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## Impact of Transcatheter Technology on Surgical Aortic Valve Replacement Volume, Outcomes and Cost

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## Abstract

**Background**—Transcatheter aortic valve replacement (TAVR) represents a disruptive technology that is rapidly expanding in use. We evaluated the impact on surgical aortic valve replacement (SAVR) patient selection, outcomes, volume and cost.

**Methods**—A total of 11,565 patients who underwent SAVR with or without coronary artery bypass grafting (2002–2015) were evaluated from the Virginia Cardiac Services Quality Initiative database. Patients were stratified by surgical era: pre-TAVR era (2002–2008, n=5,113), early-TAVR era (2009–2011, n=2,709), and commercial-TAVR era (2012–2015, n=3,743). Patient characteristics, outcomes and resource utilization were analyzed by univariate analyses.

**Results**—Throughout the study period, statewide SAVR volumes increased with median volumes of pre-TAVR: 722 cases/year, early-TAVR: 892 cases/year, and commercial-TAVR: 940 cases/year (p = 0.005). Implementation of TAVR was associated with declining STS predicted risk of mortality among SAVR patients (3.7%, 2.6%, 2.4%; p<0.0001), despite increasing rates of comorbid disease. Mortality was lowest in the current commercial-TAVR era (3.9%, 4.3%, 3.2%; p=0.05) while major morbidity decreased throughout the time period (21.2%, 20.5%, 15.2%; p<0.0001). The lowest observed to expected ratios for both occurred in the commercial-TAVR era (0.9 and 0.9 respectively). Resource utilization increased generally, including total cost increases from \$42,835 to \$51,923 to \$54,710 (p<0.0001).

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**Conclusions**—At present SAVR volumes have not been affected by the introduction of TAVR. The outcomes for SAVR continue to improve, potentially due to availability of transcatheter options for high-risk patients. Despite rising costs for SAVR, open approaches still provide a significant cost advantage over TAVR.

There are three main forces with tremendous potential to increase the number of patients who are eligible for aortic valve replacement. The aging population in the United States is expected to expand the number of Americans over age 65 from 44.7 million in 2013 to 98 million by 2060 [1]. The prevalence of aortic stenosis in this population ranges from 1.3% to 9.8%, increasing with age [2]. Yet due to perceived risk, 30 to 40% of symptomatic patients are not referred for surgery [3]. Finally, there is increasing evidence regarding the poor outcomes of patients with asymptomatic aortic stenosis managed medically that may benefit from expanded surgical indications for replacement [4].

Transcatheter aortic valve replacement (TAVR) has revolutionized the treatment of aortic stenosis, providing a safe and less invasive alternative, albeit with limited mid- and long-term follow-up. In addition to being the standard of care for inoperable patients with a reasonable life expectancy, TAVR is now approved for both moderate and high-risk patients due to noninferiority compared to surgery [5]. There is conflicting evidence regarding outcomes in low risk patients and multiple industry-sponsored trials are underway to address this population [6–9]. More mature transcatheter markets suggest that future increases in aortic valve replacement volume may be entirely treated by transcatheter procedures, directly competing with surgical aortic valve replacement (SAVR) [10].

Although recent data has suggested that surgical volume continues to increase with the introduction of TAVR, contemporary and large regional data are limited [11, 12]. There continue to be many unknowns regarding TAVR including how adoption will proceed at smaller institutions, future cost changes, and long-term durability. With the rapidly changing landscape, our study aims to identify the impact that commercialization of TAVR has had on SAVR volume, patient risk profiles, and outcomes.

## PATIENTS AND METHODS

#### Patient Data

The Virginia Cardiac Services Quality Initiative (VCSQI) currently includes 18 hospitals and cardiac surgical practices in the Commonwealth of Virginia that captures approximately 99% of adult cardiac surgery cases in the Commonwealth. VCSQI clinical and cost data acquisition and matching has been described previously [13, 14]. Clinical data is collected from each participating institution using Society of Thoracic Surgeons (STS) data entry forms. The VCSQI database pairs STS clinical data with hospital patient discharge information. Clinical variables utilize standard STS definitions including for operative mortality (in-hospital and 30-day) as well as major morbidity (permanent stroke, renal failure, prolonged ventilation, deep sternal wound infection, and reoperation).

Patient records for isolated SAVR and SAVR with coronary artery bypass grafting (CABG; n=11,565) were identified from January 1, 2002 through June 30, 2016, excluding patients

with endocarditis. Patients were stratified for analysis by surgical era: pre-TAVR era (2002–2008, n=5,113), early-TAVR era (2009–2011, n=2,709), and commercial-TAVR era (2012–2015, n=3,743). Hospitals were classified as TAVR performing if they performed the procedure in the early-TAVR era. Six hospitals met this criterion, and only since 2015 have other hospitals begun performing TAVR. For cost analyses patients were excluded for missing or zero total cost. Cases in the first six months of 2016 (n=478) were included only in the case volume analysis after extrapolating for the rest of the year. The Institutional Review Board for the University of Virginia granted exemption due to lack of Health Insurance Portability and Accountability Act patient identifiers (IRB#19457).

## Cost Data

STS clinical data is matched with Uniform Billing (UB)-04 files, and prior to 2013 was matched with UB-92 files, with a successful matching rate of 99%. These files are used to calculate charges that are classified by International Classification of Diseases, ninth revision (ICD-9)– based revenue codes. Estimated costs are derived from publicly available cost-to-charge ratios submitted to the Center for Medicare and Medicaid Services (CMS) by each institution. The cost and charge data is then categorized by phase of care for analysis (total stay, diagnostics, interventions, general care, other) as demonstrated in Supplemental Table 1. To account for medical specific inflation, cost data was adjusted to 2015 dollars using the market basket for the CMS Inpatient Prospective Payment System.

#### Statistical Analysis

Baseline characteristics, operative trends, and short-term outcomes were analyzed by univariate analysis. The Chi-Squared test was utilized for categorical variables and the Kruskal-Wallis test for continuous variables. Categorical data was summarized by proportions and continuous data by median and interquartile range due to skewedness, except for cost data, which was presented as mean and standard deviation. Hierarchic logistic regression analyzed operative mortality and major morbidity while adjusting for risk using STS predicted risk of mortality (PROM) and accounting for clustering at the hospital level. All statistical analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC). Significance was determined as alpha less than 0.05.

## RESULTS

## Impact on Surgical Volume

Throughout the study period, SAVR volumes in our statewide database increased with median volumes of 722 cases/year (pre-TAVR), 892 cases/year (early-TAVR) and 940 cases/ year (commercial-TAVR; p = 0.003; Figure 1). On a per-hospital basis, the volume increased from a median of 46 cases/year (pre-TAVR) to 52 cases/year (early-TAVR) and stayed at 52 cases/year in the commercial-TAVR era (p=0.005). For all TAVR hospitals combined, median annual volume increased from 440 cases/year pre-TAVR to 570 cases/year (early-TAVR) before a slight decrease to 563 cases/year (commercial-TAVR; p=0.005; Figure 1A), which per hospital equates to 79, 95 and 94 cases/year (p=0.007). Meanwhile, the combined non-TAVR hospital volume increased from 301 cases/year pre-TAVR to 326 cases/year (early-TAVR) and 368 cases/year (commercial-TAVR; p=0.01), which on a per hospital basis

is 29, 30 and 31 cases/year (p=0.51). Isolated SAVR volume increased over every era from a median of 357 to 498 to 565 cases per year (p=0.004; Figure 1B). This trend did not hold for combined SAVR and CABG, which demonstrated the highest median volume in the early-TAVR era (357 vs 393 vs 373 cases per year; p=0.03).

## **Changing Risk profile**

Implementation of TAVR was associated with a significant trend of declining STS PROM among SAVR patients (3.7%, 2.6%, 2.4%, p<0.0001). Driving the lower risk profile were declining rates of concomitant CABG, fewer reoperative surgeries, and more elective operations (Table 1). However, trends in patient co-morbid disease increased over surgical eras including more frequent diabetes, chronic lung disease, prior myocardial infarction, and recent heart failure (all p<0.0001; Table 1), among others. Interestingly, the severity of the aortic valve disease appears to have decreased slightly with the median maximum aortic gradient decreasing (48mmHg, 46mmHg, 45mmHg, p<0.0001).

Within isolated SAVR, STS PROM also significantly declined from a median of 2.8% in the Pre-TAVR era to 2.0% and finally 1.8% (p<0.0001). The median PROM was similar between TAVR and non-TAVR hospitals for the pre-TAVR era (3.7% vs 3.8%, p=0.15) and the early-TAVR era (2.6% vs 2.7%, p=0.32), but was lower in TAVR sites in the commercial-TAVR era (2.3% vs 2.5%, p=0.0003).

## **Operative Trends and Outcomes**

As described above patients underwent declining rates of concomitant CABG, reoperative surgery, and urgent or emergent surgery. In addition, the rate of bioprosthetic valve use increased significantly (83%, 91%, 94%, p<0.0001), while the rates of annular enlargement were slightly more common in the pre-TAVR era (5%, 4%, 4%; p=0.03). Similarly, cross clamp times (93min, 86min, 86min; P<0.0001) and cardiopulmonary bypass (CPB) times were longest in the pre-TAVR era (125min, 117min, 117min; p<0.0001).

With increasing utilization of TAVR came largely declining rates of operative mortality (3.9%, 4.3%, 3.2%; p=0.05; Table 2). More strikingly, rates of major morbidity decreased as well (21.2%, 20.5%, 15.2%, p<0.0001). In fact, all components of major morbidity had the lowest rate of complication in the current commercial-TAVR era (Table 2). Rates of transfusion significantly decreased throughout the study period (52%, 47%, 38%, p<0.0001), while rates for reoperation due to bleeding also decreased from the pre-TAVR era (4.4%, 3.3%, 3.4%, p=0.02). The only complication to increase over time was the rate of postoperative atrial fibrillation (24%, 28%, 30%, p<0.0001).

After risk adjustment, operative era remains a significant predictor of morbidity and mortality (Table 3). The early-TAVR era was independently associated with increased risk for operative mortality and major morbidity, while for isolated SAVR only mortality was increased in this era. The commercial-TAVR era was independently associated with lower rates of major morbidity. TAVR performance was not independently associated with outcomes (all p>0.05).

#### **Resource utilization**

The improvement in outcomes was accompanied by a general increase in resource utilization (Table 2). This included higher frequency of discharge to a facility (18%, 27%, 30%, p<0.0001). While length of stay from surgery to discharge did not change (6d, 6d, 6d, p=0.23), ICU stay statistically increased, although this may not be clinically relevant change (48hr, 48hr, 49.8hr, p=0.006). Finally, average total hospital cost increased from \$42,835 to \$51,923 and \$54,710 (p<0.0001) and the component costs by phase of care are displayed in Figure 2. The costs of isolated AVR increased over time (Figure 3A) with increasing mean cost (\$38,410 vs \$45,837 vs \$49,878; p<0.0001). Interestingly, TAVR hospitals had higher mean total costs compared to non-TAVR hospitals (\$50,880 vs \$45,606; p<0.0001) with the yearly trends displayed in Figure 3B.

## COMMENT

This study evaluates the impact of TAVR over three eras of implementation on SAVR outcomes, volume and cost. SAVR is unquestionably undergoing significant changes, but competition from TAVR has not resulted in declining surgical volume, which is instead continuing to increase. Additional changes include which patients are selected for surgery, leading to a generally declining risk profile. Outcomes, in particular major morbidity, are improving with the lowest rates of most complications in the current era. This contrasts with increasing resource utilization including length of stay and hospital cost.

Contrary to what many surgeons fear, declining SAVR volume due to competition from TAVR was not borne out in this analysis. TAVR volume experienced dramatically increased volume in 2015 [15]. Yet the annual statewide volume increased over every era and demonstrated similar results to recently published literature [11, 12]. Furthermore, the growth was more pronounced for TAVR hospitals during the early-TAVR phase, while for non-TAVR hospitals the growth was slower but continued steadily throughout the study (Figure 1A). On a per hospital basis volume increased between pre- and early-TAVR eras, but not from the early- to commercial-TAVR era. Volume for early adopters of TAVR appears to have stagnated around 52 cases/hospital/year, while non-TAVR hospitals have continued growth. Some of the non-TAVR hospitals in the final year of the study began performing TAVR and new heart teams and outreach likely increased their volume [12]. An overall increase in referrals is an unlikely explanation since similar risk profiles of patients in the pre- and early-TAVR era would argue against non-TAVR hospitals taking on more complex patients. However, as some of these hospitals began to perform TAVR in the commercial-TAVR era the "halo" effect brought in additional higher risk patients. In summary, SAVR continues to experience growth and currently is most predominant at hospitals that were late adopters of TAVR.

The high rate of concomitant coronary artery disease and stenting during TAVR prompted the inclusion of SAVR with CABG [16, 17]. However, the same trends in terms of patient risk, increased risk-adjusted odds of mortality during the early-TAVR period, and increasing resource utilization are seen with isolated SAVR. We hypothesize that the inclusion of extreme and high-risk patients in the TAVR clinical trials is the reason for these results. Many of these patients were deemed extreme risk for reasons not included in the STS risk

model, where in the PARTNER B trial 32% of inoperable patients had severe frailty and 15% porcelain aorta [18].

The implementation of TAVR also appears to be changing both patient selection and the operations performed. The complexity of operations is decreasing with less concomitant CABG, non-elective cases, and prior cardiac surgery. Additionally, use of bioprosthetic valves is increasing, likely due to the availability of valve-in-valve transcatheter options if required in the future. In combination with patient factors, such as better left ventricular ejection fraction (LVEF) and less advanced valve disease, these changes have resulted in lower risk profiles of patients undergoing SAVR, potentially due to higher risk patients being selected for TAVR. Paradoxically, the decreased risk comes despite increasing comorbidities nearly across the board. It is clear that with TAVR as an alternative patient selection is driving the predicted risk of mortality lower.

Changing patients and operative trends has also translated to improved outcomes. Unadjusted mortality and major morbidity have improved with current rates of operative mortality at 3.2% and major morbidity at 15%. Interestingly, the observed to expected ratios (O:E) were highest during the early-TAVR era as clinical trials were underway in high-risk patients, demonstrating some likely unaccounted for risk during this time period. The O:E has since improved to 0.92 for operative mortality and 0.80 for morbidity and mortality.

The improving outcomes have come at the price of increased resource utilization, both in hospital with longer ICU stays, and post-acute care with increasing discharges to a facility. Hospital costs increased throughout the study period (Figure 2) and no single subcomponent appears to be the clear culprit. For comparison, estimates of cost for TAVR in the state of Virginia were recently published as \$81,638, although costs vary widely [13]. On the lower end, costs were recently estimated for Medicare patients at \$55,700, while the CoreValve Pivotal Trial estimated costs were \$69,592 [19, 20]. The average cost overall of isolated SAVR compares favorably at \$44,321, but the average cost in the current commercial-TAVR era was \$49,878.

The average cost for SAVR with CABG was \$54,396 and in the commercial-TAVR era was \$62,130. This equates to a cost differential of approximately \$10,000 compared to isolated SAVR. For comparison, the average cost of percutaneous coronary intervention (PCI) is \$17,543, although there is large cost variation [21, 22]. Although cost trajectories for TAVR and PCI are not well established, the trend of increasing costs for SAVR has the potential to quickly erode this advantage. This is particularly important as TAVR devices improve with smaller devices increasing the ability to perform transfemoral deployment, which in one series had an economic advantage to SAVR in high-risk patients.[23]

This study is a retrospective review and therefore susceptible to selection bias. In addition, contemporary TAVR and PCI cost data at participating institutions was not widely available and had to be inferred using previously reported results and therefore formal cost-effectiveness modeling was not able to be performed. Any database research is inherently limited by errors in the database, although the STS database is a model for clinical databases with 97% concordance with chart abstraction [24].

The introduction of TAVR has been a significant force that is reshaping SAVR in the United States. The structural changes leading to multidisciplinary valve teams and changing referral patterns resulted in increased volume for early adopters. This is shifting as TAVR becomes more widely distributed. Additionally, SAVR patient risk continues to decrease in large part from decreased surgical complexity, despite patients having more comborbid disease. SAVR outcomes continue to improve with respect to both morbidity and mortality. Finally, despite increasing costs for SAVR, there appears to still be significant cost savings compared to TAVR. However, the rising costs of SAVR will require careful attention to maintain an advantage.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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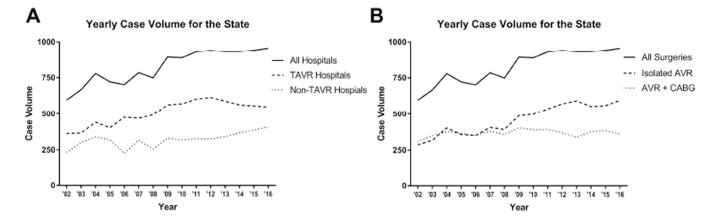
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## ABBREVIATIONS

AI	aortic insufficiency
BMI	body mass index
CABG	coronary artery bypass grafting
CCU	coronary care unit
CLD	chronic lung disease
CMS	Centers for Medicare and Medicaid Services
СРВ	cardiopulmonary bypass
ICU	intensive care unit
IPPS	Inpatient Prospective Payment Sample
IQR	interquartile range
LVEF	left ventricular ejection fraction
MR	mitral regurgitation

O:E	observed to expected ratio
ОТ	occupational therapy
РТ	physical therapy
<b>R</b> <sup>2</sup>	coefficient of determination
SAVR	surgical aortic valve replacement
STS	Society of Thoracic Surgeons
TAVR	transcatheter aortic valve replacement
PROM	predicted risk of mortality
PROMM	predicted risk of morbidity and mortality
VCSQI	Virginia Cardiac Services Quality Initiative

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#### Figure 1.

(A) The yearly total volume for the state is plotted over time with two subcategories for TAVR hospitals and non-TAVR hospitals. (B) The yearly volume is plotted over time, with subcategories for isolated SAVR and SAVR with CABG.

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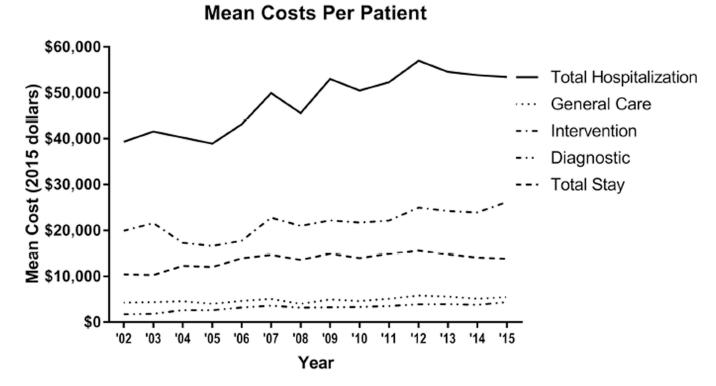
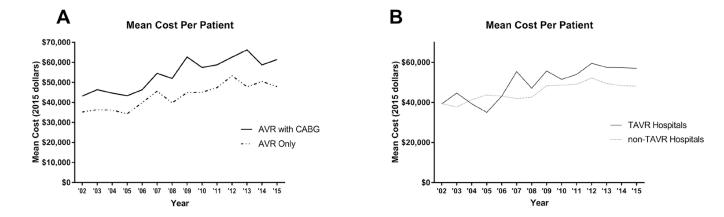


Figure 2.

The average total cost per patient is graphed over time with four subcategories of costs included.



#### Figure 3.

(A) The average cost per patient is graphed over time for SAVR with CABG and for isolated SAVR. (B) The average cost per patient is plotted for both TAVR hospitals and non-TAVR hospitals.

## Table 1

#### Surgical aortic valve replacement patient characteristics

	TAVR Era					
Baseline Characteristics	Pre-TAVR (n = 5,113)	Early-TAVR (n = 2,709)	Commercial-TAVR (n = 3,743)	p value		
Age (y, median, IQR)	72 (63–78)	72 (63–79)	71 (63–78)	0.005		
BMI (kg/m <sup>2</sup> , median, IQR)	27.8 (24.5–32.0)	28.7 (25.1–32.7)	29.0 (25.4–33.3)	<0.0001		
Female	1924 (37.6%)	1012 (37.4%)	1304 (34.8%)	0.02		
CLD (moderate/severe)	429 (8.5%)	304 (11.2%)	434 (11.8%)	< 0.0001		
Prior cerebrovascular accident	336 (6.7%)	95 (3.9%)	288 (7.7%)	< 0.0001		
Diabetes	1534 (30.0%)	895 (33.0%)	1372 (36.7%)	< 0.0001		
Dialysis dependent renal failure	103 (2.1%)	73 (2.7%)	67 (1.8%)	0.04		
Hypertension	3739 (73.1%)	2218 (81.9%)	3091 (82.6%)	< 0.0001		
Peripheral arterial disease	622 (12.2%)	324 (12.0%)	451 (12.1%)	0.96		
Coronary artery disease	2913 (57.2%)	1522 (56.2%)	2032 (55.0%)	0.11		
Prior myocardial infarction	709 (14.2%)	482 (17.8%)	680 (18.2%)	< 0.0001		
Heart failure within 2 weeks	1628 (31.8%)	1073 (39.6%)	1664 (44.5%)	< 0.0001		
LVEF (median, IQR)	55 (45-60)	60 (50-63)	60 (53–63)	< 0.0001		
AI (moderate/severe)	1388 (27.4%)	608 (22.5%)	967 (26.0%)	< 0.0001		
MR (moderate/severe)	300 (6.0%)	284 (11.3%)	457 (15.4%)	< 0.0001		
Maximum Mean Aortic Valve Gradient (mmHg, median, IQR)	48 (36–60)	46 (36–59)	45 (36–55)	< 0.0001		
Prior valve surgery	202 (4.0%)	91 (3.4%)	178 (4.8%)	0.02		
Prior CABG	503 (9.8%)	257 (9.5%)	254 (6.8%)	< 0.0001		
Previous Cardiac Intervention	1285 (25.1%)	730 (27.0%)	1054 (28.2%)	0.005		
STS PROM (median, IQR)	3.7% (2.2-6.4%)	2.6% (1.4-4.7%)	2.4% (1.4-4.2%)	<0.0001		
STS PROMM (median, IQR)	18.2% (12.5–27.1%)	18.7% (12.6–27.1%)	17.6% (12.5–25.4%)	0.003		
Operative Characteristics						
SAVR+CABG	2555 (50.0%)	1187 (43.8%)	1468 (39.2%)	< 0.0001		
Reoperative Surgery	494 (13.1%)	344 (12.7%)	395 (10.6%)	0.002		
Annular enlargement	170 (5.3%)	109 (4.0%)	157 (4.2%)	0.03		
Elective	3778 (74.0%)	2011 (74.3%)	2949 (78.8%)	<0.0001		
Bioprosthetic valve	4228 (83.2%)	2452 (91.0%)	3462 (94.1%)	< 0.0001		
Cross clamp time (min; median, IQR)	93 (73–121)	86 (67–114)	86 (66–112)	< 0.0001		
CPB time (min; median, IQR)	125 (99–160)	117 (93–151)	117 (93–150)	< 0.0001		

IQR = interquartile range; BMI = body mass index; CLD = chronic lung disease; LVEF = left ventricular ejection fraction; AI = aortic insufficiency; MR = mitral regurgitations; CABG = coronary artery bypass grafting; STS = Society of Thoracic Surgeons; PROM = predicted risk of mortality; PROMM = predicted risk of morbidity or mortality; SAVR = surgical aortic valve replacement; CPB = cardiopulmonary bypass

## Table 2

## Surgical aortic valve replacement outcomes

Characteristics	Pre-TAVR (n = 5,113)	Early-TAVR (n = 2,709)	Commercial-TAVR (n = 3,743)	p value
Operative mortality	201 (3.9%)	115 (4.3%)	118 (3.2%)	0.048
Major morbidity <sup>†</sup>	1081 (21.2%)	554 (20.5%)	570 (15.2%)	<0.0001
Permanent stroke	89 (1.8%)	61 (2.3%)	42 (1.1%)	0.0017
Cardiac arrest	124 (2.4%)	64 (2.4%)	89 (2.4%)	0.98
Atrial fibrillation	1238 (24.3%)	756 (28.0%)	1139 (30.4%)	< 0.0001
Pneumonia	210 (4.1%)	101 (3.7%)	105 (2.8%)	0.004
Prolonged ventilation	647 (12.7%)	388 (14.3%)	399 (10.7%)	<0.0001
Renal failure requiring dialysis	115 (2.3%)	56 (2.1%)	70 (1.9%)	0.44
Renal failure	328 (6.4%)	146 (5.4%)	109 (2.9%)	< 0.0001
Deep sternal wound infection	23 (0.5%)	8 (0.3%)	7 (0.2%)	0.10
Transfusion	2646 (52.2%)	1282 (47.4%)	1432 (38.3%)	< 0.0001
Transfusion (pRBC)	1602 (38.4%)	1196 (44.2%)	1252 (33.5%)	<0.0001
Reoperation for any reason	453 (8.9%)	188 (7.0%)	216 (5.8%)	< 0.0001
Reoperation for bleeding	223 (4.4%)	90 (3.3%)	127 (3.4%)	0.02
Readmission	486 (9.8%)	278 (10.6%)	364 (10.3%)	0.57
Discharge to facility	836 (18.2%)	716 (27.3%)	1081 (29.6%)	< 0.0001
Total cost (mean)	\$40,745	\$51,923	\$54,710	< 0.0001
Length of stay (d; median, IQR)	6 (5–9)	6 (5–9)	6 (5–8)	0.12
ICU stay (hr; median, IQR)	48 (25.5–95)	48 (25.8–93.8)	49.5 (27.4–95)	0.006
Operative mortality O:E	0.76	1.12	0.92	
Morbidity and mortality O:E	‡	1.0	0.80	

 $^{\dagger}$ Major morbidity includes: permanent stroke, cardiac arrest, renal failure, deep sternal wound infection, prolonged ventilation, reoperation for any reason

 $\ddagger$ STS PROMM not available for all years

IQR = interquartile range; ICU = intensive care unit; O:E = observed to expected ratio

## Table 3

## Risk-adjusted surgical aortic valve replacement outcomes

	All Surger	ies	Isolated SAVR		
Operative mortality	OR (CI)	p-value	OR (CI)	p-value	
Early-TAVR vs Pre-TAVR era	1.37 (1.07–1.75)	0.01	1.47 (1.02–2.12)	0.04	
Commercial-TAVR vs Pre-TAVR era	1.05 (0.82–1.33)	0.73	0.97 (0.67–1.41)	0.88	
Major Morbidity					
Early-TAVR vs Pre-TAVR era	1.15 (1.02–1.29)	0.03	1.11 (0.93–1.32)	0.25	
Commercial-TAVR vs Pre-TAVR era	0.86 (0.77–0.97)	0.01	0.84 (0.71–0.996)	0.045	

 $SAVR = surgical \ a ortic \ valve \ replacement; \ TAVR = transcatheter \ a ortic \ valve \ replacement$