

## Case Report

# Trends in Aortic Valve Replacement Procedures between 2016 and 2020

Steven D. Culler<sup>1\*</sup>, David J. Cohen<sup>2</sup>, Phillip P. Brown<sup>3</sup>, Aaron D. Kugelmass<sup>4</sup>, Matthew R. Reynolds<sup>5</sup>, April W. Simon<sup>3</sup>, and Marc R. Katz<sup>6</sup>

<sup>1</sup>Rollins School of Public Health, Emory University, USA

<sup>2</sup>Cardiovascular Research Foundation, NY and St. Francis Hospital and Heart Center, USA

<sup>3</sup>AWS Research, USA

<sup>4</sup>Baystate Health, USA

<sup>5</sup>The Baim Institute, MA: Lahey Hospital and Medical Center; USA

<sup>6</sup>Division of Cardiothoracic Surgery, Medical University of South Carolina, USA

**\*Corresponding author**

Steven D. Culler, Rollins School of Public Health, Emory University, 1518 Clifton Road NE, Suite 622, Atlanta, Georgia 30322, USA, Fax: 404-727-9198

**Submitted:** 10 May 2023

**Accepted:** 07 June 2023

**Published:** 10 June 2023

**ISSN:** 2373-9312

**Copyright**

© 2023 Culler SD, et al.

**OPEN ACCESS**

**Keywords**

- TAVR; SAVR
- In-hospital
- 30-day and 90-day Mortality
- Medicare Beneficiaries

**Abstract**

**Background:** Transcatheter aortic valve replacement (TAVR) has profoundly impacted the volume and outcomes of aortic valve interventions in the past decade.

**Methods:** This retrospective study used the annual Medicare Provider Analysis and Review file to identify all Medicare beneficiaries undergoing an isolated aortic valve procedure between 2016 and 2020. Outcome measures included in-hospital and short-term mortality rates and in-hospital adverse events.

**Results:** During the study period, the number of Medicare beneficiaries undergoing an isolated aortic valve procedure increased from 56,958/year to 79,972/year: a compounded annual growth rate of 8.5%. Transcatheter aortic valve replacement (TAVR) procedures per 100,000 Medicare beneficiaries grew from 58.9 in 2016 to 110.6 in 2020; while SAVR procedures per 100,000 Medicare beneficiaries decreased from 43.46 in 2016 to 19.19 in 2020. In-hospital, 30-day and 90-day post-discharge mortality rates declined annually for Medicare beneficiaries undergoing TAVR of procedures, while mortality rates for SAVR decrease until 2019, but increase in 2020. By 2020, <20% of Medicare beneficiaries undergoing TAVR had an adverse event during the index hospitalization. However, SAVR adverse events increased slightly from 45.2% in 2016 to 47.6% in 2020.

**Conclusions:** Between 2016 and 2020, the total number of Medicare beneficiaries undergoing isolated aortic valve procedures per year increased from 102.5 to 129.9 per 100,000 Medicare beneficiaries during the study period—reflecting substantial growth in TAVR with contraction of SAVR. During this time period, there was an overall improvement in survival rates and reduction in adverse outcomes.

**ABBREVIATIONS**

CABG: Coronary Artery Bypass Graft; CMS: Centers of Medicare and Medicaid Services; FY: Fiscal Year; ICD-9-CM: International Classification of Diseases, 9<sup>th</sup> Edition, Clinical Modification; MB: Medicare Beneficiaries; MedPAR: Medicare Provider Analysis and Review; SAS: Statistical Analysis System; SAVR: Surgical Aortic Valve Replacement; TAVR: Transcatheter Aortic Valve Replacement

**BACKGROUND**

Symptomatic severe aortic stenosis necessitates mechanical intervention, as medically managed symptomatic aortic valve disease is associated with a high mortality [1-3]. In an

aging United States population, the utilization of aortic valve procedures to manage aortic stenosis is expected to rise [1,4,5]. Historically, management of symptomatic aortic valve disease required surgical aortic valve replacement (SAVR). Advanced age, among other factors, contributes to a high-risk profile that impacts the referral and performance of SAVR in certain subgroups [4,6,7]. Transcatheter aortic valve replacement (TAVR) has been performed in patients deemed ineligible for surgery (2012), or as an alternative for patients with intermediate or greater surgical risk (2016), and lastly for low-risk patients (2019). First approved for commercial use in the United States in fiscal year (FY) - 2012, TAVR has demonstrated similar clinical outcomes to SAVR [6,8-13].

This report presents trends in isolated aortic valve

procedures in Medicare beneficiaries (MBs) from FY-2016 to FY-2020 and extends a previous report for the period FY-2009 to FY-2015 [14]. Annual volumes for isolated aortic valve procedures including SAVR and TAVR, are detailed for FY-2016 through FY-2020. Overall mortality rates in-hospital, and 30 and 90-days post-discharge; along with nine selected adverse events in aggregate and by aortic valve procedure type are reported.

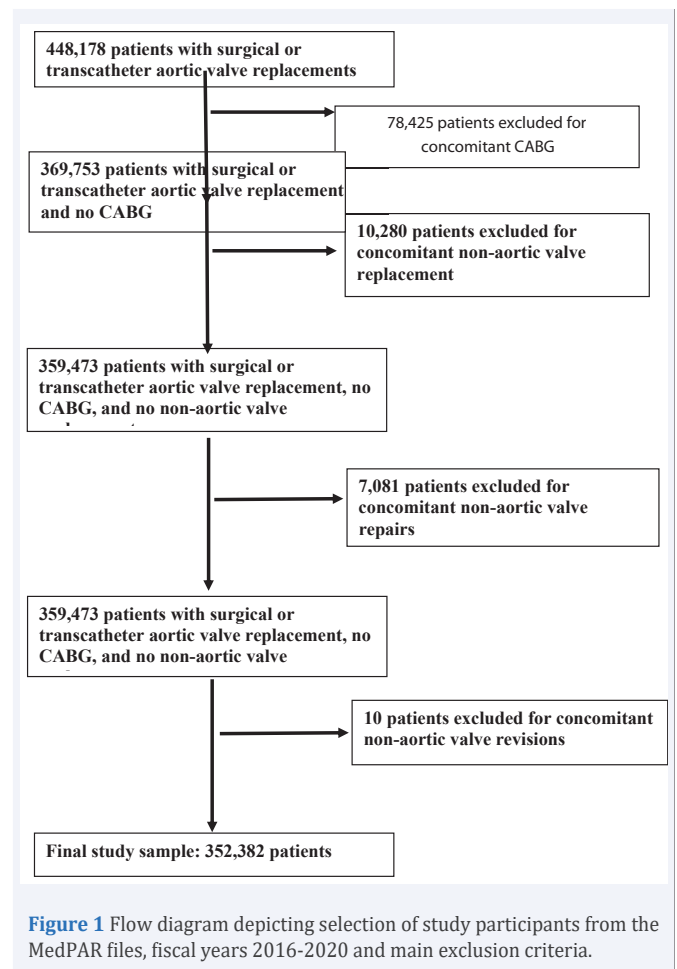
### PATIENTS AND METHODS

This retrospective study used the annual fiscal year (October 1 to September 30) version of the Medicare Provider Analysis and Review (MedPAR) files, from 2016 to 2020. The MedPAR file, maintained by the Centers for Medicare and Medicaid Services (CMS), contains all inpatient claims submitted by hospitals without patient identifiers. For each hospitalization, the MedPAR record includes selected patient information, *International Classification of Diseases, 10<sup>th</sup> Edition, Clinical Modification* (ICD-10-CM) diagnoses and procedure codes, discharge status, and days from admission to death. In addition, the MedPAR files contain up to 25 diagnosis and 25 procedure codes per admission.

The study population consisted of MBs undergoing an isolated aortic valve procedure in a U.S. hospital during the study period. For each fiscal year, the MedPAR file was searched for all hospital admissions with the following procedures: 1) aortic valve replacement with a tissue valve; 2) aortic valve replacement with other material or 3) TAVR. A total of 448,178 Medicare beneficiaries underwent one of the three aortic valve procedures during the study period. Of these, 95,796 were excluded due to performance of concomitant procedures including 78,425 coronary artery bypass graft operations; 10,280 non-aortic valve replacements; 7,081 non-aortic valve repairs, and 10 non-aortic valve revisions (Figure 1). The final study population included 352,382 MBs undergoing an isolated aortic valve procedure. **Appendix A** lists the procedure codes used for each of the inclusion and exclusion criteria.

To report trends, each MB’s isolated aortic valve procedure was classified according to type of valve utilized and approach.

Appendix A	
Variable	ICD-10-CM-Codes
SAVR-Tissue	Any procedure code equal to X2RF03Z, 02RF07Z, 02RF08Z, or 02RF0KZ
SAVR-Non-Tissue	Any procedure code equal to 02RF0JZ
TAVR	Any procedure code equal to 02RF37Z, 02RF38Z, 02RF3JZ, 02RF3KZ, 02RF37H, 02RF38H, 02RF3JH, 02RF3KH, 02RF47Z, 02RF48Z, 02RF4JZ, 02RF4KZ, X2RF33Z, or X2RF43Z
CABG	First five digits of a procedure code equal to 02100, 02110, 02120, 02130, 02104, 02114, 02124, or 02134
Any Non-Aortic Value Revision	First four digits of a procedure code equal to 02WH, 02WG, 02WJ
Any Non-Aortic Value Replacement	First four digits of a procedure code equal to 02RH, 02RG, 024J, 02RJ
Any No-Aortic Value Repair	First four digits of a procedure code equal to 02CH, 02NH, 02QH, 02TH, 02UH, 024G, 02CG, 02NG, 02QG, 02UG, 02VG, 024J, 02CJ, 02NJ, 02QJ, 02UJ, 02T9, 02TH, 02VG



**Figure 1** Flow diagram depicting selection of study participants from the MedPAR files, fiscal years 2016-2020 and main exclusion criteria.

All aortic valves include all MBs in the study population, including those who received more than one type of aortic valve procedure during their study hospitalization. For each aortic valve procedure category, the annual trend for the number of MBs undergoing that procedure, the number of procedures per 100,000 MBs, and the procedure share of all aortic valve procedures during the associated FY were reported. Demographic variables of interest included age (<65, 65-69, 70-74, 75-79, ≥80), sex (male), and race (White, Black, Hispanic, and Other).

Outcome measures included three measures of mortality and nine in-hospital adverse events. Medicare beneficiaries who underwent both TAVR and SAVR were included in the all-aortic MB category, but were not included in either TAVR or SAVR categories. The total number of hospitalizations for dual procedures was too small to report separately according to our data use agreement. Mortality was assessed at 3 timepoints: in-hospital, 30-days post-discharge and 90-days post discharge. The nine adverse events of interest were: transfusion; vascular complications (bleeding or surgical repairs); infection (post-operative infection or sepsis); post-operative stroke; pulmonary edema or heart failure; post-operative adult respiratory distress syndrome; acute renal failure; new onset hemodialysis; and pacemaker implantation during the hospitalization. The any adverse event rate included these nine events as well as in-hospital mortality.

**Table 1:** Trends for Aortic Valve Procedures Performed on MBs Undergoing Isolated Aortic Valve Procedure by FY

	FY-2016	FY-2017	FY-2018	FY-2019	FY-2020
All Aortic MBs:	56,958	64,947	70,956	79,549	79,972
Procedures/ 100,000 MBs <sup>16</sup>	102.48	113.50	120.79	132.05	129.93
<b>Types of Procedures:</b>					
SAVR Replacement with Tissue Valve: Count	21,031	18,678	18,247	16,031	10,519
Procedures/100,000 MBs (% of All Aortic Procedures)	37.84 (36.92)	32.64 (28.76)	31.06 (25.72)	26.61 (20.15)	17.09 (13.15)
SAVR Replacement with Mechanical Valve: Count	3,123	2,097	1,886	1,730	1,292
Procedures/100,000 MBs (% of All Aortic Procedures)	5.62 (5.48)	3.66 (3.23)	3.21 (2.66)	2.87 (2.17)	2.10 (1.62)
TAVR procedure: Count	32,731	44,096	50,758	61,714	68,056
Procedures/100,000 MBs (% of All Aortic Procedures)	58.89 (57.47)	77.06 (67.90)	86.41 (71.53)	102.44 (77.58)	110.57 (85.10)
Combination Aortic Valve Procedures Count	73	76	65	74	105
Procedure/100,000 MBs (% of All Aortic Procedures)	(0.13)	(0.13)	(0.11)	(0.12)	(0.17)
Medicare Enrollment	55,578,132	57,223,765	58,741,843	60,242,615	61,551,947

Original Source: Centers for Medicare & Medicaid Services, Office of Enterprise Data and Analytics, Chronic Conditions Data Warehouse.  
Number obtained: Total Number of Medicare Beneficiaries by Type of Coverage: State Health Facts.

All tables report standard descriptive statistics using counts or proportions. Observed adverse event rates are reported as the proportion of hospitalizations during which a MB experienced an adverse event out of all study hospitalizations in that FY for the appropriate type of aortic valve procedure. The annual number of Medicare enrollees was obtained from the CMS, Medicare Enrollment for selected years and rounded to the nearest thousand beneficiaries [15]. All p-values were assessed with chi-square analysis comparing rates over the study period. All analyses were performed using Statistical Analysis System (SAS) 9.4 (SAS Institute, Cary, North Carolina).

## RESULTS

The number of MBs undergoing isolated aortic valve procedures increased annually from 56,958 in FY-2016 to 79,972 in FY-2020 (Table 1). In addition, the number of aortic valve procedures performed per 100,000 MBs increased annually from 102.5 to 132.1 in FY-2019 before declining to 129.9 in FY-2020. The number of MBs undergoing SAVR declined from 43.5 per 100,000 in FY-2016 to 19.2 per 100,000 MBs by FY-2020. However, the number of MBs undergoing TAVR increased from 58.9 per 100,000 beneficiaries in FY-2016 to over 110 per 100,000 by FY-2020. During FY-2020, TAVR accounted for 85.1% of all isolated aortic valve replacement procedures in the Medicare program.

MBs undergoing SAVR were overwhelmingly white (over 85%) and more likely to be male (between 58.6% and 63.0%) (Table 2). Among the SAVR MBs, the proportion of MBs age 75 and older decreased from 42.9% in FY-2016 to 26.8% by FY-2020. During FY-2020 over 60% of the SAVR MBs were age 65 to 74 up from slightly less than 50% in FY2016. Over 80% of all MBs undergoing TAVR were age 75 or older in FY2016 compared to approximately 72% in FY-2020. By FY-2020 over 25% of the TAVR MBs were between age 65 and 74. TAVR patients were sicker as denoted by a greater proportion of MBs having each

comorbid condition more often than those MBs undergoing SAVR procedures.

During the study period, observed mortality rates for all MBs undergoing an isolated aortic valve procedure declined at each timepoint (in-hospital, 30-days and 90-days post discharge) (Table 3). MBs undergoing SAVR with tissue compared to non-tissue valves experienced lower mortality rates each year; except for 30-day and 90-day post discharge mortality rates in FY-2019. In-hospital mortality rates for MBs undergoing TAVR decreased from 1.8% to 0.97% during the study period.

Observed in-hospital event rates for nine adverse events by type of aortic valve procedure are reported in Table 4. Among all MBs undergoing isolated aortic valve replacement, the rate of any adverse event decreased from 37.34% in FY-2016 to 23.77% in FY-2020. The annual proportion of TAVR MBs experiencing an observed adverse event fell to a low of 19.56% by FY-2020, compared to a rate of between 47.44% to 49.07% among SAVR MBs.

## DISCUSSION

This study documents major volume trends among MBs undergoing isolated aortic valve procedures between 2016 and 2020 and demonstrated several key findings. First, isolated aortic valve procedures grew by 8.9%/year—continuing a trend that has been evident since the approval of TAVR in the US in late 2011[14]. Second, this increase was driven primarily by a 20.1% compounded annual growth rate in the number of MBs undergoing isolated TAVR between FY-2016 and FY-2020. During FY-2016, MBs undergoing TAVR accounted for 57.5% of all isolated aortic valve procedures in the Medicare population compared to 85.1% during FY-2020. Over this same time period, the number of MBs undergoing SAVR (with either a tissue or mechanical valve) decreased from 42.4 to 19.2 per 100,000 MB/year—a decrease of 16.4%/year.

**Table 2:** Demographic Characteristics of MBs Undergoing Isolated Aortic Valve Procedures by FY.

<b>SAVR:</b>	<b>FY-2016</b>	<b>FY-2017</b>	<b>FY-2018</b>	<b>FY-2019</b>	<b>FY-2020</b>
<b>Age (Categories):</b>					
<65, %	7.99	9.28	9.39	10.03	12.44
65-69, %	22.80	25.17	25.95	28.37	32.27
70-74, %	26.35	28.66	30.18	29.09	28.46
75-79, %	23.10	22.36	22.25	22.22	17.73
≥80, %	19.79	14.53	12.22	10.29	9.09
<b>Gender:</b>					
Male, %	58.57	60.39	61.13	62.20	62.98
<b>Race:</b>					
White, %	89.19	88.40	87.89	87.33	85.91
Black, %	5.13	5.34	5.45	5.45	6.36
Hispanic, %	1.59	1.60	1.68	2.00	1.79
All Other, %	4.09	4.65	4.98	5.22	5.94
<b>Comorbidities:</b>					
Heart failure, %	33.93	35.07	35.58	36.97	40.80
Hypertension, %	82.66	83.34	84.00	84.06	83.18
Previous myocardial infarction, %	5.83	5.38	5.40	5.26	5.64
Atrial fibrillation, %	28.61	29.46	30.83	30.57	23.85
Prior Cerebral Vascular Disease, %	7.51	7.28	6.80	6.93	7.03
Chronic obstructive pulmonary disease, %	16.39	15.67	15.66	15.24	15.47
Peripheral vascular disease, %	7.92	5.68	4.76	4.71	4.11
Chronic kidney disease, %	11.47	11.85	11.74	12.45	13.85
Dialysis Dependent, %	2.30	2.41	2.37	2.31	2.79
Diabetes, %	30.52	27.57	26.89	25.81	24.41
Previous CABG, %	5.20	3.77	3.81	3.45	3.50
Previous PCI, %	8.31	8.32	7.79	7.27	6.55
Previous ICD, %	1.01	1.06	0.91	0.98	1.16
Previous pacemaker implantation, %	4.05	3.52	3.25	3.34	3.44
Previous valve surgery, %	2.67	2.07	2.90	3.45	4.78
<b>TAVR:</b>	<b>FY-2016</b>	<b>FY-2017</b>	<b>FY-2018</b>	<b>FY-2019</b>	<b>FY-2020</b>
<b>Age (Categories):</b>					
<65, %	1.98	1.98	2.12	2.19	2.20
65-69, %	7.55	7.59	7.94	8.70	10.00
70-74, %	9.45	10.85	11.01	12.71	15.69
75-79, %	15.07	17.23	17.91	19.49	21.26
≥80, %	65.60	62.35	61.02	56.90	50.85
<b>Gender:</b>					
Male, %	52.77	53.52	53.49	54.52	56.24
<b>Race:</b>					
White, %	92.11	92.37	91.81	91.68	91.51
Black, %	4.02	3.89	4.18	4.10	3.96
Hispanic, %	1.20	1.13	1.14	1.19	1.24
All Other, %	2.67	2.61	2.87	3.03	3.29
<b>Comorbidities:</b>					
Heart failure, %	73.49	73.17	73.24	72.74	69.41
Hypertension, %	88.46	90.33	90.99	90.98	90.45
Previous myocardial infarction, %	13.45	13.13	12.68	12.34	11.44
Atrial fibrillation, %	30.11	31.34	30.88	30.04	16.65
Prior Cerebral Vascular Disease, %	12.32	12.70	12.48	12.31	11.52
Chronic obstructive pulmonary disease, %	26.84	24.57	23.10	22.16	19.31
Peripheral vascular disease, %	18.32	16.19	13.60	12.36	11.04
Chronic kidney disease, %	24.95	24.27	24.27	24.51	23.02
Dialysis Dependent, %	4.33	3.83	3.89	3.94	3.57
Diabetes, %	33.63	28.95	28.59	28.78	29.14
Previous CABG, %	21.07	18.75	17.35	15.72	13.36
Previous PCI, %	23.03	23.04	23.70	22.94	21.89
Previous ICD, %	3.07	2.74	2.57	2.53	2.21
Previous pacemaker implantation, %	11.57	10.48	10.26	9.80	9.01
Previous valve surgery, %	2.70	2.34	3.25	3.28	3.23

**Table 3: Mortality Rates (In-Hospital and Post Discharge) for Isolated Aortic Valve Procedures by Year.**

	FY-2016	FY-2017	FY-2018	FY-2019	FY-2020	p-Value
<b>All Aortic MBs:</b>						
In-Hospital, %	2.03	1.78	1.65	1.41	1.29	p< 0.001
Mortality Rate through 30-days Post Discharge, %	1.55	1.41	1.34	1.28	1.29	p< 0.001
Mortality Rate through 90-days Post Discharge, %	3.43	3.23	3.22	2.95	3.05	p< 0.001
<b>SAVR Replacement with Tissue:</b>						
In-Hospital, %	2.10	2.26	2.24	2.06	2.95	p< 0.001
Mortality Rate through 30-days Post Discharge, %	1.35	1.15	1.18	1.30	1.41	p< 0.184
Mortality Rate through 90-days Post Discharge, %	2.31	1.87	2.12	2.08	2.40	p< 0.012
<b>SAVR Replacement with Mechanical:</b>						
In-Hospital, %	3.17	3.48	3.71	2.83	3.02	p< 0.580
Mortality Rate through 30-days Post Discharge, %	1.99	2.00	1.43	1.27	1.47	p< 0.215
Mortality Rate through 90-days Post Discharge, %	2.85	3.10	2.70	1.97	2.94	p< 0.261
<b>TAVR:</b>						
In-Hospital, %	1.84	1.44	1.32	1.16	0.97	p< 0.001
Mortality Rate through 30-days Post Discharge, %	1.63	1.49	1.46	1.28	1.26	p< 0.001
Mortality Rate through 90-days Post Discharge, %	4.21	3.81	3.63	3.20	3.14	p< 0.001

**Table 4: Adverse In-Hospital Events among MBs following Isolated Aortic Valve Procedures by Year.**

	FY-2016	FY-2017	FY-2018	FY-2019	FY-2020	p-Value
<b>All Aortic MBs:</b>						
Any Adverse Events*, %	37.34	32.85	30.14	27.08	23.77	p< 0.001
New Onset Hemodialysis, %	0.89	0.82	0.74	0.76	0.66	p< 0.001
Transfusion, %	15.53	12.48	10.87	8.78	7.49	p< 0.001
Vascular Complications, %	2.57	3.60	3.39	3.04	3.27	p< 0.001
Infection, %	1.49	1.20	1.11	1.02	0.83	p< 0.001
Stroke, %	0.88	0.79	0.87	0.71	0.68	p< 0.001
Pulmonary Edema or CHF, %	6.25	5.73	5.22	5.08	4.06	p< 0.001
Post-Operative ARDS, %	4.76	3.56	3.10	2.86	2.00	p< 0.001
Acute Renal Failure, %	11.17	8.57	7.83	6.98	5.64	p< 0.001
Pacemaker Implanted, %	8.43	8.24	8.17	7.67	7.41	p< 0.001
<b>SAVR Replacement with Tissue:</b>						
Any Adverse Events*, %	45.10	44.22	43.99	44.32	47.44	p< 0.001
New Onset Hemodialysis, %	1.20	1.43	1.38	1.53	2.06	p< 0.001
Transfusion, %	23.89	23.65	22.82	21.54	23.95	p< 0.001
Vascular Complications, %	1.67	2.17	2.29	2.16	2.64	p< 0.001
Infection, %	1.99	1.98	1.91	2.06	2.46	p< 0.022
Stroke, %	0.95	0.77	0.73	0.67	0.82	p< 0.027
Pulmonary Edema or CHF, %	6.34	6.64	6.71	7.46	8.01	p< 0.001
Post-Operative ARDS, %	7.61	7.33	7.51	8.61	9.23	p< 0.001
Acute Renal Failure, %	14.84	13.41	13.72	14.37	15.21	p< 0.001
Pacemaker Implanted, %	5.69	5.51	6.27	5.85	6.70	p< 0.001
<b>SAVR Replacement with Mechanical:</b>						
Any Adverse Events*, %	45.98	45.73	44.49	45.26	49.07	P= 0.1324
New Onset Hemodialysis, %	1.25	1.67	1.27	2.54	2.55	p< 0.001
Transfusion, %	24.50	33.94	23.59	20.23	22.91	p< 0.015
Vascular Complications, %	1.92	3.15	2.86	1.85	3.17	p< 0.006
Infection, %	2.05	2.48	2.54	2.72	2.48	p=0.62
Stroke, %	0.77	0.72	0.69	0.69	0.54	p=0.953
Pulmonary Edema or CHF, %	6.12	5.10	5.67	6.42	7.89	p< 0.019
Post-Operative ARDS, %	8.55	9.82	8.43	10.00	10.22	p=0.049
Acute Renal Failure, %	14.25	13.64	14.00	16.30	15.63	p< 0.110
Pacemaker Implanted, %	5.38	6.96	5.78	7.46	7.82	p=0.004
<b>TAVR:</b>						
Any Adverse Events*, %	31.47	27.36	24.58	22.04	19.56	p< 0.001
New Onset Hemodialysis, %	0.65	0.51	0.49	0.49	0.40	p< 0.001
Transfusion, %	9.23	7.14	6.06	5.09	4.60	p< 0.001
Vascular Complications, %	3.19	4.21	3.77	3.29	3.35	p< 0.001

Infection, %	1.10	0.79	0.76	0.69	0.53	p< 0.001
Stroke, %	0.85	0.81	0.92	0.72	0.65	p< 0.001
Pulmonary Edema or CHF, %	6.21	5.34	4.64	4.42	3.36	p=0.107
Post-Operative ARDS, %	2.54	1.65	1.30	1.14	0.71	p< 0.001
Acute Renal Failure, %	8.47	6.25	5.46	4.77	3.93	p< 0.001
Pacemaker Implanted, %	10.49	9.46	8.94	8.15	7.51	p< 0.001

\*Any Adverse Event include in-hospital mortality plus the nine adverse events identified in this table.

In addition to these marked changes in procedural volumes, our study highlights four trends in observed mortality rates. First, over the 5-year study period, observed in-hospital mortality rates for all procedures decreased from 2.0% to slightly less than 1.3%. In addition, post-discharge mortality rates decreased at both 30-days (from 1.6% to 1.3%) and 90-days (from 3.4% to 3.1%) for all procedures. Second, the observed in-hospital mortality rate among MBs undergoing TAVR decreased from 1.8% in FY-2016 to 0.97% in FY-2020, despite the rapid growth in this procedure. Notably, the cumulative mortality rate through 90-days post-discharge also decreased from 4.2% to 3.1%. Third, among patients undergoing SAVR, mortality rates at all 3 timepoints increased between 2016 and 2020, but there was substantial variation year to year. Further research is warranted to determine if changes in demographic and comorbid conditions among MBs undergoing TAVR impacted the observed mortality rates. Of note, in a study of all aortic valve procedures between 2012 and 2019, Mori and colleagues found similar trends in both unadjusted and risk-adjusted TAVR and SAVR 30-day mortality rates [15].

Finally, we found that rates of adverse events during the initial hospitalization for isolated aortic valve replacement decreased substantially over our study period. However, nearly all of this improvement in in-hospital outcomes was driven by patients undergoing TAVR (31% in FY-2016 to 20% in FY-2020) rather than SAVR (45% in FY-2016 to 47.6% in FY-2020). Among patients undergoing TAVR, the largest contributors to reduced complications were reductions in transfusions, acute renal failure, and permanent pacemaker implantation, although eight of 9 complications actually decreased with vascular complications having a slight increase. Overall, adverse event rates for TAVR in this study appear to be similar to adverse event rates reported in other studies [11,13].

Our study should be interpreted in light of several important limitations. First, all mortality rates and adverse event rates reported in this study are observed rates. Trends in observed mortality and adverse event rates should be interpreted with caution because these rates have not been adjusted for changes in severity of illness among MBs over time. However, the observed rates are of interest in that they report what happened to all MBs undergoing aortic valve procedures in a given year. A second limitation is that the MedPAR dataset lacks echocardiographic data or other relevant clinical data such as mean aortic valve gradients, left ventricular function, or the extent of coronary artery disease. A third limitation is identification of MBs undergoing isolated aortic valve procedures depends on ICD-10-CM procedure codes, which restricts the ability to evaluate the

appropriateness of the procedure performed. A related limitation is the identification of study adverse events was dependent on ICD-10-CM coding. This limitation is mitigated by the fact that the MedPAR file contains 25 procedures and diagnosis codes along with present on admission codes to differentiate between diagnoses that existed on admission from those that occurred during the hospitalization.

## CONCLUSIONS

Between FY 2016 and FY-2020, the number of isolated aortic valve replacement procedures in MBs has continued to increase—driven entirely by increased use of TAVR. Despite this continued growth, both morbidity and mortality after AVR has continued to decrease on a population level. These findings suggest that the introduction and expansion of TAVR has been an important advance in the care of patients with severe aortic stenosis.

## AUTHOR DISCLOSURE

Steven Culler, April Simon, Aaron Kugelmass and Phillip Brown have nothing to disclose.

David J Cohen reports a relationship with Edwards Lifesciences Corporation that includes: consulting or advisory and funding grants. David J Cohen reports a relationship with Medtronic Inc that includes: funding grants. David J Cohen reports a relationship with Boston Scientific Corp that includes: consulting or advisory and funding grants. David J Cohen reports a relationship with Abbott Laboratories that includes: consulting or advisory and funding grants.

Matthew Reynolds reports a relationship with Edwards Lifesciences Corporation that includes: consulting or advisory. Matthew R. Reynolds reports a relationship with Medtronic Inc that includes: consulting or advisory.

Marc Katz reports a relationship with Abbott Cardiovascular Structural Heart Division that includes: consulting or advisory. Marc Katz reports a relationship with Boston Scientific Corp that includes: consulting or advisory. Marc Katz reports a relationship with Edwards Lifesciences Corporation that includes: consulting or advisory. Marc Katz reports a relationship with Medtronic Inc that includes: consulting or advisory.

## REFERENCES

1. Nishimura RA, Otto CM, Bonow RO, Carabello BA, Erwin JP, Guyton RA, et al. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of

- Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2014; 129: e521-e643.
2. Freeman RV, Otto CM. Spectrum of calcific aortic valve disease. *Circulation*. 2005; 111: 3316-3326.
  3. Carabello BA, Paulus WJ. Aortic stenosis. *The Lancet*. 2009; 373: 956-966.
  4. Barreto-Filho JA, Wang Y, Dodson JA, Desai MM, Sugeng L, Geirsson A, et al. Trends in aortic valve replacement for elderly patients in the United States, 1999-2011. *JAMA*. 2013; 310: 2078-2084.
  5. Supino PG, Borer JS, Preibisz J, Bornstein A. The epidemiology of valvular heart disease: a growing public health problem. *Heart Failure Clinics*. 2006; 2: 379-393.
  6. Webb JG, Pasupati S, Humphries K, Thompson C, Altwegg L, Moss R, et al. Percutaneous transarterial aortic valve replacement in selected high-risk patients with aortic stenosis. *Circulation*. 2007; 116: 755-763.
  7. Brown JM, O'Brien SM, Wu C, Sikora JAH, Griffith BP, Gammie JS. Isolated aortic valve replacement in North America comprising 108,687 patients in 10 years: changes in risks, valve types, and outcomes in the Society of Thoracic Surgeons National Database. *J Thorac Cardiovasc Surg*. 2009; 137: 82-90.
  8. Leon MB, Smith CR, Mack M, Miller DC, Moses JW, Svensson L, et al. 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.
  9. Smith CR, Leon MB, Mack M, Miller DC, Moses JW, Svensson L, et al. for the PARTNER Trial Investigators. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med*. 2011; 364: 2187-2198.
  10. Adams DH, Popma JJ, Reardon MJ, Yakubov SJ, Coselli JS, Deeb G, et al. for the U. S. CoreValve Clinical Investigators. Transcatheter aortic-valve replacement with a self-expanding prosthesis. *N Engl J Med*. 2014; 370: 1790-1798.
  11. Mack MJ, Leon MB, Smith CR, Miller DC, Moses JW, Tuzcu EM, et al. for the PARTNER 1 trial investigators. 5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial. *The Lancet*. 2015; 385: 2477-2484.
  12. Webb JG, Wood DA. Current status of transcatheter aortic valve replacement. *J Am Coll Cardiol*. 2012; 60: 483-492.
  13. Carroll JD, Mack MJ, Vemulapalli S, Herrmann HC, Gleason TG. for the STS/ACC TVT Registry of Transcatheter Aortic Valve Replacement. *Ann Thorac Surg*. 2021; 111: 701-722.
  14. Culler SD, Cohen DJ, Brown PP, Kugelmass AD, Reynolds MR, Ambrose K, et al. 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.
  15. Mori M, Gupta A, Wang Y, Vahl T, Nazif T, Kirtane AJ, et al. Trends in Transcatheter and Surgical Aortic Valve Replacement among Older Adults in the United States. *J Am Coll Cardiol*. 2021; 78: 2161-2172.
  16. The Centers for Disease Control and Prevention (CDC), National Vital Statistics Reports (NVSR), Vol. 66, No. 1: Births: Final Data for 2015.