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.**

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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

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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.