 99.5% of the FRANCE 2 patients and 97.2% of the FRANCE TAVI patients, thus leading to rates of 0.5% and 2.8% of unknown 30-day vital status, respectively.

Abbreviations as in Tables 1 and 5.

paravalvular leaks were less frequent than in FRANCE 2. These findings are likely the result of growing experience of operators, refined annulus sizing using 3-dimensional imaging techniques, and the availability of devices with a dedicated sealing skirt. Interestingly, unlike with baseline characteristics, changes in procedural aspects were more pronounced among centers that did not participate in FRANCE 2. As previously demonstrated (26), these centers probably benefited from the global knowledge and shared experience of trained operators at the start of their TAVR program and therefore promptly achieved favorable technical and clinical outcomes.

The reported 4.4% and 5.4% in-hospital and 30-day mortality rates, respectively, in the present study were within the range of recent publications. Reporting outcomes of patients treated between 2011

CENTRAL ILLUSTRATION **Temporal Trends in TAVR in France**



Auffret, V. et al. J Am Coll Cardiol. 2017;70(1):42–55.

In this comparison of patients from the FRANCE 2 (French Aortic National CoreValve and Edwards 2) (2010 to 2012) and FRANCE TAVI (French Transcatheter Aortic Valve Implantation) (2013 to 2015) registries who underwent transcatheter aortic valve replacement (TAVR), patients in FRANCE TAVI had a lower risk profile and significantly lower mortality rates but significantly higher rates of tamponade and pacemaker implantation. AR = aortic regurgitation; ESV = Edwards SAPIEN valve (Edwards Lifesciences, Irvine, California); LES = logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE); PPI = permanent pacemaker implantation; TEE = transesophageal echocardiography.

and 2013, the German Aortic Valve Registry (GARY) (10) and STS/ACC TVT (9) registries demonstrated in-hospital mortality rates of 5.2% and 5.5%, respectively, whereas the 30-day mortality rate was 7.6% in the STS/ACC TVT registry. The gradual decrease in mortality rates demonstrated in the present study also was highlighted in the U.K. TAVR registry during the period from 2007 to 2012 (14). This trend was even more pronounced in 2015 in FRANCE TAVI because the 3.3% 30-day mortality rate achieved during this single year among experienced centers in an all-comers population compared favorably with the 3.9% mortality rate of the selected PARTNER 2 group of patients (7). Stroke rates were low (2.0%), stable over time, and comparable to those reported by the STS/ACC TVT registry, which provided central adjudication of these neurological events (13). The stability of infrequent but potentially life-threatening

complications (annular rupture, aortic dissection) and the unexpected increase of cardiac tamponade should, however, be emphasized. Given the rapid expansion of TAVR indications, German centers without on-site cardiac surgery have been allowed to perform transfemoral procedures, provided they have documented cooperation with an external surgical center. An analysis of the German AQUA (Aortic Valve Replacement Quality Assurance) registry (27) demonstrated similar rates of complications likely to benefit from emergency cardiac operations, with comparable mortality rates related to these complications, among centers with and without on-site cardiac surgery. However, in the background setting of treating lower-risk patients, the findings of the present study suggest caution regarding the dispersion of TAVR in centers without on-site cardiac surgery, at least until a dedicated series confirms the results of the AQUA registry.

Although debate remains regarding the clinical impact of PPI post-TAVR (28), given that TAVR is set to expand to lower-surgical risk and potentially younger patients, the deleterious consequences of long-term pacing requires careful attention. Moreover, PPI prolongs hospitalization and may jeopardize the cost-effectiveness of TAVR (29). Therefore, the significant increase of PPI observed from FRANCE 2 to FRANCE TAVI is a notable and important finding. Because this trend was exclusively observed in ESV recipients, this is likely to reflect the availability of the latest iteration of ESV (the SAPIEN 3 valve) that was associated with higher rates of PPI during its early use (30,31). Implantation depth is a consistent predictor of PPI, and an implantation technique aiming at a 70% aortic valve position produced rates of PPI comparable to those observed with previous ESV iterations (31). Whether the implementation of this recommendation yields similar results in large multicenter settings requires careful evaluation in future studies.

STUDY LIMITATIONS. Data completeness in this national registry was acceptable. However, data were site reported and not subject to external validation or adjudication. Therefore, data on numbers of procedures and survival were likely extremely accurate, yet data on procedural morbidity and complications could be less so. Although registries are the only way to capture all-comers data on a national scale, specific details could be lacking, thus allowing a description of trends and associations without providing firm evidence of causality. For 2012, only procedures performed in January were included in the present analysis according to the inclusion period of the FRANCE 2 registry. We excluded patients with missing data on valve type or approach, which we regarded as crucial information to analyze the results of a TAVR procedure. Similarly, 30-day mortality was reported for a subgroup of patients and centers. These exclusion criteria could raise concerns regarding selective reporting, especially underreporting of poor outcomes. However, comparisons of excluded versus included patients and of patients with versus without reported 30-day follow-up demonstrated that excluded patients had a lower risk profile as assessed by the logistic EuroSCORE and that patients without reported 30-day mortality had a lower in-hospital mortality rate (Online Tables 1 and 2). Therefore, underreporting of poor outcomes in the present analysis is unlikely.

CONCLUSIONS

In this first report of the French national TAVR monitoring program (FRANCE TAVI) during the period from 2013 to 2015, device success was achieved in 96.8% of patients, whereas in-hospital and 30-day mortality rates were 4.4% and 5.4%, respectively. These rates compared favorably with those of FRANCE 2 and probably reflected a more refined selection of lower-surgical risk patients, improved procedural planning and execution, newer iterations of transcatheter devices, and enhanced post-procedural care. Nonetheless, given that TAVR indications are likely to expand officially to lower-surgical risk patients, concerns remain regarding rare but potentially life-threatening complications and PPI that should be addressed in future studies.

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PERSPECTIVES

COMPETENCY IN PATIENT CARE AND PROCEDURAL SKILLS: Patients undergoing TAVR in France increasingly have a low to intermediate surgical risk. In-hospital and 30-day mortality rates were in the range of those observed in recent randomized trials among intermediate-risk patients. However, conduction disturbances requiring pacemaker implantation remain a concern.

TRANSLATIONAL OUTLOOK: Ongoing randomized trials will shed light on the exact role of TAVR among low-surgical risk patients. Meanwhile, strategies to reduce the incidence of pacemaker implantation should be evaluated. Given the exponential increase in TAVR procedures, the feasibility of TAVR without on-site cardiac surgery may also be elucidated.

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KEY WORDS national registry, outcomes, pacemaker, transfemoral

APPENDIX For key personnel, institutions, and organizations participating in the FRANCE TAVI registry, definitions used in the registry, and supplemental tables, please see the online version of this article.