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Evolving trends in aortic valve replacement: A statewide experience

Karen M. Kim MD[1] | Francis Shannon MD[2] | Gaetano Paone MD, MHSA[2] |
Shelly Lall MD[2] | Sanjay Batra MD[2] | Theodore Boeve MD[2] |
Alphonse DeLucia MD[2] | Himanshu J. Patel MD[2] | Patricia F. Theurer MSN[2] |
Chang He MS[2] | Melissa J. Clark MSN[2] | Ibrahim Sultan MD[3] |
George Michael Deeb MD[1] | Richard L. Prager MD[1]

[1] Department of Cardiac Surgery, University of Michigan, Ann Arbor, Michigan

[2] Michigan Society of Thoracic and Cardiovascular Surgeons Quality Collaborative, Ann Arbor, Michigan

[3] Division of Cardiac Surgery, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania

Correspondence
Karen M. Kim MD, University of Michigan, Dept. of Cardiac Surgery, 5164 Frankel Cardiovascular Center, 1500 E. Medical Center Dr., SPC 5864, Ann Arbor, MI 48109.
Email: kimkaren@med.umich.edu

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Abstract

Background: Transcatheter aortic valve replacement (TAVR) is an alternative to surgical aortic valve replacement (SAVR) for the treatment of aortic stenosis in patients at intermediate, high, and extreme risk for mortality from SAVR. We examined recent trends in aortic valve replacement (AVR) in Michigan.

Methods: The Michigan Society of Thoracic and Cardiovascular Surgeons Quality Collaborative (MSTCVS-QC) database was used to determine the number of SAVR and TAVR cases performed from January 2012 through June 2017. Patients were divided into low, intermediate, high, and extreme risk groups based on STS predicted risk of mortality (PROM). TAVR patients in the MSTCVS-QC database were also matched with those in the Transcatheter Valve Therapy Registry to determine their Heart Team-designated risk category.

Results: During the study period 9517 SAVR and 4470 TAVR cases were performed. Total annual AVR volume increased by 40.0% (from 2086 to 2920), with a 13.3% decrease in number of SAVR cases (from 1892 to 1640) and a 560% increase in number of TAVR cases (from 194 to 1280). Greater than 90% of SAVR patients had PROM ≤8%. While >70% of TAVR patients had PROM ≤ 8%, they were mostly designated as high or extreme risk by a Heart Team.

Conclusions: During the study period, SAVR volume gradually declined and TAVR volume dramatically increased. This was mostly due to a new group of patients with lower STS PROM who were designated as higher risk by a Heart Team due to characteristics not completely captured by the STS PROM score.

KEYWORDS
aortic valve replacement, database, TAVI, TAVR

1 | INTRODUCTION

Since transcatheter aortic valve replacement (TAVR) was first approved by the US Food and Drug Administration (FDA) in November 2011 for the treatment of severe aortic stenosis in patients not considered candidates for surgical aortic valve replacement (SAVR), there has been steady expansion of criteria for use based on data from prospective randomized clinical trials.[1–5] Today, TAVR is no longer just for inoperable patients; it is now FDA-approved for the treatment of severe aortic stenosis in patients who are at extreme, high, and intermediate risk for mortality and morbidity from SAVR as determined by a Heart Team.

The most recent update from the Society of Thoracic Surgeons (STS) Adult Cardiac Surgical Database (ACSD) revealed a "meteoric" rise in TAVR volume since the database began capturing this procedure in 2012.[6] A previous study from the Michigan Society of Thoracic and Cardiovascular Surgeons Quality Collaborative (MSTCVS-QC) showed that overall SAVR volume in Michigan increased in the early years of TAVR implementation.[7] This study builds on the previous study by utilizing the MSTCVS-QC database to examine more recent trends in aortic valve replacement (AVR) in Michigan, determine factors that influenced trends, compare patient characteristics between those undergoing SAVR and TAVR, and predict future trends based on known factors.

2 | PATIENTS AND METHODS

The MSTCVS-QC is a statewide database of collective surgical cases and associated perioperative, operative, and outcomes data entered into the STS ACSD with state-specific data fields. It comprises 33 sites that perform cardiac surgery, 21 of which also perform TAVR. The MSTCVS-QC database was used to identify patients who underwent SAVR, either with or without coronary artery bypass grafting (CABG), and patients who underwent TAVR from January 1, 2012 to June 30, 2017. (In the STS database, one can only tell if a patient underwent percutaneous coronary intervention (PCI) ≤6 h or >6 h prior to TAVR. Therefore, selecting patients who underwent TAVR automatically includes any patient who underwent TAVR + PCI, which would be equivalent to the SAVR + CABG patients in the study). Patients who underwent SAVR + CABG were included because patients who undergo TAVR with PCI either concomitantly or in staged fashion would have undergone SAVR + CABG had TAVR not been available.

The STS Short-Term Risk Calculator was used to calculate predicted risk of mortality (PROM) for patients undergoing SAVR and TAVR with the most recent clinical information available prior to the procedure. Patients were stratified into low (PROM ≤3%), intermediate (3% <PROM ≤8%), high (8% <PROM ≤15%), and extreme (PROM >15%) risk groups based on the STS PROM, consistent with risk group stratification performed in previous clinical trials.

Patients who underwent TAVR who were in the MSTCVS-QC database were also matched with patients who underwent TAVR in the Michigan TAVR database, which consists of patients entered into the Society of Thoracic Surgeons/American College of Cardiology (STS/ACC) Transcatheter Valve Therapy (TVT) Registry for the state of Michigan. The Heart Team-designated risk category for matched patients was obtained from the TVT Registry, and based on risk group stratification performed in the SURTAVI trial were stratified into intermediate, high, and extreme risk groups.[5] Because the TVT database only contains patients in whom TAVRs were implanted commercially, not all of the TAVR patients in the MSTCVS-QC database (which contains patients who were enrolled in a clinical trial as well) had a corresponding match in the TVT Registry.

Risk factors in the STS Short-Term Risk Calculator, as well as other risk factors not in the calculator that have been associated with increased operative mortality or are used by Heart Teams to add incremental risk when assessing patients for SAVR,[8] were compared between SAVR and TAVR groups stratified by STS PROM or Heart Team-designated risk category. These include models for end-stage liver disease score, prolonged 5-m walk test, home oxygen use, bronchodilator therapy, and abnormal pulmonary function tests. Student's t-test was performed for continuous variables. Chi-square test or Fisher's exact test was used to compare categorical variables.

The impact of expanded FDA approval dates on TAVR volume over time was assessed using interrupted time series regression analysis (Supplemental File). The effect of additional number of TAVR sites, cumulatively assessed at the end of each year, was also studied using this analysis.

All statistical analysis was performed using SAS version 9.3 (SAS Institute, Cary, NC).

3 | RESULTS

From January 2012 through June 2017, 60 419 cardiac surgical operations were performed in the state of Michigan, of which 13 987 were surgical or transcatheter AVR. A total of 5763 patients underwent SAVR, 3754 patients underwent SAVR + CABG, and 4470 patients underwent TAVR ± PCI (Figure 1). From January 2012 through December 2016, overall annual AVR volume increased by 40% (from 2086 to 2920), with a 14% decrease in the number of SAVR cases (from 1149 to 984), a 12% decrease in the number of SAVR + CABG cases (from 743 to 656), and a 560% increase in the number of TAVR cases (from 194 to 1280). Trends in SAVR, SAVR + CABG, and TAVR ± PCI volume are shown in Figure 2.

Stratification by STS PROM of patients who underwent SAVR or SAVR + CABG and the change over time is shown in Figure 3. There were 5945 patients with STS PROM ≤3%, 2896 patients with 3% <PROM ≤8%, 515 patients with 8% <PROM ≤15%, and 161 patients with PROM >15%. The majority of patients had STS PROM ≤8% (ie, low- and intermediate-risk patients).

Stratification by Heart Team-designated risk category (Figure 4A) or by STS PROM (Figure 4B) of patients who underwent TAVR and the change over time is shown in Figure 4. There were 695 patients with STS PROM ≤3%, 2508 patients with 3% <PROM ≤8%, 962 patients with 8% <PROM ≤15%, and 305 patients with PROM >15%. Of the
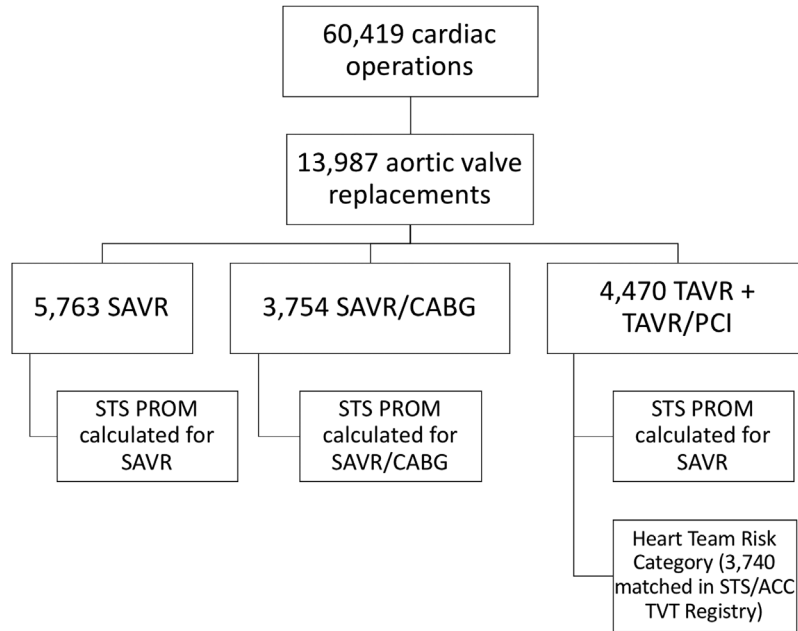
FIGURE 1 Flowchart of patients included in the study from the Michigan Society of Thoracic and Cardiovascular Surgeons Quality Collaborative (MSTCVS-QC) database from January 1, 2012 to June 30, 2017. ACC, American College of Cardiology; CABG, coronary artery bypass grafting; PCI, percutaneous coronary intervention; PROM, predicted risk of mortality; SAVR, surgical aortic valve replacement; STS, Society of Thoracic Surgeons; TAVR, transcatheter aortic valve replacement; TVT, transcatheter valve therapy

4470 patients who underwent TAVR who are in the MSTCVS-QC database, 3740 patients were able to be matched with a patient in the STS/ACC TVT Registry. By Heart Team-designated risk category, 11 patients were low risk, 329 patients were intermediate risk, 2000 patients were high risk, and 1400 patients were extreme risk.

Comparison of patient characteristics between SAVR and TAVR patients stratified by STS PROM is shown in Table 1 and by Heart Team-designated risk category in Table 2. When SAVR and TAVR patients were stratified by STS PROM and compared across low, intermediate, high, and extreme risk groups, patients undergoing TAVR were statistically significantly older, had more peripheral arterial

disease, more previous PCI or CABG, more heart failure and history of arrhythmia, and more home oxygen use. When SAVR and TAVR patients were stratified by Heart Team-designated risk category and compared across intermediate, high, and extreme risk groups, patients undergoing TAVR were statistically significantly older and had more previous PCI or CABG. Interestingly, SAVR was more common in higher-risk patients with renal dysfunction including dialysis, chronic or
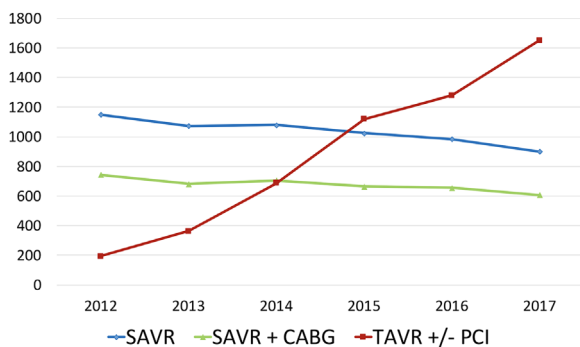
FIGURE 2 Annual aortic valve replacement volume from 2012 to 2016 with projected volume in 2017 based on data from January 1, 2017 to June 30, 2017. ACC, American College of Cardiology; CABG, coronary artery bypass grafting; PROM, predicted risk of mortality; SAVR, surgical aortic valve replacement; STS, Society of Thoracic Surgeons; TAVR, transcatheter aortic valve replacement; TVT, transcatheter valve therapy
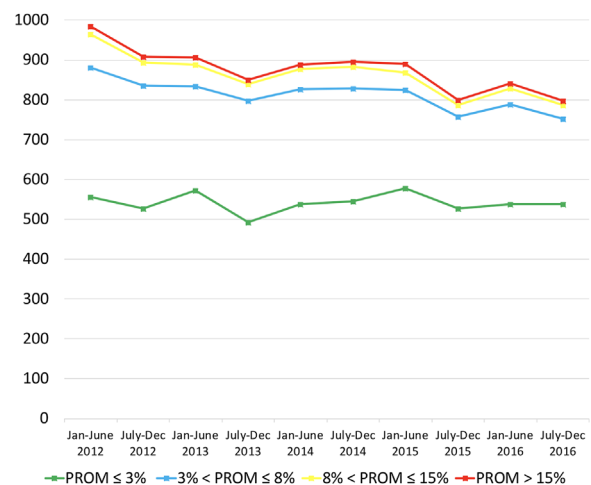
FIGURE 3 Change in surgical aortic valve replacement volume stratified by PROM. ACC, American College of Cardiology; CABG, coronary artery bypass grafting; PROM, predicted risk of mortality; SAVR, surgical aortic valve replacement; STS, Society of Thoracic Surgeons; TAVR, transcatheter aortic valve replacement; TVT, transcatheter valve therapy
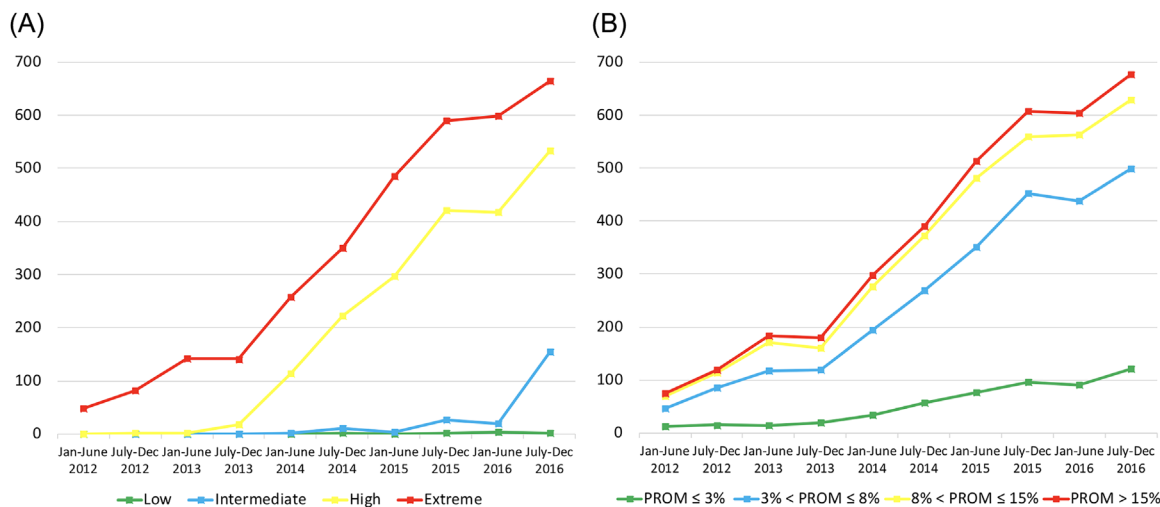
FIGURE 4 A, Change in TAVR volume stratified by risk category as designated by the Heart Team in the Transcatheter Valve Therapy Registry. B, Change in TAVR volume stratified by PROM. ACC, American College of Cardiology; CABG, coronary artery bypass grafting; PROM, predicted risk of mortality; SAVR, surgical aortic valve replacement; STS, Society of Thoracic Surgeons; TAVR, transcatheter aortic valve replacement; TVT, transcatheter valve therapy

severe lung disease, immunosuppression, native coronary disease, and lower albumin level (<3.3 g/dL).

Interrupted time series regression analysis of the effect of FDA approval dates on TAVR volume showed only two out of eight dates at which there was a statistically significant change in level ($\log_{\text{TAVR volume}}$) but not slope ($\log_{\text{TAVR volume/mo}}$): before and after FDA approval of the Edwards SAPIEN valve (Edwards Lifesciences, Irvine, CA) for high-risk patients which occurred in October 2012 ($P < 0.0001$; 95% confidence interval [CI] 1.96, 5.29) and before and after FDA approval of the Edwards SAPIEN XT valve for native and bioprosthetic valve disease in high- and extreme-risk patients which occurred in October 2015 ($P = 0.0363$; 95%CI 1.10, 20.9). Analysis of additional number of TAVR sites on TAVR volume as assessed at the end of each calendar year showed only one time point—before and after December 31, 2012 when the total number of TAVR sites was 9—at which there was a statistically significant change, again in level but not in slope ($P = 0.002$; 95%CI 1.72, 5.60).

4 | DISCUSSION

Our observations in the state of Michigan are similar to those reported nationally by the STS ACSD.[6] Namely, there has been a gradual decrease in number of SAVR cases performed, including SAVR + CABG, and there has been a dramatic rise in the number of TAVR cases. Based on the first two quarters of data we obtained from 2017, that trend is predicted to accelerate. When examining the change in SAVR volume stratified by STS PROM, although there has been a slight decrease in the number of high- and extreme-risk patients undergoing SAVR, this does not explain the rise in TAVR volume.

When examining TAVR patients stratified into risk groups by STS PROM or Heart Team-designated risk category, one notes disparity between the two graphs (Figure 4). During this time period TAVR was

only commercially approved for extreme- and high-risk patients until August 2016. Interestingly, when patients were stratified by STS PROM, the majority of patients receiving TAVR were intermediate-risk patients. Possible reasons to explain this include consideration of factors that may increase the risk of SAVR but are not in the STS Short-Term Risk Calculator. Several factors defined by the Valve Academic Research Consortium include porcelain or severely atherosclerotic aorta, frailty, hostile chest, or previous coronary bypass grafts closely adherent to the sternum or crossing the midline.[9] There are also other factors to consider that may decrease the benefit of SAVR, such as extreme age, underlying malignancy, or disability. These factors are all taken into consideration by the Heart Team when determining surgical risk and making therapy decisions. Another possible explanation is that these are patients not previously referred for or offered SAVR due to incremental risk factors who are now offered therapy with TAVR. They are not necessarily patients who would subtract from SAVR volume, which suggests why we have not yet seen a dramatic decrease in SAVR volume.

When comparing how SAVR and TAVR patients differ with regards to procedural risk, the most consistent differences appear to be older age, history of previous PCI or CABG, and home oxygen use in patients undergoing TAVR. The higher proportion of TAVR patients who have history of previous PCI may be due to their undergoing staged or concomitant PCI for coronary artery disease (as opposed to undergoing SAVR + CABG). Interestingly, high- and extreme-risk SAVR patients also have more co-morbidities in the areas of renal dysfunction, chronic lung disease, immunosuppression, and low albumin level. It is worthwhile to note that there are 12 sites in Michigan that perform SAVR but not TAVR. Of the nearly 14 000 AVRs performed during the study time period, approximately 11% were performed at sites at which TAVR is not performed. High- or extreme-risk patients at those sites may not have been able to travel to a site that performs TAVR and would have added to the morbidity of SAVR patients in the database.

TABLE 1 Comparison of patient characteristics of surgical aortic valve replacement (SAVR) and transcatheter aortic valve replacement (TAVR) patients stratified by Society of Thoracic Surgeons Predicted Risk of Mortality (PROM)

	PROM ≤3%			3% <PROM ≤8%			83% <PROM ≤15%			PROM >15%		
	SAVR (N = 5945)	TAVR (N = 695)	P	SAVR (N = 2896)	TAVR (N = 2508)	P	SAVR (N = 515)	TAVR (N = 962)	P	SAVR (N = 161)	TAVR (N = 305)	P
Age, mean (SD), y	65.8 (10.7)	72.0 (9.9)	<0.0001	75.0 (9.2)	81.1 (7.9)	<0.0001	75.5 (10.5)	83.4 (8.3)	<0.0001	73.3 (11.5)	83.8 (8.4)	<0.0001
Men, No. (%)	4200 (70.7)	475 (68.4)	0.2083	1704 (58.8)	1359 (54.2)	0.0006	293 (56.9)	425 (44.2)	<0.0001	95 (59.0)	127 (41.6)	0.0004
BMI, mean (SD), kg/m²	31.2 (9.9)	30.9 (6.7)	0.3415	30.6 (8.7)	29.5 (12.3)	0.0001	30.0 (7.3)	28.2 (7.0)	<0.0001	31.7 (8.0)	26.9 (6.8)	<0.0001
HTN, No. (%)	4772 (80.3)	582 (83.7)	0.0296	2664 (92.0)	2316 (92.5)	0.5240	479 (93.0)	910 (94.6)	0.2201	153 (95.0)	291 (95.4)	0.8226
Diabetes, No. (%)	1705 (28.7)	224 (32.3)	0.0495	1354 (46.8)	970 (38.7)	<0.0001	277 (53.8)	485 (50.4)	0.2167	111 (68.9)	181 (59.3)	0.0416
PAD, No. (%)	418 (7.1)	113 (16.3)	<0.0001	587 (20.3)	714 (28.5)	<0.0001	150 (29.1)	361 (37.6)	0.0011	42 (26.1)	147 (48.4)	<0.0001
CVD, No. (%)	882 (15.0)	218 (31.4)	<0.0001	772 (26.8)	837 (33.5)	<0.0001	176 (34.4)	349 (36.4)	0.4418	44 (27.3)	111 (36.8)	0.0407
Cr, mean (SD), mg/dL	0.97 (0.49)	0.99 (0.46)	0.4723	1.24 (1.08)	1.22 (0.84)	0.4621	1.87 (1.80)	1.56 (1.19)	0.0004	2.87 (2.53)	2.19 (1.65)	0.0021
Dialysis, No. (%)	17 (0.3)	1 (0.14)	1.0000	74 (2.6)	47 (1.9)	0.0911	66 (12.8)	63 (6.6)	<0.0001	47 (26.2)	60 (19.7)	0.0201
Chronic lung disease, No. (%)	1333 (22.6)	201 (29.2)	0.0001	1175 (40.9)	1028 (41.3)	0.7483	292 (57.5)	573 (60.1)	0.3271	112 (69.6)	216 (71.8)	0.6202
Immuno suppression, No. (%)	133 (2.2)	44 (6.3)	<0.0001	161 (5.6)	171 (6.8)	0.0546	60 (11.7)	80 (8.3)	0.036	33 (20.5)	49 (16.1)	0.2322
CAD, No. (%)	2496 (44.0)	403 (61.1)	<0.0001	2053 (72.9)	1572 (66.4)	<0.0001	408 (81.3)	636 (70.2)	<0.0001	120 (79.0)	220 (76.1)	0.5026
Previous MI, No. (%)	733 (12.4)	167 (24.1)	<0.0001	767 (26.6)	694 (27.9)	0.2536	230 (44.9)	319 (33.6)	<0.0001	85 (53.1)	127 (41.8)	0.0197
Previous PCI, No. (%)	1353 (22.8)	406 (58.4)	<0.0001	1142 (39.5)	1645 (65.7)	<0.0001	243 (47.2)	719 (74.9)	<0.0001	79 (49.1)	237 (77.7)	<0.0001
Previous CABG, No. (%)	172 (2.9)	122 (17.6)	<0.0001	279 (9.6)	644 (25.7)	<0.0001	79 (15.3)	304 (31.7)	<0.0001	24 (14.9)	116 (38.0)	<0.0001
LVEF, mean (SD), %	58 (10)	58 (12)	0.1836	55 (12)	55 (13)	0.2224	50 (14)	52 (15)	0.0023	47 (14)	47 (16)	0.6197
CHF, No. (%)	1169 (19.7)	332 (47.9)	<0.0001	1205 (41.7)	1614 (64.4)	<0.0001	353 (68.8)	792 (82.3)	<0.0001	132 (82.0)	288 (94.4)	<0.0001
Arrhythmia, No. (%)	813 (13.7)	169 (24.3)	<0.0001	870 (30.1)	1058 (42.3)	<0.0001	231 (44.9)	546 (56.8)	<0.0001	83 (51.6)	198 (64.9)	0.0050
Prior AVR, No. (%)	71 (1.2)	51 (7.3)	<0.0001	79 (2.7)	129 (5.1)	<0.0001	25 (4.9)	73 (7.6)	0.0442	10 (6.21)	29 (9.5)	0.2216
Liver disease, No. (%)	202 (3.4)	42 (6.1)	0.0004	83 (2.9)	69 (2.8)	0.8092	12 (2.3)	39 (4.1)	0.0813	7 (4.4)	10 (3.3)	0.6072
Severe lung disease, No. (%)	133 (9.8)	55 (16.5)	0.0005	293 (33.0)	384 (31.3)	0.4155	96 (62.3)	242 (55.3)	0.1264	56 (73.7)	110 (74.3)	0.9175
Home oxygen use, No. (%)	71 (1.2)	55 (7.9)	<0.0001	110 (3.8)	296 (11.8)	<0.0001	37 (7.2)	186 (19.4)	<0.0001	15 (9.3)	63 (20.7)	0.0018
BMI <21 kg/m², No. (%)	157 (2.6)	20 (2.9)	0.7143	121 (4.2)	150 (6.0)	0.0024	36 (7.0)	93 (9.7)	0.0825	10 (6.2)	45 (14.8)	0.0066
Albumin <3.3 g/dL, No. (%)	266 (4.9)	62 (9.5)	<0.0001	400 (15.0)	297 (12.6)	0.0128	133 (27.5)	189 (21.1)	0.008	73 (49.0)	119 (41.5)	0.1331

AVR, aortic valve replacement; BMI, body mass index; CABG, coronary artery bypass grafting; CAD, coronary artery disease; CHF, congestive heart failure; Cr, Creatinine; CVD, cerebrovascular disease; HTN, hypertension; LVEF, left ventricular ejection fraction; MI, myocardial infarction; PAD, peripheral arterial disease; PCI, percutaneous coronary intervention; SD, standard deviation.

TABLE 2 Comparison of patient characteristics of surgical aortic valve replacement (SAVR) and transcatheter aortic valve replacement (TAVR) patients stratified by heart team-designated risk category

	Intermediate			High			Extreme		
	SAVR (N = 2896)	TAVR (N = 329)	P	SAVR (N = 515)	TAVR (N = 2000)	P	SAVR (N = 161)	TAVR (N = 1400)	P
Age, mean (SD), y	75.0 (9.2)	79.4 (7.6)	<0.0001	75.5 (10.5)	80.5 (9.0)	<0.0001	73.3 (11.5)	80.6 (9.3)	<0.0001
Men, No. (%)	1704 (58.8)	187 (57.2)	0.5650	293 (56.9)	1058 (53.0)	0.1122	95 (59.0)	700 (50.0)	0.0304
BMI, mean (SD), kg/m²	30.6 (8.7)	30.3 (6.6)	0.4342	30.0 (7.3)	29.0 (9.1)	0.0123	31.7 (8.0)	28.6 (7.0)	<0.0001
HTN, No. (%)	2664 (92.0)	300 (91.2)	0.6126	479 (93.0)	1839 (92.1)	0.4849	153 (95.0)	1280 (91.4)	0.1146
Diabetes, No. (%)	1354 (46.8)	147 (44.7)	0.4750	277 (53.8)	794 (39.7)	<0.0001	111 (68.9)	609 (43.5)	<0.0001
PAD, No. (%)	587 (20.3)	103 (31.4)	<0.0001	150 (29.1)	592 (29.7)	0.8131	42 (26.1)	444 (31.7)	0.1427
CVD, No. (%)	772 (26.8)	112 (34.0)	0.0052	176 (34.4)	719 (36.2)	0.4553	44 (27.3)	455 (32.6)	0.1735
Cr, mean (SD), mg/dL	1.24 (1.08)	1.15 (0.88)	0.0953	1.87 (1.80)	1.33 (1.01)	<0.0001	2.87 (2.53)	1.35 (0.98)	<0.0001
Dialysis, No. (%)	74 (2.6)	5 (1.5)		66 (12.8)	68 (3.4)	<0.0001	47 (29.2)	72 (5.1)	<0.0001
Chronic lung disease, No. (%)	1175 (40.9)	107 (32.5)	0.0034	292 (57.5)	887 (44.8)	<0.0001	112 (69.6)	724 (52.1)	<0.0001
Immunosuppression, No. (%)	161 (5.6)	16 (4.9)	0.6067	60 (11.7)	162 (8.1)	0.0107	33 (20.5)	103 (7.4)	<0.0001
CAD, No. (%)	2053 (72.9)	200 (64.1)	0.0010	408 (81.3)	1302 (69.8)	<0.0001	120 (79.0)	879 (66.1)	0.0014
Previous MI, No. (%)	767 (26.6)	568 (28.3)	0.1758	230 (44.9)	268 (33.5)	<0.0001	85 (53.1)	112 (43.4)	0.0531
Previous PCI, No. (%)	1142 (39.5)	194 (59.0)	<0.0001	243 (47.2)	1362 (68.2)	<0.0001	79 (49.1)	968 (69.2)	<0.0001
Previous CABG, No. (%)	279 (9.6)	70 (21.3)	<0.0001	79 (15.3)	516 (25.9)	<0.0001	24 (14.9)	421 (30.1)	<0.0001
LVEF, mean (SD), %	55 (12)	57 (11)	0.0020	50 (14)	54 (14)	<0.0001	47 (14)	53 (14)	<0.0001
CHF, No. (%)	1205 (41.7)	181 (55.2)	<0.0001	353 (68.8)	1468 (73.5)	0.0348	132 (82.0)	932 (66.6)	<0.0001
Arrhythmia, No. (%)	870 (30.1)	133 (40.4)	0.0001	231 (44.9)	888 (44.5)	0.8889	83 (51.6)	638 (45.6)	0.1517
Prior AVR, No. (%)	79 (2.7)	11 (3.3)	0.5206	25 (4.9)	119 (5.6)	0.3399	10 (6.2)	96 (6.9)	0.7577
Liver disease, No. (%)	83 (2.9)	3 (0.9)	0.0441	12 (2.3)	69 (3.5)	0.1957	7 (4.4)	54 (3.9)	0.6717
Severe lung disease, No. (%)	293 (33.0)	26 (16.7)	<0.0001	96 (62.3)	306 (37.6)	<0.0001	56 (73.7)	349 (45.9)	<0.0001
Home oxygen use, No. (%)	110 (3.8)	18 (5.5)	0.1382	37 (7.2)	250 (12.5)	0.0007	15 (9.3)	248 (17.7)	0.0069
BMI <21 kg/m², No. (%)	121 (4.2)	13 (4.0)	0.8535	36 (7.0)	131 (6.6)	0.7225	10 (6.2)	125 (8.9)	0.2453
Albumin <3.3 g/dL, No. (%)	400 (15.0)	15 (5.1)	<0.0001	133 (27.5)	287 (15.5)	<0.0001	73 (49.0)	260 (19.5)	<0.0001

AVR, aortic valve replacement; BMI, body mass index; CABG, coronary artery bypass grafting; CAD, coronary artery disease; CHF, congenstive heart failure; Cr, Creatinine; CVD, cerebrovascular disease; HTN, hypertension; LVEF, left ventricular ejection fraction; MI, myocardial infarction; PAD, peripheral arterial disease; PCI, percutaneous coronary intervention; SD, standard deviation.

Since FDA approval of TAVR for intermediate-risk patients in August 2016, there has been a notable increase in the proportion of intermediate-risk patients who have received commercial TAVR (Figure 4A); this trend is expected to continue. FDA approval of TAVR in low-risk patients with severe aortic stenosis is anticipated. Based on the fact that the majority of patients undergoing SAVR are low-risk patients, we will likely continue to see a rapid increase in TAVR volume, perhaps this time accompanied by the beginning of a more dramatic decline in SAVR volume. Continued refinement of risk assessment tools to appropriately assess risk of SAVR versus TAVR,

especially in younger patients for whom long-term valve durability and the effect of permanent pacemaker placement are a concern, will become even more important as we analyze long-term outcomes and recommend therapy decisions to our patients.

Our analysis is limited by its retrospective and observational nature and use of a large database that does not allow us to more closely examine data at the individual patient level. Missing data points for patient variables may have affected our ability to accurately detect differences between SAVR and TAVR patients. Furthermore, we did not examine the effect of same-day admissions and the "minimalist

approach" to TAVR on TAVR volumes.[10,11] Finally, short- (30-day) and long-term outcomes were not reported following TAVR to determine whether better patient selection by Heart Teams improved survival, as has been reported in other series, so that patients do not die from, as opposed to with, aortic stenosis.[11–13]

ORCID

Karen M. Kim http://orcid.org/0000-0002-5641-7572
Ibrahim Sultan http://orcid.org/0000-0002-1737-4012

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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