Contemporary Real-World Outcomes of Surgical Aortic Valve Replacement in 141,905 Low-Risk, Intermediate-Risk, and High-Risk Patients

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Background. **The introduction of transcatheter aortic valve replacement mandates attention to outcomes after surgical aortic valve replacement (SAVR) in low-risk, intermediate-risk, and very high-risk patients.**

Methods. **The study population included 141,905 patients who underwent isolated primary SAVR from 2002 to 2010. Patients were risk-stratified by Society of Thoracic Surgeons (STS) predicted risk of mortality (PROM) <4% (group 1, n = 113,377), 4% to 8% (group 2, n = 19,769), and >8% (group 3, n = 8,759). The majority of patients were considered at low risk (80%), and only 6.2% were categorized as being at high risk. Outcomes were analyzed based on two time periods: 2002 to 2006 (n = 63,754) and 2007 to 2010 (n = 78,151).**

Results. **The mean age was 65 years in group 1, 77 in group 2, and 77 in group 3 ($p < 0.0001$). The median STS PROM for the entire population was 1.84: 1.46% in group 1, 5.24% in group 2, and 11.2% in group 3 ($p < 0.0001$). Compared with PROM, in-hospital mean mortality was lower than expected in all patients (2.5% vs 2.95%) and when analyzed within risk groups was as follows: group 1 (1.4% vs 1.7%), group 2 (5.1% vs 5.5%), and group 3 (11.8% vs 13.7%) ($p < 0.0001$). In the most recent surgical era, operative mortality was significantly reduced in group 2 (5.4% vs 6.4%, $p = 0.002$) and group 3 (11.9% vs 14.4%, $p = 0.0004$) but not in group 1.**

Conclusions. **Nearly 80% of patients undergoing SAVR have outcomes that are superior to those by the predicted risk models. In the most recent era, early results have further improved in medium-risk and high-risk patients. This large real-world assessment serves as a benchmark for patients with aortic valve stenosis as therapeutic options are further evaluated.**

(Ann Thorac Surg 2015;99:55–61)

Aortic valve disease is the most common acquired valvular disease in elderly patients [1]. As the general population ages [2] it is reasonable to expect that the number of patients seeking treatment for aortic valve disease will also increase in the coming years. Surgical aortic valve replacement (SAVR) has remained the most effective treatment for this disease process and is currently recommended for patients after the onset of symptoms [3].

Since the introduction of transcatheter aortic valve replacement (TAVR) in 2002, its use has been extensively studied and its indications broadened [4]. Initially, use was restricted to patients who were considered inoperable for SAVR. The results of several studies have shown TAVR to be far superior to standard medical therapy with respect to survival at 2 years in that patient population [5–7]. These findings, coupled with the procedure's minimally invasive nature and encouraging safety profile, have led interventional cardiologists

Accepted for publication June 9, 2014.

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Dr Guyton discloses a financial relationship with Medtronic; Dr Dewey with Edwards Lifesciences; and Dr Thourani with Edwards Lifesciences, St. Jude Medical, Boston Scientific, Abbott, Medtronic, Sorin, and Apica.

0003-4975/$36.00
http://dx.doi.org/10.1016/j.athoracsur.2014.06.050

and cardiothoracic surgeons to expand the use of TAVR use to include patients considered operable for SAVR but who are considered at high risk. Subsequent studies in high-risk patients have surmised that TAVR may be an acceptable alternative to operation, with comparable morbidity and mortality [8, 9].

Although multiple predictive risk scores have been used to define the low-risk, intermediate-risk, or high-risk patient, the one most commonly used remains the Society of Thoracic Surgeons (STS) Predictive Risk of Operative Mortality (PROM). By use of this system, the most recently updated outcomes are reported for aortic valve replacement through 2006 [10–12]. Recent studies have reported decreasing measured mortality over time, despite a higher-risk population, as determined by their STS PROM [13, 14]. We performed a retrospective review of the STS Adult Cardiac Surgery Database to describe the outcomes of SAVR in low-risk, intermediate-risk, and high-risk patients in the current, real-world surgical era.

Patients and Methods

The study population consisted of 141,905 patients who underwent first-time isolated SAVR at STS-participating institutions between January 1, 2002, and December 31, 2010. From a starting population of 384,584 SAVR operations, we excluded 233,506 patients who underwent a combination procedure and an additional 9,173 patients who had a prior valve operation. Patients with causes of disease requiring isolated SAVR included 91,559 (64.5%) with pure aortic stenosis (AS), 27,340 (19.3%) with mixed AS and regurgitation, 18,594 (13.1%) with pure regurgitation, and 4,412 (3.1%) who did not have transthoracic echocardiographic data entered in the database. Operative mortality was defined as death during the same hospitalization as SAVR or after discharge but within 30 days of SAVR. Patients were categorized as PROM <4%, 4% to 8%, or >8%. Operations were further classified into two time periods: 2002 to 2006 (n = 63,754) and 2007 to 2010 (n = 78,151). Data were summarized as percentages for categoric variables and as means (± standard deviation) and medians for continuous variables. Patient characteristics and outcomes were compared across subgroups by the Kruskal-Wallis test for continuous variables and Pearson's χ^2 test for categoric variables. Analyses were performed with SAS (version 9.2; SAS Institute, Cary, NC). The Duke University institutional review board granted a waiver of informed consent and authorization for this study. The authors had full access to the data, take responsibility for its integrity, and have read and agree to the manuscript as written.

Table 1. Baseline Patient Characteristics by STS PROM

Characteristic	All Patients (n = 141,905)	PROM <4% (n = 113,377)	PROM 4%–8% (n = 19,769)	PROM >8% (n = 8,759)	*p* Value
Age, mean ± SD	67.6 ± 13.4 Median = 70.0	65.3 ± 13.0 Median = 67.0	77.2 ± 9.9 Median = 80.0	76.8 ± 11.8 Median = 80.0	<0.0001
Female gender, n (%)	59,561 (42.0)	43,703 (38.6)	11,084 (56.1)	4,774 (54.5)	<0.0001
Ejection fraction, mean ± SD	54.9 ± 12.9 Median = 58.0	56.0 ± 12.0 Median = 60.0	51.8 ± 14.3 Median = 55.0	46.8 ± 15.7 Median = 50.0	<0.0001
NYHA III or IV, n (%)	54,453 (38.4)	35,937 (31.7)	11,520 (58.3)	6,996 (79.9)	<0.0001
CHF, n (%)	52,071 (36.7)	31,470 (27.8)	12,917 (65.3)	7,684 (87.7)	<0.0001
Prior CABG, n (%)	13,950 (9.8)	6,814 (6.0)	4,602 (23.3)	2,534 (28.9)	<0.0001
Prior CVA, n (%)	8,926 (6.3)	5,923 (5.2)	1,920 (9.7)	1,083 (12.4)	<0.0001
History of cerebrovascular disease, n (%)	17,919 (12.6)	11,749 (10.4)	4,079 (20.6)	2,091 (23.9)	<0.0001
History of PVD, n (%)	13,019 (9.2)	6,693 (5.9)	3,821 (19.3)	2,505 (28.6)	<0.0001
COPD, n (%)					<0.0001
None	110,709 (78.0)	94,038 (82.9)	12,499 (63.2)	4,172 (47.6)	
Mild	16,429 (11.6)	11,845 (10.5)	3,196 (16.2)	1,388 (15.9)	
Moderate	8,660 (6.1)	4,788 (4.2)	2,355 (11.9)	1,517 (17.3)	
Severe	5,124 (3.6)	1,885 (1.7)	1,615 (8.2)	1,624 (18.5)	
Immunosuppressive therapy, n (%)	4,839 (3.4)	2,360 (2.1)	1,361 (6.9)	1,118 (12.8)	<0.0001
Diabetes mellitus, n (%)	36,190 (25.5)	23,949 (21.1)	7,841 (39.7)	4,400 (50.2)	<0.0001
Last creatinine, mean ± SD	1.18 ± 0.96 Median = 1.00	1.05 ± 0.65 Median = 1.00	1.49 ± 1.39 Median = 1.15	2.14 ± 1.93 Median = 1.40	<0.0001
Renal failure (creatinine >2.0), n (%)	5,886 (4.2)	1,549 (1.4)	1,893 (9.6)	2,444 (27.9)	<0.0001
Dialysis, n (%)	3,220 (2.3)	793 (0.7)	1,029 (5.2)	1,398 (16.0)	<0.0001
STS PROM, mean ± SD	2.95 ± 3.71 Median = 1.84	1.67 ± 0.94 Median = 1.46	5.48 ± 1.10 Median = 5.24	13.72 ± 7.56 Median = 11.21	<0.0001

CABG = coronary artery bypass grafting; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; CVA = cerebrovascular accident; MI = myocardial infarction; NYHA = New York Heart Association; PROM = predicted risk of mortality; PVD = peripheral vascular disease; STS = The Society of Thoracic Surgeons.

Results

The first analysis stratified these patients on the basis of their STS PROM and baseline characteristics (Table 1). The majority of patients were low-risk: 80% were in group 1 (PROM <4%), 13.9% in group 2 (PROM 4% to 8%), and the remaining 6.2% in group 3 (PROM ≥8%). The overall mean STS PROM was 2.95 ± 3.7%: 1.7 ± 0.9% in group 1, 5.5 ± 1.1% in group 2, and 13.7 ± 7.6% in group 3 ($p < 0.0001$). Nearly every individual risk factor increased in accordance with risk category.

Risk category did not alter operative technique significantly, with the exception of valve type and use of intraaortic balloon pump (Table 2). Increasing preference for biologic prostheses over mechanical prostheses was observed as risk increased: 75.8% in group 1 received bioprosthetic valves, and the rates in groups 2 and 3 were 91.2% and 89.9%, respectively ($p < 0.0001$).

All measured morbidity increased with increasing PROM, as did resource utilization (Table 3). Operative mortality (observed) was 1.7%, 5.8%, and 12.9% for PROM groups 1, 2, and 3, respectively. The observed mortality rate was close to expected in group 1 (1.7% vs 1.7%), slightly higher than expected in group 2 (5.8% vs 5.5%), and slightly lower than expected in group 3 (12.9% vs 13.7%).

Inasmuch as the current STS PROM risk models were constructed from data during the time period 2002 to 2006 [10], we compared patients operated on during that time period with those in the more modern time period (2007 to 2010, Table 4). The overall PROM increased slightly over the two time periods, from 2.8 ± 3.7% in 2002 to 2006 to 3.1 ± 3.7% in 2007 to 2010 ($p < 0.0001$).

The operative data by time period is presented in Table 5. Of note, the use of bioprosthetic valves increased with time: 72.6% in 2002 to 2006 vs 83.8% in 2007 to 2010 ($p < 0.0001$). All other operative variables were similar between the two time periods.

Postoperative morbidity was largely similar across time periods (Table 6). Operative mortality was lower in the later time period (2.7% vs 2.5%, $p = 0.018$) despite the increased PROM for 2007 to 2010. Table 7 further distinguishes this difference by risk group. In patients operated on in the most recent surgical era, operative mortality was significantly reduced in group 2 (5.4% vs 6.4%, $p = 0.002$) and group 3 (11.9% vs 14.4%, $p = 0.0004$) but not in group 1 (1.7% vs 1.7%, $p = 0.54$, Fig 1).

Comment

Current census projections indicate a general aging of the population, with an expected 5.4 million Americans over the age of 85 and 88.5 million Americans over the age of 65 by the year 2050 [2]. When combined with the increased rates of symptomatic aortic valve disease among elderly patients, this will mean an increase in the number of patients seeking treatment for this disease process. Surgical intervention remains the mainstay of treatment and carries some urgency because the mortality rate after symptom onset approaches 25% per year [15].

Over the course of the study period, an increase in the absolute number of patients undergoing SAVR was captured in the STS Adult Cardiac Surgery Database: 63,754 patients from 2002 to 2006 to 78,151 patients from 2007 to 2010 inclusive. The vast majority of patients were in the low-risk group (80% were at low risk, 13.9% at intermediate risk, and 6.2% at high risk). Similar distributions of patients by risk have been reported elsewhere,

Table 2. Operative Characteristics

Characteristic	All Patients (n = 141,905)	PROM <4% (n = 113,377)	PROM 4%–8% (n = 19,769)	PROM >8% (n = 8,759)	*p* Value
Valve implant type, n (%)					<0.0001
Mechanical	28,434 (20.0)	26,116 (23.0)	1,546 (7.8)	772 (8.8)	
Bioprosthetic	111,791 (78.8)	85,880 (75.8)	18,036 (91.2)	7,875 (89.9)	
Other	930 (0.7)	766 (0.7)	91 (0.5)	73 (0.8)	
Valve size implanted, n (%)					<0.0001
<19 mm	565 (0.4)	430 (0.4)	95 (0.5)	40 (0.5)	
19–20 mm	14,094 (9.9)	9,427 (8.3)	3,184 (16.1)	1,483 (16.9)	
21–22 mm	39,583 (27.9)	29,660 (26.2)	6,946 (35.1)	2,977 (34.0)	
23–24 mm	44,122 (31.1)	35,636 (31.4)	5,854 (29.6)	2,632 (30.1)	
25–26 mm	28,232 (19.9)	24,373 (21.5)	2,674 (13.5)	1,185 (13.5)	
≥27 mm	14,152 (10.0)	12,908 (11.4)	863 (4.4)	381 (4.4)	
IABP, n (%)	3,114 (2.2)	1,494 (1.3)	794 (4.0)	826 (9.4)	<0.0001
BMI, mean ± SD	29.3 ± 6.6 Median = 28.3	29.6 ± 6.4 Median = 28.5	28.4 ± 7.0 Median = 27.1	28.2 ± 7.6 Median = 26.6	<0.0001
Cross-clamp time (min), mean ± SD	77.0 ± 28.5 Median = 72.0	77.4 ± 28.7 Median = 73.0	75.0 ± 27.0 Median = 71.0	76.7 ± 29.0 Median = 72.0	<0.0001
CPB time (min), mean ± SD	104.9 ± 39.1 Median = 99.0	104.3 ± 38.5 Median = 98.0	106.0 ± 40.2 Median = 100.0	110.7 ± 44.2 Median = 103.0	<0.0001

BMI = body mass index; CPB = cardiopulmonary bypass; IABP = intra-aortic balloon pump; PROM = predictive risk of mortality.

Table 3. Short-Term Outcomes

Outcome	All Patients (n = 141,905)	PROM <4% (n = 113,377)	PROM 4%–8% (n = 19,769)	PROM >8% (n = 8,759)	*p* Value
TIA, n (%)	853 (1.1)	562 (0.9)	201 (1.9)	90 (1.9)	<0.0001
Stroke, n (%)	2,154 (1.5)	1,384 (1.2)	462 (2.3)	308 (3.5)	<0.0001
Reoperation for bleeding, n (%)	5,467 (3.9)	4,050 (3.6)	925 (4.7)	492 (5.6)	<0.0001
Deep sternal infection, n (%)	386 (0.3)	285 (0.3)	58 (0.3)	43 (0.5)	<0.0001
Pneumonia, n (%)	4,270 (3.0)	2,354 (2.1)	1,124 (5.7)	792 (9.0)	<0.0001
Multisystem failure, n (%)	1,431 (1.0)	640 (0.6)	393 (2.0)	398 (4.5)	<0.0001
Atrial fibrillation, n (%)	37,626 (26.5)	29,496 (26.0)	5,895 (29.8)	2,235 (25.5)	<0.0001
Heart block, n (%)	5,664 (4.0)	4,150 (3.7)	992 (5.0)	522 (6.0)	<0.0001
Renal failure, n (%)	5,936 (4.2)	3,174 (2.8)	1,624 (8.2)	1,138 (13.0)	<0.0001
New dialysis, n (%)	2,174 (1.5)	891 (0.8)	642 (3.3)	641 (7.3)	<0.0001
Prolonged ventilation, n (%)	14,581 (10.3)	7,891 (7.0)	3,786 (19.2)	2,904 (33.2)	<0.0001
Postoperative ventilator hours, mean ± SD	25.7 ± 101.5 Median = 8.0	18.2 ± 72.1 Median = 7.0	44.3 ± 145.1 Median = 12.3	81.6 ± 217.9 Median = 18.0	<0.0001
Total ICU length of stay (h), mean ± SD	74.0 ± 127.3 Median = 44.0	60.6 ± 98.7 Median = 33.0	110.9 ± 167.6 Median = 65.0	164.7 ± 244.0 Median = 90.0	<0.0001
Postoperative length of stay (days), mean ± SD	7.9 ± 7.2 Median = 6.0	7.0 ± 5.7 Median = 6.0	10.4 ± 9.4 Median = 8.0	13.3 ± 13.0 Median = 9.0	<0.0001
In-hospital mortality, n (%)	3,609 (2.5)	1,564 (1.4)	1,014 (5.1)	1,031 (11.8)	<0.0001
Operative mortality, n (%)	4,214 (3.0)	1,930 (1.7)	1,153 (5.8)	1,131 (12.9)	<0.0001

ICU = intensive care unit; PROM = predictive risk of mortality; TIA = transient ischemic attack.

Table 4. Baseline Patient Characteristics: Time Period Analysis

Characteristic	All Patients (n = 141,905)	2002–2006 (n = 63,754)	2007–2010 (n = 78,151)	*p* Value
Age, mean ± SD	67.6 ± 13.4 Median = 70.0	66.7 ± 13.6 Median = 69.0	68.4 ± 13.1 Median = 71.0	<0.0001
Female gender, n (%)	59,561 (42.0)	26,649 (41.8)	32,912 (42.1)	0.2379
Ejection fraction, mean ± SD	54.9 ± 12.9 Median = 58.0	54.0 ± 13.4 Median = 55.0	55.5 ± 12.4 Median = 60.0	<0.0001
NYHA III or IV, n (%)	54,453 (38.4)	31,482 (49.4)	22,971 (29.4)	<0.0001
CHF, n (%)	52,071 (36.7)	23,246 (36.5)	28,825 (36.9)	0.1213
Prior CABG, n (%)	13,950 (9.8)	5,873 (9.2)	8,077 (10.3)	<0.0001
Prior CVA, n (%)	8,926 (6.3)	4,084 (6.4)	4,842 (6.2)	0.1154
History of cerebrovascular disease, n (%)	17,919 (12.6)	7,417 (11.6)	10,502 (13.4)	<0.0001
History of PVD, n (%)	13,019 (9.2)	5,591 (8.8)	7,428 (9.5)	<0.0001
COPD, n (%)				<0.0001
None	110,709 (78.0)	50,782 (79.7)	59,927 (76.7)	
Mild	16,429 (11.6)	6,594 (10.3)	9,835 (12.6)	
Moderate	8,660 (6.1)	3,796 (6.0)	4,864 (6.2)	
Severe	5,124 (3.6)	1,980 (3.1)	3,144 (4.0)	
Immunosuppressive therapy, n (%)	4,839 (3.4)	1,953 (3.1)	2,886 (3.7)	<0.0001
Diabetes mellitus, n (%)	36,190 (25.5)	14,440 (22.7)	21,750 (27.8)	<0.0001
Last creatinine, mean ± SD	1.18 ± 0.96 Median = 1.00	1.19 ± 0.98 Median = 1.00	1.17 ± 0.94 Median = 1.00	<0.0001
Renal failure (creatinine >2.0), n (%)	5,886 (4.2)	2,655 (4.2)	3,231 (4.1)	0.4651
Dialysis, n (%)	3,220 (2.3)	1,374 (2.2)	1,846 (2.4)	0.0073
STS PROM, mean ± SD	2.95 ± 3.71 Median = 1.84	2.82 ± 3.69 Median = 1.73	3.05 ± 3.73 Median = 1.93	<0.0001

CABG = coronary artery bypass grafting; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; CVA = cerebrovascular accident; MI = myocardial infarction; NYHA = New York Heart Association; PROM = predicted risk of mortality; PVD = peripheral vascular disease; STS = The Society of Thoracic Surgeons.

Table 5. Operative Characteristics: Time Period Analysis

Characteristic	All Patients (n = 141,905)	2002–2006 (n = 63,754)	2007–2010 (n = 78,151)	*p* Value
Valve implant type, n (%)				<0.0001
Mechanical	28,434 (20.0)	16,342 (25.6)	12,092 (15.5)	
Bioprosthetic	111,791 (78.8)	46,284 (72.6)	65,507 (83.8)	
Other	930 (0.7)	664 (1.0)	266 (0.3)	
Valve size implanted, n (%)				<0.0001
<19 mm	565 (0.4)	298 (0.5)	267 (0.3)	
19–20 mm	14,094 (9.9)	6,325 (9.9)	7,769 (9.9)	
21–22 mm	39,583 (27.9)	17,442 (27.4)	22,141 (28.3)	
23–24 mm	44,122 (31.1)	19,428 (30.5)	24,694 (31.6)	
25–26 mm	28,232 (19.9)	12,662 (19.9)	15,570 (19.9)	
≥27 mm	14,152 (10.0)	6,894 (10.8)	7,258 (9.3)	
IABP, n (%)	3,114 (2.2)	1,464 (2.3)	1,650 (2.1)	0.015
BMI, mean ± SD	29.3 ± 6.6 Median = 28.3	29.0 ± 6.5 Median = 28.0	29.5 ± 6.7 Median = 28.4	<0.0001
Cross-clamp time (min), mean ± SD	77.0 ± 28.5 Median = 72.0	77.1 ± 28.6 Median = 72.0	77.0 ± 28.3 Median = 72.0	0.303
CPB time (min), mean ± SD	104.9 ± 39.1 Median = 99.0	105.2 ± 39.3 Median = 99.0	104.6 ± 39.0 Median = 98.0	0.0013

BMI = body mass index; CPB = cardiopulmonary bypass; IABP = intra-aortic balloon pump.

indicating that low-risk patients continue to constitute the majority of patients receiving SAVR [16]. There was a small but measurable increase in higher-risk patients over the two time periods, from 5.7% in group 3 in 2002 to 2006 to 6.6% in 2007 to 2010, and from 12.8% in group 2 in 2002 to 2006 to 14.9% in 2007 to 2010.

Despite this increase in the proportion of higher-risk patients, it is important to note that actual operative mortality has decreased for medium-risk (group 2) and high-risk (group 3) surgical patients. Likewise, despite increasing STS PROM in the current surgical era, operative mortality for all patients combined remained remarkably stable, at 2.7% in 2002 to 2006 and 2.5% in 2007 to 2010 ($p = 0.018$) (Table 6). Brown and colleagues [13] reported similar decreases in mortality over time in their prior study using the same database as the current series. They found a decrease in observed/expected mortality ratio from 1.2 in 1997 to 0.8 in 2006. They attributed this decrease to improved surgical performance, which appears to continue to improve in the current time period. This is particularly encouraging, given the increasing numbers of high-risk patients

Table 6. Short-Term Outcomes: Time Period Analysis

Outcome	All Patients (n = 141,905)	2002–2006 (n = 63,754)	2007–2010 (n = 78,151)	*p* Value
TIA, n (%)	853 (1.1)	671 (1.1)	182 (1.0)	0.6309
Stroke, n (%)	2,154 (1.5)	925 (1.5)	1,229 (1.6)	0.1936
Reoperation for bleeding, n (%)	5,467 (3.9)	2,493 (3.9)	2,974 (3.8)	0.0635
Deep sternal infection, n (%)	386 (0.3)	191 (0.3)	195 (0.3)	0.0388
Pneumonia, n (%)	4,270 (3.0)	1,798 (2.8)	2,472 (3.2)	0.0025
Multisystem failure, n (%)	1,431 (1.0)	623 (1.0)	808 (1.0)	0.4228
Atrial fibrillation, n (%)	37,626 (26.5)	16,303 (25.6)	21,323 (27.3)	<0.0001
Heart block, n (%)	5,664 (4.0)	2,599 (4.1)	3,065 (3.9)	0.0496
Renal failure, n (%)	5,936 (4.2)	2,544 (4.0)	3,392 (4.3)	0.0196
New dialysis, n (%)	2,174 (1.5)	890 (1.4)	1,284 (1.6)	<0.0001
Prolonged ventilation, n (%)	14,581 (10.3)	5,630 (8.8)	8,951 (11.5)	<0.0001
Postoperative ventilator hours, mean ± SD	25.7 ± 101.5 Median = 8.0	25.4 ± 103.0 Median = 8.0	26.0 ± 100.3 Median = 8.0	<0.0001
Total ICU length of stay (h), mean ± SD	74.0 ± 127.3 Median = 44.0	69.4 ± 125.4 Median = 35.0	77.4 ± 128.6 Median = 46.2	<0.0001
Postoperative length of stay (days), mean ± SD	7.9 ± 7.2 Median = 6.0	7.9 ± 7.4 Median = 6.0	7.9 ± 7.0 Median = 6.0	<0.0001
In-hospital mortality, n (%)	3,609 (2.5)	1,691 (2.7)	1,918 (2.5)	0.0183

ICU = intensive care unit; TIA = transient ischemic attack.

Table 7. Outcomes by STS PROM: Time Period Analysis

Outcome	All Patients (n =141,905)	2002–2006 (n = 63,754)	2007–2010 (n = 78,151)	*p* Value
Operative mortality, n (%)	4,214 (3.0)	1,946 (3.1)	2,268 (2.9)	0.0097
Operative mortality (PROM <4%), n (%)	1,930 (1.7)	898 (1.7)	1,032 (1.7)	0.54
Predicted operative mortality (PROM <4%), n (%)	1.7 ± 0.9 Median = 1.5	1.6 ± 0.9 Median = 1.4	1.7 ± 1.0 Median = 1.5	<0.0001
Operative mortality (PROM 4%–8%), n (%)	1,153 (5.8)	525 (6.4)	628 (5.4)	0.0023
Predicted operative mortality (PROM 4%–8%), n (%)	5.5 ± 1.1 Median = 5.2	5.5 ± 1.1 Median = 5.2	5.5 ± 1.1 Median = 5.3	0.34
Operative mortality (PROM ≥8%), n (%)	1,131 (12.9)	523 (14.4)	608 (11.9)	0.0004
Predicted operative mortality (PROM ≥8%), n (%)	13.7 ± 7.6 Median = 11.2	13.9 ± 8.0 Median = 11.3	13.6 ± 7.3 Median = 11.2	0.25

PROM = predicted risk of mortality; STS = The Society of Thoracic Surgeons.

seeking surgical therapy. In the current series, the improvement in the observed operative mortality is most likely multifactorial. Advancements in preoperative assessment, intraoperative expeditious surgical techniques, and intensive postoperative care have contributed to improved outcomes in this higher-risk patient cohort.

The mean STS PROM for both intermediate-risk and high-risk groups remained unchanged during the two time periods (5% for group 2 and 14% for group 3). Although the PROM for group 2 slightly underestimated measured mortality for both time periods, it overestimated the mortality in group 3 in the more recent time period. In their study of risk algorithms for operative mortality after SAVR, Dewey and colleagues [17] found that the STS risk calculation underestimated actual mortality, with an observed/expected mortality ratio of 1.41, though their series demonstrated that the STS algorithm is the most accurate in predicting operative mortality in high-risk patients. Correspondingly, the use of the STS PROM remains controversial in predicting mortality in those undergoing TAVR. For instance, it is quite feasible that the STS PROM does not accurately represent certain patient populations who are better served with a TAVR based on the heart team evaluation. This may include those patients with cirrhosis, porcelain aorta, frailty, dementia, or severe pulmonary hypertension.

As expected, resource utilization increased as preoperative risk increased. The rates of prolonged ventilation increased from 7.0% in group 1, to 19.2% in group 2, to 33.2% in group 3. Correspondingly, overall postoperative length of stay (LOS) increased from a mean of 7.0 days in group 1, to 10.4 days in group 2, to 13.3 days in group 3 ($p < 0.0001$). In a series of high-risk patients (defined as STS PROM >10%) undergoing SAVR, Thourani and colleagues [18] from a multiinstitutional group in the United States found similar results, with a mean

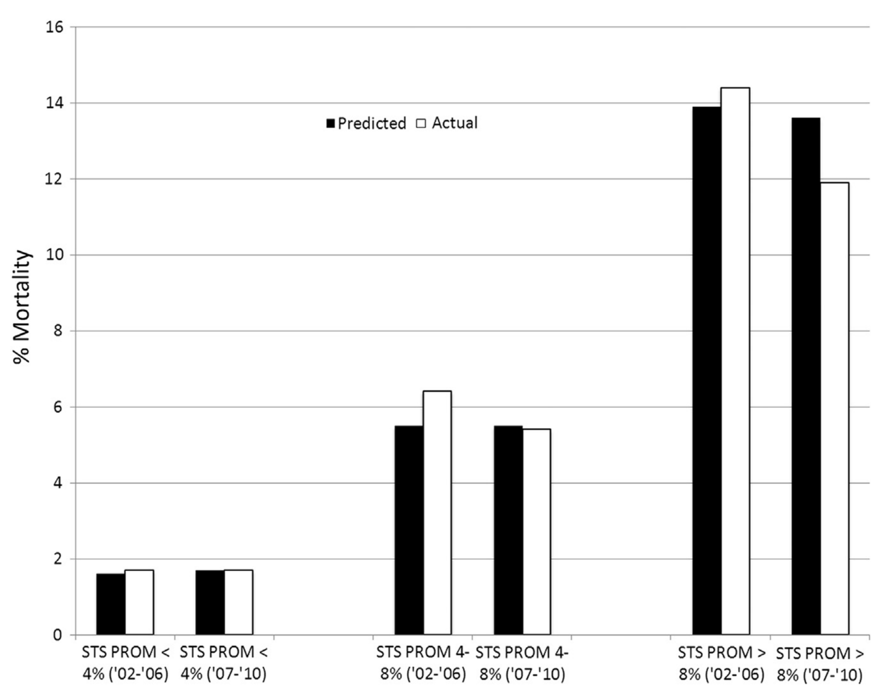

Fig 1. Outcomes by The Society of Thoracic Surgeons (STS) predicted risk of mortality (PROM) compared with actual operative mortality for the two time periods.

postoperative stay in the intensive care unit of 165.6 hours and postoperative LOS of 12.6 days. This increase is likely related to the overall increase in higher-risk patients over time, but it may also be part of a general trend of increasing resource utilization in health care [19]. In the previous series that used the STS database, Brown and colleagues [13] reported a mean LOS at 8 days throughout the length of their study, indicating that this has remained stable as far back as 1997.

The current series follows a trend of increasing use of bioprosthetic valves. In the time period 2007 to 2010, 83.8% of patients received bioprosthetic valves, an increase from 72.6% in the 2002 to 2006 period ($p < 0.0001$). Brown and colleagues [13] reported a 43.6% rate of bioprosthetic valve implantation in 1997, which increased considerably to a rate of 78.4% in 2006. Dunning and colleagues [14] reported similar data from Great Britain, with an increase in bioprosthetic valve implantation from a rate of 65% in 2004 to 2005 to 78% in 2008 to 2009. The guidelines of the American College of Cardiology and the American Heart Association state that despite a slight advantage of mechanical valves, the increase in bioprosthetic valve implantation is likely due to an older patient population undergoing SAVR, perceived improvements in valve durability, and a desire to avoid short-term and long-term anticoagulation if possible [3]. Although the current series did not examine the effect of valve type on operative outcomes, it has been reported that the results of bioprosthetic valves are better with increasing age [20–22].

Currently, only patients deemed to be at prohibitive risk or high risk for SAVR qualify for TAVR as approved for on-label use by the US Food and Drug Administration. The outcomes for TAVR in the intermediate risk patient population are ongoing. This study has shown that the number of such high-risk or inoperable patients may be on the rise, and given current population projections, the number of patients may continue to increase. The current study reveals that SAVR provides excellent results in low-risk, intermediate-risk, and high-risk patients, and it serves as an updated real-world benchmark for patients whose conditions are being evaluated for any form of aortic valve replacement therapy.

The authors thank The Society of Thoracic Surgeons, through the process within the Access and Publications Task Force, for the opportunity to perform this research and for the funding associated with it.

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