

# Trends in Outcomes of Transcatheter and Surgical Aortic Valve Replacement in the United States (2012–2017)



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**As the use of transcatheter aortic valve implantation (TAVI) expands to varying patient populations, impacting the landscape of surgical aortic valve replacement (SAVR), this study sought to assess volume and performance trends of aortic valve replacement (AVR) in the United States during 2012–2017. The Nationwide Readmissions Database was queried for patients who underwent endovascular/transapical TAVI, isolated SAVR, or complex aortic valve surgery between 2012 and 2017. Temporal trends in annual case volume, admission costs, in-hospital outcomes, and 30-day readmission were evaluated. Of 624,303 patients (median age 72 years) who received AVR, 387,011 (62%) were men. Among these patients, 170,521 (27%) underwent TAVI and 453,782 (73%) underwent SAVR with 299,398 isolated and 154,384 complex aortic valve surgery. TAVI patients were significantly older and higher risk compared with SAVR patients. From 2012 to 2017, the annual number of TAVI increased from 8,295 to 55,168 whereas SAVR volume remained remarkably stable. Patients who underwent AVR demonstrated significant improvements in mortality, stroke, duration of hospitalization, and 30-day readmission. In conclusion, this large contemporary analysis reports the considerable growth of AVR in the United States. It remains unequivocal that the treatment of aortic stenosis is improving overall with reduced mortality following AVR, highlighting the effectiveness of various process improvements such as newer valves, enhanced patient selection, and the interdisciplinary Heart Team approach. © 2020 Elsevier Inc. All rights reserved. (Am J Cardiol 2021;141:79–85)**

Owing to its high prevalence and an aging population, aortic valve pathology remains a clinical and public health burden that warrants intervention. In particular, aortic stenosis has become the most frequent type of native valvular heart disease in the industrialized world.<sup>1,2</sup> The inability to rely on conservative medical therapy due to particularly poor outcomes confers an even greater need for aortic valve replacement (AVR).<sup>3,4</sup> The increasing use of transcatheter aortic valve replacement (TAVI) as an alternative to surgical aortic valve replacement (SAVR) for severe aortic stenosis has previously been reported,<sup>5,6</sup> and comes in light of not only evolving device technology and advancements in procedural techniques, but also several randomized trials demonstrating its efficacy among patient populations of varying surgical risk.<sup>7–10</sup> There is increased availability of treatment options for aortic stenosis patients with the

availability and expanding indication of TAVI, yet our understanding of its impact on overall outcomes of AVR remains limited. In the most contemporary population-based analysis to date, we aimed to define the patient characteristics and temporal trends in procedural volume, total admission costs, in-hospital outcomes, and 30-day readmission rates following TAVI and SAVR from 2012 to 2017 using a nationally representative sample of over 600,000 patients.

## Methods

We conducted a retrospective analysis following the STROBE checklist and using the Nationwide Readmissions Database (NRD) released by the Healthcare Cost and Utilization Project of the Agency for Healthcare Research and Quality.<sup>11,12</sup> The NRD is a nationally-representative registry of nonfederal hospital admissions within the United States that accounts for up to 57% of all nationwide hospitalizations and has included up to 17 million discharged patients annually. Importantly, it allows for weighted data at discharge that can be used to provide national estimates. The registry employed the *International Classification of Diseases*, Ninth Revision, Clinical Modification (ICD-9-CM) codes until September 30, 2015 and *International Classification of Diseases*, Tenth Revision, Clinical

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Modification (ICD-10-CM) thereon out. Approval from institutional review board was waived because of the anonymized and deidentified nature of the publicly available data in the NRD.

Weighted NRD estimates were used to include patients aged 18 years or older who were admitted to undergo AVR between January 2012 and December 2017. Supplementary Table 1 lists the ICD-9-CM and ICD-10-CM procedure and diagnosis codes used for this selection and detailing baseline characteristics. TAVI procedures were further stratified into endovascular and transapical TAVI. SAVR procedures were subgrouped into isolated SAVR or complex aortic valve surgery defined as combined SAVR and coronary artery bypass grafting.

Patient characteristics at baseline were reported for each group. The following in-hospital outcomes were identified: length of stay (LOS), total admission cost, mortality, stroke, acute kidney injury, need for blood transfusion, permanent pacemaker (PPM) implantation, and patient disposition including those discharged with disability. The NRD categorizes patient disposition into the following categories: (1) routine discharge, (2) transfer to a short-term hospital, skilled nursing facility, intermediate care facility, or other facilities, (3) home healthcare, and (4) discharge against medical advice.<sup>12</sup> “Discharged with disability” was defined as any disposition category not reported as routine discharge. All patients were followed for at least 30 days after discharge to monitor for hospital readmission. Postprocedural outcomes and its associated trends were determined in patients who underwent TAVI and SAVR over the study period.

Categorical variables were compared using Fisher’s exact test and presented as numbers and %. Continuous variables were assessed using the Mann-Whitney *U* test and the Kruskal-Wallis test, and reported as median (interquartile range). Utilization trends of AVR were assessed using the Joinpoint Regression Software of the National Cancer Institute to calculate the annual percentage change (APC).<sup>13</sup> Trends analyses were performed using linear-by-linear chi-square. All tests were 2-sided with a significance level of 0.05. All statistical analyses were conducted using IBM SPSS Statistics, version 26 (IBM Corporation, Armonk, New York).<sup>14</sup>

## Results

Our study included 624,303 AVR procedures, of which 170,521 (27%) were TAVI and 453,782 (73%) were SAVR with 299,398 isolated and 154,384 complex aortic valve surgery. The median age of all included patients was 73 years, and higher among those undergoing TAVI (82 years) compared with SAVR (70 years). As shown in Table 1, TAVI patients were higher risk at baseline with increased rates of co-morbidities relative to SAVR patients. Overall rates of in-hospital outcomes and procedural complications are further reported in Table 1.

The number of overall AVR significantly increased over the study period from 83,267 in 2012 to 123,970 in 2017 with an APC of 8.61% (95% confidence interval [CI] [7.24 to 10.00],  $p < 0.001$ ). During this time, nearly all postprocedural outcomes including LOS, in-hospital stroke, need for blood transfusion, discharge with disability, and 30-day

readmission demonstrated significant rate reductions. Notably, in-hospital mortality significantly improved from 4% in 2012 to 2.8% in 2017. As the exception, the need for PPM concurrently increased from 5.6% to 7.8% across the study period (Figure 1; Table 2).

As shown in Table 3, the number of TAVI procedures increased significantly over the study period from 8,295 in 2012 to 55,168 in 2017 with an APC of 46.4% (95% CI [38.9 to 54.2],  $p < 0.001$ ). This increase was more pronounced in endovascular compared to transapical TAVI with an APC of 55.2% (95% CI [45.9 to 65],  $p < 0.001$ ). Further, the number of hospitals performing TAVI rose from 200 in 2012 to 421 in 2017 (Supplementary Figure 1). The median LOS following TAVI decreased from 6 days in 2012 to 2 days in 2017 ( $p < 0.001$ ). Additional outcomes of TAVI including in-hospital mortality, stroke, and acute kidney injury, need for blood transfusion, discharge with disability, as well as 30-day readmission all significantly improved throughout the study period. Yet, PPM following TAVI increased from 7.4% in 2012 to 12.1% in 2015, and subsequently decreased to 9.9% in 2017 (Table 3). On stratified analysis, PPM implantation significantly increased over years following both endovascular and transapical TAVI (Supplementary Table 2). Although the median cost of a TAVI admission initially increased from 2012 to 2014, it decreased with each subsequent year to \$173,655 in 2017 (Figure 1).

Despite a steady increase in the number of hospitals performing SAVR from 521 in 2012 to 738 in 2017 (Supplementary Figure 1), the total number of annual SAVR remained relatively unchanged throughout the study period (Supplementary Table 4), with an APC of  $-1.4\%$  (95% CI [ $-4.4$  to  $1.6$ ],  $p = 0.26$ ). Yet, the number of complex SAVR cases significantly declined with an APC of  $-2.9\%$  (95% CI [ $-5.3$  to  $-0.5$ ],  $p = 0.03$ ). Annual rates of in-hospital mortality and stroke following SAVR showed no significant change across years. Blood transfusions, LOS, discharge with disability, and 30-day readmission decreased across years in both the SAVR group and subgroups (Supplementary Table 4, Table 4). The median cost of a SAVR admission increased from \$153,912 in 2012 to \$192,168 in 2017 (Figure 1).

## Discussion

In the most recent analysis of trends in utilization, total admission costs, and in-hospital outcomes of AVR, our primary findings on over 600,000 patients who underwent AVR in the United States between 2012 and 2017 are five-fold: (1) the absolute number of AVR increased over a 5-year period, mainly due to an increase in TAVI; (2) TAVI patients comprised a significantly older population with greater co-morbid conditions; (3) in-hospital mortality, in-hospital stroke, discharge with disability, and 30-day readmission rates following AVR declined, which may be derived from the increasing use of TAVI; (4) PPM placement post-AVR gradually increased throughout the study period yet significantly declined following TAVI across 2015–2017; (5) the total hospitalization cost for both isolated SAVR and complex aortic valve surgery increased across years. Our data builds upon previous reports<sup>15</sup>

Table 1  
Baseline characteristics and overall outcomes of patients who underwent aortic valve replacement from 2012 to 2017

Variable	TAVI (n = 170,521)	SAVR (n = 453,782)	p	Total AVR (n = 624,303)
Age (years)	82 (76-87)	70 (61-77)	<0.001	73 (64-81)
Gender			<0.001	
Men	91,091 (53.4%)	295,919 (65.2%)		387,011 (62%)
Women	79,430 (46.6%)	157,862 (34.8%)		237,292 (38%)
Diabetes mellitus	59,500 (34.9%)	132,320 (29.2%)	<0.001	191,821 (30.7%)
Hypertension	101,758 (59.7%)	307,611 (67.8%)	<0.001	409,369 (65.6%)
Congestive heart failure	124,381 (72.9%)	166,722 (36.7%)	<0.001	291,104 (46.6%)
Renal failure	55,935 (32.8%)	72,924 (16.1%)	<0.001	128,860 (20.6%)
Dyslipidemia*	109,711 (64.3%)	259,810 (57.3%)	<0.001	369,521 (59.2%)
Atrial fibrillation	59,693 (35%)	171,517 (37.8%)	<0.001	231,209 (37%)
Liver disease	4,263 (2.5%)	9,560 (2.1%)	<0.001	13,824 (2.2%)
Coagulopathy	28,461 (16.7%)	152,582 (33.6%)	<0.001	181,043 (29%)
Active malignancy	7,650 (4.5%)	10,944 (2.4%)	<0.001	18,593 (3%)
Prior CVA	20,469 (12%)	32,581 (7.2%)	<0.001	53,051 (8.5%)
Prior PCI	35,021 (20.5%)	36,430 (8%)	<0.001	71,450 (11.4%)
Prior CABG	34,387 (20.2%)	25,950 (5.7%)	<0.001	60,337 (9.7%)
Obesity	27,027 (15.8%)	96,056 (21.2%)	<0.001	123,084 (19.7%)
Smoking	56,916 (33.4%)	158,851 (35%)	<0.001	215,767 (34.6%)
Alcohol abuse	1,548 (0.9%)	12,346 (2.7%)	<0.001	13,895 (2.2%)
Drug abuse	512 (0.3%)	8,005 (1.8%)	<0.001	8,517 (1.4%)
Length of stay (days)	4 (2-7)	7 (5-13)	<0.001	7 (4-11)
Admission cost (US dollars)	179,450 (129,940-261,726)	167,184 (114,615-264,399)	<0.001	170,893 (119,470-263,415)
In-hospital mortality	4,167 (2.4%)	16,929 (3.7%)	<0.001	21,096 (3.4%)
In-hospital stroke	3,454 (2%)	13,955 (3.1%)	<0.001	17,409 (2.8%)
In-hospital AKI	22,411 (13.1%)	87,819 (19.4%)	<0.001	110,230 (17.7%)
In-hospital blood transfusion	24,571 (14.4%)	141,383 (31.2%)	<0.001	165,954 (26.6%)
In-hospital pacemaker implantation	17,822 (10.5%)	25,683 (5.7%)	<0.001	43,504 (7%)
Discharge with disability <sup>†</sup>	81,064 (48.7%)	289,216 (66.2%)	<0.001	370,280 (61.4%)
30-day readmission <sup>‡</sup>	22,184 (14.7%)	57,169 (14.3%)	<0.001	79,353 (14.4%)

Categorical variables are presented as number (%) and continuous variables as median (interquartile range). Categorical outcomes are reported as total aggregates over the study period. AKI = acute kidney injury; CABG, coronary artery bypass graft; CVA = cerebrovascular accident; PCI = percutaneous coronary intervention; SAVR = surgical aortic valve replacement; TAVI = transcatheter aortic valve implantation.

\* Disorders of lipid metabolism. Specific ICD codes used are listed in supplementary table 1.

<sup>†</sup> Only includes patients who were discharged alive.

<sup>‡</sup> Only includes patients who were discharged alive and underwent their procedure before December of each year to allow for a minimum 30 days of follow-up.

generalizable in the United States by including population data from 2017, which is ever important in an age of rapid growth in AVR, and specifically with the FDA approval of TAVI for intermediate-risk patients in 2016. Additionally, our novel analysis identifies the APC in utilization trends of AVR and all subgroups using linear regression models, in turn highlighting the trajectory of each intervention in further detail.

Despite an expectedly older age with more co-morbidities, TAVI patients demonstrated improved short-term outcomes throughout the study period.<sup>7-10</sup> The persistent decline in mortality and stroke is encouraging and consistent with previous analyses of large international registries.<sup>16,17</sup> The marked decrease in mortality from 5.1% to 1.6% over such short period is striking in light of the notable increase in TAVI procedures and hospitals performing TAVI, yet is in line with an analysis of the French Aortic National CoreValve and Edwards 2 and French Transcatheter Aortic Valve Implantation registries that demonstrated a reduction from 8.6% in 2010 to 2.7% in 2015.<sup>16</sup> Notably across years, mortality remained unchanged after complex aortic valve surgery, yet dramatically decreased following

concomitant TAVR and percutaneous coronary intervention despite a nearly fivefold rise in such cases. It is reasonable that various process improvements such as newer valves, optimized implantation through preprocedural imaging, and enhanced patient selection have played crucial roles in the favorable TAVI trends, suggesting that quantity is facilitating rather than hampering quality.<sup>18,19</sup> The advent of the interdisciplinary Heart Team and increased TAVI device accessibility and comfort level among practitioners have further influenced clinical practice around aortic valve disease.<sup>20</sup>

Importantly, whereas the number of hospitals performing SAVR increased from 521 in 2012 to 738 in 2017, the absolute amount of surgeries remained remarkably stable, as did rates of in-hospital mortality and stroke after SAVR. The adoption of TAVI expanded to inoperable, high-, and intermediate-risk patients across this period, with respective FDA approval granted in 2011, 2012, and 2016.<sup>7-9</sup> As more contemporary data becomes publicly available, we anticipate a continued uptrend of TAVI in lieu of SAVR as recent studies have demonstrated noninferior outcomes of TAVI in patients at low surgical risk, a population that comprises

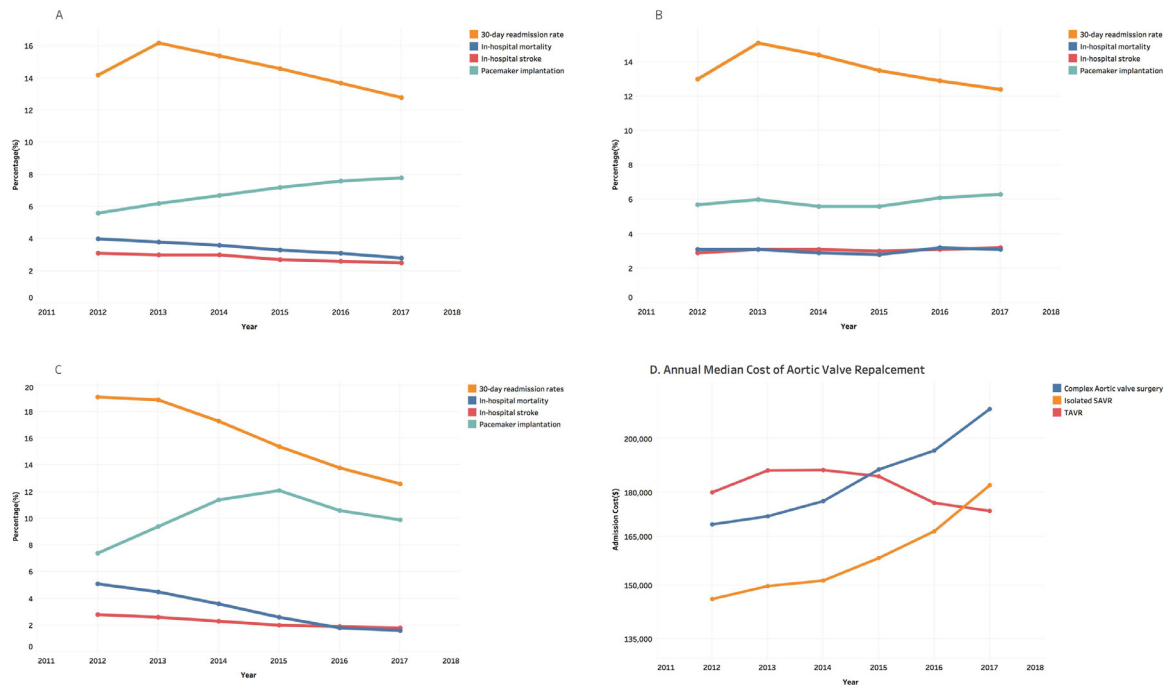


Figure 1. Outcomes of (a) aortic valve replacement, (b) transcatheter aortic valve implantation and (c) isolated surgical aortic valve replacement, and (d) annual median cost of aortic valve replacement.

Table 2  
Trends in outcomes following aortic valve replacement between 2012 and 2017

	2012	2013	2014	2015	2016	2017	p
Overall cases	83,267	91,634	97,995	107,394	120,043	123,970	
30-day readmission*	10,339 (14.2%)	13,092 (16.2%)	13,330 (15.4%)	13,863 (14.6%)	14,599 (13.7%)	14,130 (12.8%)	<0.001
Length of stay	8 (5-13)	8 (5-13)	7 (5-12)	7 (5-12)	6 (4-10)	5 (3-9)	<0.001
In-hospital mortality	3,312 (4%)	3,524 (3.8%)	3,514 (3.6%)	3,587 (3.3%)	3,701 (3.1%)	3,458 (2.8%)	<0.001
In-hospital stroke	2,596 (3.1%)	2,742 (3%)	2,907 (3%)	2,952 (2.7%)	3,129 (2.6%)	3,083 (2.5%)	<0.001
Acute kidney injury	15,335 (18.4%)	17,963 (19.6%)	19,444 (19.8%)	15,761 (14.7%)	21,422 (17.8%)	20,304 (16.4%)	<0.001
Blood transfusion	32,491 (39%)	34,135 (37.3%)	32,133 (32.8%)	27,737 (25.8%)	19,558 (16.3%)	19,899 (16.1%)	<0.001
Permanent pacemaker	4,651 (5.6%)	5,720 (6.2%)	6,595 (6.7%)	7,689 (7.2%)	9,125 (7.6%)	9,725 (7.8%)	<0.001
Discharge with disability†	53,977 (67.5%)	59,524 (67.6%)	62,680 (66.4%)	65,887 (63.5%)	66,398 (57.1%)	61,814 (51.3%)	<0.001

Categorical variables are presented as number (%) and length of stay as median (interquartile range).

\* Only includes patients who were discharged alive and underwent their procedure before December of each year to allow for a minimum 30 days of follow-up.

† Only includes patients who were discharged alive.

Table 3  
Trends in outcomes following TAVI between 2012 and 2017

	2012	2013	2014	2015	2016	2017	p
Overall cases	8,295	13,959	19,723	28,893	44,482	55,168	
30-day readmission*	1,302 (19.1%)	2,290 (18.9%)	2,967 (17.3%)	3,930 (15.4%)	5,451 (13.8%)	6,244 (12.6%)	<0.001
Length of stay	6 (4-11)	7 (4-10)	6 (4-9)	4 (3-8)	3 (2-6)	2 (2-5)	<0.001
In-hospital mortality	427 (5.1%)	626 (4.5%)	716 (3.6%)	738 (2.6%)	795 (1.8%)	864 (1.6%)	<0.001
In-hospital stroke	230 (2.8%)	361 (2.6%)	449 (2.3%)	592 (2%)	825 (1.9%)	998 (1.8%)	<0.001
Acute kidney injury	1,527 (18.4%)	2,840 (20.3%)	3,660 (18.6%)	3,266 (11.3%)	5,301 (11.9%)	5,818 (10.5%)	<0.001
Blood transfusion	2,498 (30.1%)	3,921 (28.1%)	4,039 (20.5%)	3,720 (12.9%)	3,327 (7.5%)	7,065 (12.8%)	<0.001
Permanent pacemaker	610 (7.4%)	1,308 (9.4%)	2,247 (11.4%)	3,488 (12.1%)	4,716 (10.6%)	5,452 (9.9%)	0.08
Discharge with disability†	5,520 (70.2%)	9,409 (70.6%)	12,217 (64.3%)	15,573 (55.3%)	18,969 (43.5%)	19,376 (35.7%)	<0.001

Categorical variables are presented as number (%) and length of stay as median (interquartile range). TAVI = transcatheter aortic valve implantation.

\* Only includes patients who were discharged alive and underwent their procedure before December of each year to allow for a minimum 30 days of follow-up.

† Only includes patients who were discharged alive.

Table 4  
Trends in outcomes following isolated SAVR and complex aortic valve surgery between 2012 and 2017

	Isolated SAVR (n = 299,398)							Complex aortic valve surgery (n = 154,384)						
	2012	2013	2014	2015	2016	2017	P	2012	2013	2014	2015	2016	2017	P
Overall cases	48,302	50,700	51,458	52,276	50,705	45,956	<0.001	26,669	26,975	26,814	26,225	24,856	22,845	<0.001
30-day readmission*	5,615 (13%)	6,795 (15.1%)	6,618 (14.4%)	6,317 (13.5%)	5,853 (12.9%)	5,082 (12.4%)	<0.001	3,421 (14.8%)	4,007 (17.1%)	3,745 (16%)	3,617 (15.8%)	3,295 (15.3%)	2,834 (14.3%)	<0.001
Length of stay	7 (5-13)	7 (5-12)	7 (5-12)	7 (5-11)	7 (5-11)	7 (5-11)	<0.001	9 (6-15)	9 (6-14)	8 (6-14)	8 (6-14)	8 (6-14)	8 (6-13)	<0.001
In-hospital mortality	1,492 (3.1%)	1,585 (3.1%)	1,514 (2.9%)	1,466 (2.8%)	1,603 (3.2%)	1,410 (3.1%)	0.82	1,393 (5.2%)	1,313 (4.9%)	1,283 (4.8%)	1,383 (5.3%)	1,303 (5.2%)	1,183 (5.2%)	0.23
In-hospital stroke	1,422 (2.9%)	1,560 (3.1%)	1,585 (3.1%)	1,577 (3%)	1,567 (3.1%)	1,479 (3.2%)	0.046	944 (3.5%)	821 (3%)	874 (3.3%)	783 (3%)	736 (3%)	607 (2.7%)	<0.001
Acute kidney injury	8,011 (16.6%)	8,872 (17.5%)	9,189 (17.9%)	7,569 (14.5%)	9,684 (19.1%)	8,620 (18.8%)	<0.001	5,798 (21.7%)	6,252 (23.2%)	6,596 (24.6%)	4,927 (18.8%)	6,437 (25.9%)	5,867 (25.7%)	<0.001
Blood transfusion	18,751 (38.8%)	19,144 (37.8%)	17,621 (34.2%)	15,147 (29%)	10,097 (19.9%)	6,971 (15.2%)	<0.001	11,242 (42.2%)	11,070 (41%)	10,473 (39.1%)	8,870 (33.8%)	6,134 (24.7%)	5,863 (25.7%)	<0.001
Permanent pacemaker	2,748 (5.7%)	3,301 (6%)	2,894 (5.6%)	2,916 (5.6%)	3,084 (6.1%)	2,910 (6.3%)	<0.001	1,293 (4.8%)	1,381 (5.1%)	1,454 (5.4%)	1,284 (4.9%)	1,325 (5.3%)	1,68 (6%)	<0.001
Discharge with disability†	30,309 (64.8%)	31,607 (64.4%)	32,003 (64.1%)	32,331 (63.7%)	30,745 (62.7%)	27,292 (61.3%)	<0.001	18,148 (71.8%)	18,508 (72.1%)	18,460 (72.4%)	17,983 (72.5%)	16,684 (70.9%)	15,146 (69.9%)	<0.001

Categorical variables are presented as number (%) and length of stay as median (interquartile range). SAVR = surgical aortic valve replacement.

\*Only includes patients who were discharged alive and underwent their procedure before December of each year to allow for a minimum 30 days of follow-up.

†Only includes patients who were discharged alive.

the overwhelming majority of those with severe aortic stenosis.<sup>10,21</sup> However, the ultimate decision about the applicability of SAVR and TAVI will hinge on long-term outcomes.

Notwithstanding these favorable trends, the need for PPM implantation following AVR, particularly after TAVI,<sup>22</sup> remains a critical issue. The PPM rate among the 115,843 all-comer TAVI patients was 10.7% across this study and 12.1% by 2015, which is comparable to The Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry report.<sup>23</sup> This strongly suggests an association with the commercial introduction and ensuing dissemination of self-expanding valves in 2014, which occupied a 33% share of utilized valve types by 2015 and with traditionally higher 30-day PPM rates relative to balloon-expanding valves.<sup>22-24</sup> Greater adoption of the Edwards SAPIEN 3 balloon-expandable valve, which has consistently shown a higher PPM need than prior-generation devices,<sup>25</sup> Although the clinical impact of PPM placement after TAVI remains controversial, reducing its need has beneficial implications as TAVI expands to lower risk patients with increased life expectancy and given the associated economic burden.<sup>22,26-28</sup>

The favorable trend in 30-day readmission rates after TAVI, isolated SAVR, and complex aortic valve surgery would tenably improve the long-term healthcare costs associated with each intervention. As reported in a cost-effectiveness analysis of the PARTNER trial, the economic advantage of TAVI is drawn out by use of the transfemoral as opposed to transapical approach as well as reduction in LOS.<sup>29</sup> Further, cost of TAVI appears at its lowest when performed in the catheterization laboratory.<sup>27</sup> As transapical TAVI has been associated with higher risk patients and worse outcomes,<sup>7,30</sup> it is conceivable that the factors driving the improved cost-effectiveness of TAVI are partly a result of its extension into lower risk patient populations, with increased use of a transfemoral approach with conscious sedation.

Although the amount of data in this study was highly robust owing to the sheer number of patients, several limitations are worth noting. The NRD relies on administrative reporting and is therefore subject to under/over/misreporting. The inherent limitations of an observational study restrict the ability to identify causality. Further, patients were all-comers, and clinical outcomes were not stratified by potential confounders such as indication for AVR, patient surgical risk, valve device type, valve implantation height, or operator experience. Additionally, important hemodynamic and echocardiographic features were not assessed. Lastly, only short-term outcomes were analyzed as permitted by database completeness. Identifying trends in long-term outcomes is crucial in an age of rapidly shifting practice around aortic valve disease.

This contemporary cohort study revealed tremendous annual growth in TAVI and stable SAVR from 2012 to 2017 in the United States, as the treatment of aortic stenosis is advancing overall with consistently improved short-term outcomes including mortality and stroke after AVR.

## Author Contributions

Anas M. Saad: Conceptualization, Data curation, Formal analysis, Methodology, Project administration, Writing - original draft. Nicholas Kassis: Conceptualization, Methodology, Writing - original draft. Toshiaki Isogai: Conceptualization, Methodology, Validation, Supervision, Writing - review & editing. Mohamed M. Gad: Conceptualization, Validation, Methodology, Writing - review & editing. Keerat Rai Ahuja: Visualization, Software, Writing - review & editing. Omar Abdelfattah: Methodology, Writing - original draft. Shashank Shekhar: Methodology, Writing - review & editing. Medhat Farwati: Methodology, Writing - review & editing. James J. Yun: Conceptualization, Supervision, Validation, Writing - review & editing. Amar Krishnaswamy: Conceptualization, Supervision, Validation, Writing - review & editing. Lars G. Svensson: Conceptualization, Supervision, Validation, Writing - review & editing. Samir Kapadia: Conceptualization, Supervision, Validation, Writing - review & editing, Project administration, Resources.

## Disclosures

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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## Supplementary materials

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- Iung B, Baron G, Butchart EG, Delahaye F, Gohlke-Bärwolf C, Levang OW, Tornos P, Vanoverschelde J-L, Vermeer F, Boersma E, Ravaud P, Vahanian A. A prospective survey of patients with valvular heart disease in Europe: the Euro Heart Survey on Valvular Heart Disease. *Eur Heart J* 2003;24:1231–1243.
- Nkomo VT, Gardin JM, Skelton TN, Gottdiener JS, Scott CG, Enriquez-Sarano M. Burden of valvular heart diseases: a population-based study. *Lancet* 2006;368:1005–1011.
- Taniguchi T, Morimoto T, Shiomi H, Ando K, Kanamori N, Murata K, Kitai T, Kawase Y, Izumi C, Miyake M, Mitsuoka H, Kato M, Hirano Y, Matsuda S, Nagao K, Inada T, Murakami T, Takeuchi Y, Yamane K, Toyofuku M, Ishii M, Minamino-Muta E, Kato T, Inoko M, Ikeda T, Komasa A, Ishii K, Hotta K, Higashitani N, Kato Y, Inuzuka Y, Maeda C, Jinnai T, Morikami Y, Sakata R, Kimura T, on behalf of the CURRENT AS Registry Investigators. Initial surgical versus conservative strategies in patients with asymptomatic severe aortic stenosis. *J Am Coll Cardiol* 2015;66:2827–2838.
- Rossebø AB, Pedersen TR, Boman K, Brudi P, Chambers JB, Egstrup K, Gerds E, Gohlke-Bärwolf C, Holme I, Kesäniemi YA, Malbecq W, Nienaber CA, Ray S, Skjærpe T, Wachtell K, Willenheimer R, for the SEAS Investigators. Intensive lipid lowering with simvastatin and ezetimibe in aortic stenosis. *N Engl J Med* 2008;359:1343–1356.
- Culler SD, Cohen DJ, Brown PP, Kugelmass AD, Reynolds MR, Ambrose K, Schlosser ML, Simon AW, Katz MR. Trends in aortic valve replacement procedures between 2009 and 2015: has transcatheter aortic valve replacement made a difference? *Ann Thorac Surg* 2018;105:1137–1143.
- Goldswieg AM, Tak HJ, Chen LW, Aronow HD, Shah B, Kolte DS, Velagapudi P, Desai N, Szerlip M, Abbot JD. The evolving management of aortic valve disease: 5-year trends in SAVR, TAVR, and medical therapy. *Am J Cardiol* 2019;124:763–771.
- Leon MB, Smith CR, Mack M, Miller DC, Moses JW, Svensson LG, Tuzcu EM, Webb JG, Fontana GP, Makkar RR, Brown DL, Block PC, Guyton RA, Pichard AG, Bavaria JE, Herrmann HC, Douglas PS, Petersen JL, Akin JJ, Anderson WN, Wang D, Pocock S, for the PARTNER Trial Investigators. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med* 2010;363:1597–1607.
- Smith CR, Leon MB, Mack MJ, Miller DC, Moses JW, Svensson LG, Tuzcu EM, Webb JG, Fontana GP, Makkar RR, Williams M, Dewey T, Kapadia SR, Babaliaros V, Thourani VH, Corso P, Pichard AD, Bavaria JE, Herrmann HC, Akin JJ, Anderson WN, Wang D, Pocock SJ, for the PARTNER Trial Investigators. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med* 2011;364:2187–2198.
- Leon MB, Smith CR, Mack MJ, Makkar RR, Svensson LG, Kodali SK, Thourani VH, Tuzcu EM, Miller DC, Herrmann HC, Doshi D, Cohen DJ, Pichard AD, Kapadia SR, Dewey T, Babaliaros V, Szeto WY, Williams MR, Kereiakes D, Zajarias A, Greason KL, Whisenant BK, Hodson RW, Moses JW, Trento A, Brown DL, Fearon WF, Pibarot P, Hahn RT, Jaber WA, Anderson WN, Alu MC, Webb JG, for the PARTNER 2 Investigators. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. *N Engl J Med* 2016;374:1609–1620.
- Mack MJ, Leon MB, Thourani VH, Makkar R, Kodali SK, Russo M, Kapadia SR, Malaisrie SC, Cohen DJ, Pibarot P, Leipsic J, Hahn RT, Blanke P, Williams MR, McCabe JM, Brown DL, Babaliaros V, Goldman S, Szeto WY, Genereux P, Pershad A, Pocock SJ, Alu MC, Webb JG, Smith CR, for the PARTNER 3 Investigators. Transcatheter aortic-valve replacement with a balloon expanding valve in low-risk patients. *N Engl J Med* 2019;380:1695–1705.
- von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP, for the STROBE Initiative. The Strengthening of Reporting of Observational Studies in Epidemiology (STROBE) Statement: Guidelines for reporting observational studies. *Int J Surg* 2014;12:1495–1499.
- Healthcare Cost and Utilization Project (HCUP). *HCUP NIS Database Documentation*. Rockville, MD: Agency Health Res Qual; 2018.
- Joinpoint Regression Program, Version 4.5.0.1. June, 2017; Statistical Research and Applications Branch NCI. Joinpoint Regression Program, Version 4.5.0.1. June, 2017; Statistical Research and Applications Branch, National Cancer Institute. <https://surveillance.cancer.gov/joinpoint>
- IBM Corp. Released 2017. IBM SPSS Statistics for Windows VA, NY: IBM Corp.
- Alkhouli M, Alqahtani F, Ziada KM, Aljohani S, Holmes DR, Verghese M. Contemporary trends in the management of aortic stenosis in the USA. *Eur Heart J* 2019;0:1–9.
- Auffret V, Lefevre T, Van Belle E, Eltchaninoff H, Iung B, Konig R, Motreff P, Leprince P, Verhoye JP, Manigold T, Souteyrand G, Boulmier D, Joly P, Pinaud F, Himbert D, Collet JP, Rioufol G, Ghostine S, Bar O, Dibie A, Champagnac D, Leroux L, Collet F, Teiger E, Darremont O, Folliguet T, Leclercq F, Lhermusier T, Olhmann P, Huret B, Lorgis L, Drogoul L, Bertrand B, Spaulding C, Quilliet L, Cuisset T, Delomez M, Beygui F, Claudel J-P, Hepp A, Jegou A, Gommeaux A, Mirode A, Christiaens L, Christophe C, Cassat C, Metz D, Mangin L, Isaaz K, Jacquemin L, Guyon P, Pouillot C, Makowski S, Bataille V, Rodés-Cabau J, Gilard M, Le Breton H, FRANCE TAVI Investigators. Temporal trends in transcatheter aortic valve replacement in France: FRANCE 2 to FRANCE TAVI. *J Am Coll Cardiol* 2017;70:42–55.
- Ludman PF, Moat N, de Belder MA, Blackman DJ, Duncan A, Banya W, MacCarthy PA, Cunningham D, Wender O, Marlee D, Hildick-Smith D, Young CP, Kovac J, Uren NG, Spyt T, Trivedi U, Howell J, Gray H, UK TAVI Steering Committee and the National Institute for Cardiovascular Outcomes Research. Transcatheter aortic valve implantation in the United Kingdom: temporal trends, predictors of outcome, and 6-year follow-up: a report from the UK Transcatheter Aortic Valve Implantation (TAVR) registry, 2007 to 2012. *Circulation* 2015;131:1181–1190.

18. Carroll JD, Vemulapalli S, Dai D, Matsouaka R, Blackstone E, Edwards F, Masoudi FA, Mack M, Peterson ED, Holmes D, Rumsfeld JS, Tuzcu EM, Grover F. Procedural experience for transcatheter aortic valve replacement and relation to outcomes: the STS/ACC TVT Registry. *J Am Coll Cardiol* 2017;70:29–41.
19. Pilgrim T, Lee JKT, O'Sullivan CJ, Stortecky S, Ariotti S, Franzone A, Lanz J, Heg D, Asami M, Praz F, Siontis GCM, Vollenbroich R, Räber L, Valgimigli M, Roost E, Windecker S. Early versus newer generation devices for transcatheter aortic valve implantation in routine clinic practice: a propensity score matched analysis. *Open Heart* 2018;5:e000695.
20. Holmes DR Jr, Rich JB, Zoghbi WA, Mack MJ. The heart team of cardiovascular care. *J Am Coll Cardiol* 2013;61:903–907.
21. Thourani VH, Suri RM, Gunter RL, Sheng S, O'Brien SM, Ailawadi G, Szeto WY, Dewey TM, Guyton RA, Bavaria JE, Babaliaros V, Gammie JS, Svensson L, Williams M, Badhwar V, Mack MJ. Contemporary real-world outcomes of surgical aortic valve replacement in 141,905 low-risk, intermediate-risk, and high-risk patients. *Ann Thorac Surg* 2015;99:55–61.
22. Fadahunsi OO, Olowoyeye A, Ukaigwe A, Li Z, Vora AN, Vemulapalli S, Elgin E, Donato A. Incidence, predictors, and outcomes of permanent pacemaker implantation following transcatheter aortic valve replacement: analysis from the U.S. Society of Thoracic Surgeons/American College of Cardiology TVT Registry. *J Am Coll Cardiol Intv* 2016;9:2189–2199.
23. Grover FL, Vemulapalli S, Carroll JD, Edwards FH, Mack MJ, Thourani VH, Brindis RG, Shahian DM, Ruiz CE, Jacobs JP, Hanzel G, Bavaria J, Tuzcu EM, Peterson ED, Fitzgerald S, Kourtis M, Michaels J, Christensen B, Seward WF, Hewitt K, Holmes DR Jr, for the STS/ACC TVT Registry. 2016 annual report of the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry. *J Am Coll Cardiol* 2017;69:1215–1230.
24. Deharo P, Bisson A, Herbert J, Lacour T, Etienne CS, Grammatico-Guillon L, Porto A, Collart F, Bourguignon T, Cuisset T, Fauchier L. Impact of Sapien 3 balloon-expandable versus Evolut R self-expandable transcatheter aortic valve implantation in patients with aortic stenosis: data from a nationwide analysis. *Circulation* 2020;141:260–268.
25. De Torres-Alba F, Kaleschke G, Diller GP, Vormbrock J, Orwat S, Radke R, Reinke F, Fischer D, Reinecke H, Baumgartner H. Changes in the pacemaker rate after transition from Edwards SAPIEN XT to SAPIEN 3 transcatheter aortic valve implantation: the critical role of valve implantation height. *J Am Coll Cardiol Intv* 2016;9:805–813.
26. Nazif TM, Dizon JM, Hahn RT, Xu K, Babaliaros V, Douglas PS, El-Chami MF, Herrmann HC, Mack M, Makkar RR, Miller DC, Pichard A, Tuzcu EM, Szeto WY, Webb JG, Moses JW, Smith CR, Williams MR, Leon MB, Kodali SK, PARTNER Publications Office. Predictors and clinical outcomes of permanent pacemaker implantation after transcatheter aortic valve replacement: the PARTNER (Placement of AoRtic TranNscathetER Valves) Trial and Registry. *J Am Coll Cardiol Intv* 2015;8:60–69.
27. Chevreul K, Brunn M, Cadier B, Haour G, Eltchaninoff H, Prat A, Leguerrier A, Blanchard D, Fournial G, Iung B, Donzeau-Gouge P, Tribouilloy C, Debrux JL, Pavie A, Gilard M, Gueret P, on behalf of the FRANCE registry investigators. Cost of transcatheter aortic valve implantation and factors associated with higher hospital stay cost in patients of the FRANCE (French Aortic National Core Valve and Edwards) registry. *Arch Cardiovasc Dis* 2013;106:209–219.
28. Babaliaros V, Devireddy C, Lerakis S, Leonardi R, Iturra SA, Mavromatis K, Leshnower BG, Guyton RA, Kanitkar M, Keegan P, Simone A, Stewart JP, Ghasemzadeh N, Block P, Thourani VH. Comparison of transfemoral transcatheter aortic valve replacement performed in the catheterization laboratory (minimalist approach) versus hybrid operating room (standard approach): outcomes and cost analysis. *J Am Coll Cardiol Intv* 2014;7:898–904.
29. Reynolds MR, Magnuson EA, Lei Y, Wang K, Vilain K, Li H, Walczak J, Pinto DS, Thourani VH, Svensson LG, Mack MJ, Miller DC, Satler LE, Bavaria J, Smith CR, Leon MB, Cohen DJ, PARTNER Investigators. Cost effectiveness of transcatheter aortic valve replacement compared with surgical aortic valve replacement in high-risk patients with severe aortic stenosis: results of the PARTNER (Placement of Aortic Transcatheter Valves) trial (cohort A). *J Am Coll Cardiol* 2012;60:2683–2692.
30. Gilard M, Eltchaninoff H, Iung B, Donzeau-Gouge P, Chevreul K, Fajadet J, LePrince P, Leguerrier A, Lievre M, Prat A, Teiger E, Lefevre T, Himbert D, Tchetché D, Carrié D, Albat B, Cribier A, Rioufol G, Sudre A, Blanchard D, Collet F, Dos Santos P, Meneveau N, Tirouvanziam A, Caussin C, Guyon P, Bosch J, Le Breton H, Collart F, Houel R, Delpine S, Souteyrand G, Favereau X, Ohlmann P, Doisy V, Grollier G, Gommeaux A, Claudel JP, Bourlon F, Bertrand B, Van Belle E, Laskar M, FRANCE 2 Investigators. Registry of transcatheter aortic-valve implantation in high-risk patients. *N Engl J Med* 2012;366:1705–1715.