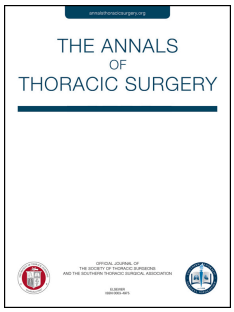
Journal Pre-proof



Survival Following Surgical Aortic Valve Replacement in Low-Risk Patients: A Contemporary Trial Benchmark

Vinod H. Thourani, MD, Robert Habib, PhD, Wilson Y. Szeto, MD, Joseph F. Sabik, MD, Jennifer C. Romano, MD, MS, Thomas E. MacGillivray, MD, Vinay Badhwar, MD

PII: S0003-4975(23)01064-0

DOI: https://doi.org/10.1016/j.athoracsur.2023.10.006

Reference: ATS 37092

To appear in: *The Annals of Thoracic Surgery*

Received Date: 29 September 2023

Revised Date: 11 October 2023

Accepted Date: 11 October 2023

Please cite this article as: Thourani VH, Habib R, Szeto WY, Sabik JF, Romano JC, MacGillivray TE, Badhwar V, Survival Following Surgical Aortic Valve Replacement in Low-Risk Patients: A Contemporary Trial Benchmark, *The Annals of Thoracic Surgery* (2023), doi: https://doi.org/10.1016/j.athoracsur.2023.10.006.

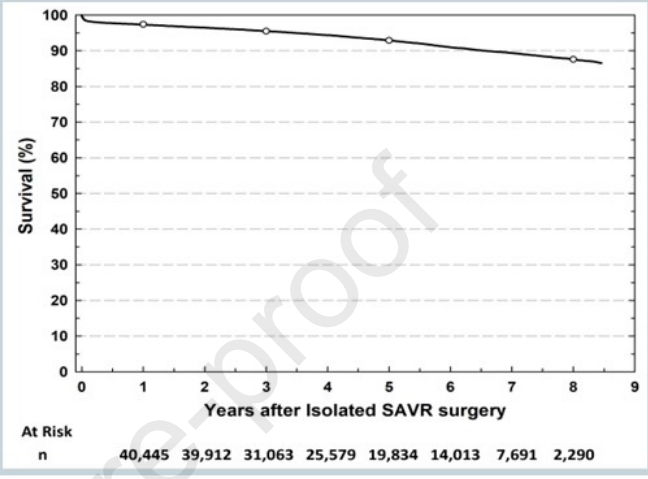
Survival Following Surgical Aortic Valve Replacement in Low-Risk Patients: *A Contemporary Trial Benchmark*

STUDY POPULATION

42,586 Low Risk Isolated SAVR
STS Adult Cardiac Surgery Database
Matched with National Death Index

Study Inclusions/Exclusions Matched Those Used in Contemporary Low Risk TAVR SAVR Trials
Partner 3 and Evolut Low Risk

Survival Following Isolated SAVR



The Survival Following SAVR is 92.9% at 5 years

THE ANNALS OF THORACIC SURGERY
Official Journal of The Society of Thoracic Surgeons and the Southern Thoracic Surgical Association

Thourani VH et al, 2023

#VisualAbstract #AnnalsImages
@annalsthorsurg

Survival Following Surgical Aortic Valve Replacement in Low-Risk Patients: A Contemporary Trial Benchmark

Short Title: Survival Following Low Risk SAVR

Vinod H. Thourani, MD[1], Robert Habib, PhD[2], Wilson Y. Szeto, MD[3], Joseph F. Sabik, MD[4], Jennifer C. Romano, MD, MS[5], Thomas E. MacGillivray, MD[6], and Vinay Badhwar, MD[7]

[1]Department of Cardiothoracic Surgery, Piedmont Healthcare, Atlanta, GA
[2]The Society of Thoracic Surgeons Research and Analytic Center, Chicago, IL
[3]Division of Cardiovascular Surgery, University of Pennsylvania, Philadelphia, PA
[4]Department of Surgery, University Hospitals, Cleveland, OH
[5]Department of Cardiac Surgery, University of Michigan, Ann Arbor, MI
[6]Department of Cardiac Surgery, MedStar Health, Washington, DC
[7]Department of Cardiovascular and Thoracic Surgery, West Virginia University, Morgantown, WV

Word Count: 3,538

References: 15

Tables/Figures: 2, 3

Key Words: Aortic Valve Replacement; Low Risk; Surgical Outcomes; TAVR

Correspondence:

Vinay Badhwar, MD
Department of Cardiovascular and Thoracic Surgery
West Virginia University
1 Medical Center Drive,
Morgantown, WV 26506
Email: vinay.badhwar@wvumedicine.org

ABSTRACT (250/250)

BACKGROUND: The use of transcatheter aortic valve replacement (TAVR) for severe aortic stenosis in low-risk patients necessitates an evaluation of contemporary long-term, real-world outcomes of similar patients undergoing surgical aortic valve replacement (SAVR) in a national cohort.

METHODS: All patients undergoing primary, isolated SAVR in the STS database between 2011-2019 were examined. The study population of 42,586 adhered to the inclusion/exclusion criteria of the PARTNER 3 and Evolut Low Risk randomized trials. Patients were further stratified by STS predicted risk of mortality (PROM), age, and left ventricular ejection fraction (LVEF). The primary end-point was all-cause National Death Index mortality. Unadjusted survival to 8 years was estimated using the Kaplan–Meier method.

RESULTS: The mean age was 74.3±5.7 years and mean STS PROM was 1.9%±0.8%. The overall Kaplan-Meier time to event analysis for all-cause mortality at 1-, 3-, 5-, and 8-years was 2.6%, 4.5%, 7.1% and 12.4%, respectively. In subset analyses, survival was significantly better for 1) lower STS PROM ($p<0.001$), 2) younger versus older age ($p<0.001$), and 3) higher versus lower LVEF ($p<0.001$). When STS PROM was below 1% or the patient age was below age 75 years, the 8-year survival following SAVR was 95%.

CONCLUSIONS: The results of this national study confirm that the long-term survival following SAVR remains excellent, at 92.9% at 5 years. These contemporary longitudinal data serve to aid in the balanced interpretation of current and future trials comparing SAVR and TAVR and may assist in the clinical decision-making process for patients of lower surgical risk.

Abbreviations

ACSD – Adult Cardiac Surgery Database

AS – Aortic Stenosis

AR – Aortic Regurgitation

LVEF – Left Ventricular Ejection Fraction

NDI – National Death Index

PROM – Predicted Risk of Mortality

SAVR – Surgical Aortic Valve Replacement

STS – Society of Thoracic Surgeons

TAVR – Transcatheter Aortic Valve Replacement

Transcatheter aortic valve replacement (TAVR) has become an alternative to surgical aortic valve replacement (SAVR) for patients with severe symptomatic aortic stenosis (AS) across all risk groups. Surgical risk is defined by The Society of Thoracic Surgeons (STS) predicted risk of mortality (PROM). Approval for TAVR by the U.S. Food and Drug Administration (FDA) for patients considered to be of high- and intermediate-risk was based on non-inferiority composite 1-year outcomes of TAVR compared to SAVR, with results comparable to 5 years.[1,2] Selection criteria for these trials are based on local heart team assessments of patients with trileaflet aortic stenosis and STS PROM score.[3-5] The comparative exploration of TAVR and SAVR has now extended into low-risk populations.

The two most vigorous, contemporary randomized trials comparing SAVR and TAVR in low-risk patients include the Placement of Aortic Transcatheter Valves (PARTNER) 3 and Evolut Low Risk trials.[4-7] Notably, there has been little data from these highly selective trials comparing low risk patients undergoing SAVR or TAVR beyond 2-3 years. The PARTNER 3 Trial compared 496 TAVR patients with 454 SAVR and noted similar all-cause mortality at one (TAVR 1.0% vs SAVR 2.5%, p=0.08) and two years (TAVR 2.4% vs SAVR 3.2%, p=0.47), with the final SAVR population at risk at 2 years was only 345 patients.[6] The Evolut Low Risk Trial compared 730 TAVR patients with 684 undergoing surgery and noted similar all-cause mortality at one (TAVR 2.1% vs SAVR 2.7%, p=0.446)[7], two (TAVR 3.5% vs SAVR 4.4%, p=0.366)[7] and three years (TAVR 6.3% vs SAVR 8.3%, p=0.16), with the final SAVR population at risk at 3 years was only 537 patients.[8]

The purpose of the current analysis is to evaluate the long-term, real-world outcomes of patients undergoing SAVR for severe AS using the inclusion and exclusion criteria of the

PARTNER 3 and Evolut Low Risk randomized trials using the STS Adult Cardiac Surgery Database (ACSD) and the National Death Index (NDI).

PATIENTS AND METHODS

STUDY POPULATION

All patients undergoing isolated first time SAVR were identified from the STS ACSD between July 1, 2011, and March 31, 2019. Two primary criteria were applied to identify the study population: 1) adherence to the inclusion and exclusion criteria utilized in the PARTNER 3 and Evolute Low Risk clinical trials in low-risk patients[4-7]; and 2) patients reside and underwent SAVR in the United States and sufficient patient-level information was available to qualify as a NDI vital status searchable record. A record was deemed NDI searchable if it included one of 3 combinations of minimum available patient identifiers: First Name, Last Name, Middle Initial, Date of Birth (Year, month, day), Gender, or Social Security Number. The large majority of records had more than this minimum or all fields available that increased matching quality (probabilistic score).

Longitudinal follow-up through 12/31/2019 was derived from matched records including linkage of the STS ACSD and NDI using matching algorithms based on direct patient identifiers (First, middle, and last names, date of birth, sex, and social security number). Matches were further adjudicated based on comparison of key STS ACSD and death certificate data elements (e.g., surgery, discharge and mortality dates, state of residence, race, etc.). The sequential steps used to arrive at the final low-risk patient cohort of isolated SAVR are summarized in the CONSORT diagram (Figure 1).

All analyses were conducted at the STS Research and Analytic Center. The authors vouch for the accuracy of the analyses reported herein. Waiver of informed consent for non-human subjects was obtained from the Northwestern University institutional review board (# STU00206997) to facilitate NDI linkage.

STATISTICAL ANALYSIS

Summary statistics are presented as percentages and as means with standard deviations in case of categorical or continuous variables, assessing for normality. The primary end point was all-cause mortality. Unadjusted survival curves for the overall low-risk isolated SAVR study population between 0 and 8.5 years were estimated using the Kaplan–Meier method. Stratified all-cause mortality (survival) were also calculated and derived and compared for the following patient sub-cohorts: i) STS PROM groups (<1%; 1-2%; 2-3%; and 3-4%), ii) age groups (65-74 years; 75-84 years; and ≥85 years); and iii) left ventricular function groups (ejection fraction: 30-45%; 46-55%; >55%).

All-cause mortality estimates at 1, 2, 3, 4, 5, 6, 7 and 8 years were summarized and compared to same post-procedure time points available for SAVR and TAVR study arms from the PARTNER 3 and Evolut Low Risk trials.[4-7]

RESULTS

STUDY POPULATION

A total of 220,095 cases from 1,211 unique STS ACSD participating programs [number of cases: 182 ± 225 (mean ± standard deviation) 110 (median)] met the STS definition of isolated SAVR surgery over the pre-defined study period and represented 39.2% of all aortic valve

surgeries (Supplemental Table 2). The final analyzed low-risk cohort based on record linked to the NDI comprised of 42,586 low-risk SAVR cases derived from 981 unique STS ACSD programs [44.5 ± 60.9; (median = 25) cases per participant program] (Figure 1).

PATIENT CHARACTERISTICS

Table 1 summarizes the patient characteristics in the analyzed patient population. Application of the low-risk trial inclusion and exclusion criteria resulted in the study cohort of isolated SAVR that was remarkably similar to the SAVR and TAVR arms of both of the PARTNER 3 and Evolut Low Risk trials[4-7], with nearly identical mean age and STS PROM at 74.3 ± 5.7 years and 1.92% ± 0.83%, respectively.

OUTCOMES

The overall Kaplan Meier time to event analysis for all-cause mortality revealed overall 1-, 3-, 5-, and 8-year mortality rates of 2.6%, 4.5%, 7.1% and 12.4%, respectively (Figure 2).

In subset analyses, survival was significantly and appreciably better for 1) lower STS PROM (Figure 3A; $p<0.001$), 2) younger versus older patient age (Figure 3B; $p<0.001$), and 3) higher versus lower left ventricular ejection fraction (Figure 3C; $p<0.001$).

Table 2 summarizes the longitudinal all-cause mortality at annual time points for the STS ACSD low-risk SAVR benchmark cohort compared to corresponding data available from the PARTNER 3 and Evolut Low Risk trials.[4-7]

When STS PROM was below 1% or the patient age was below age 75 years, the 8-year survival following SAVR was 95%.

COMMENT

This study examined the longitudinal vital status following isolated primary low-risk surgical aortic valve replacement in the United States and generated several important findings. First, the overall survival of patients undergoing isolated SAVR was over 87% through 8 years. Second, the 3-year and 5-year survival was 95.5% and 92.9%, respectively. Third, when the STS PROM was below 1% or the patient age was below age 75 years, the 8-year survival following SAVR was 95%. Finally, the study population examined closely matched the criteria used for the two contemporary low-risk trials comparing TAVR and SAVR,[4-7] with nearly identical age and STS PROM. As the long-term survival of this real-world analysis of SAVR extends beyond those in current comparative trials, they hereby serve as the new benchmark for current and future trials that may examine SAVR outcomes.

Aortic valve replacement remains among the most commonly performed operations recorded in the STS ACSD.[9] Following FDA approval of TAVR in high and intermediate risk patient populations, the frequency of TAVR has surpassed that of SAVR. Furthermore, the current study noted a steady decline in the number of low risk SAVR cases performed on an annual basis, particularly after lower risk TAVR approvals. Key to the safe and appropriate delivery of care is the proper functioning of the multidisciplinary heart team. The heart team is to carefully weigh the risks, benefits, and estimated long-term outcomes of therapy and tailor clinical decision-making to fit the optimal needs of each unique patient. While in the United States, the Centers of Medicare and Medicaid Services (CMS) currently mandates a heart team assessment with a surgical evaluation prior to TAVR, there has been an unfortunate decline in the optimal utilization of the heart team worldwide.[10] Furthermore, one of the fastest growing operations performed over the last 5 years is TAVR explant with rising experience in many

centers, often with inferior outcomes to primary isolated SAVR.[11,12] Recent real-world assessments of TAVR reveal that persistent heart failure and sudden cardiac death account for a fifth of the 18% 2-year mortality following contemporary device implantation.[13] With TAVR availability in low risk patient cohorts, the balanced heart team assessment *must* be maintained to mitigate indication creep and ensure appropriate use of both TAVR and SAVR informed by objective scientific evidence.

In current clinical practice, the use of TAVR, particular in lower risk patients may be commonly applied to those not representative in current low risk trials.[4-7] The average age in low-risk trials was 73 years, all patients had trileaflet stenosis, minimal aortic regurgitation, and the majority had preserved ejection fraction. Current practice in the United States may often see lower risk patients with bicuspid AS and of younger age receiving TAVR. Therefore, the vigilance of an active heart team with both surgeons and cardiologists directly evaluating risk, as well as discussing options with the patient to include mechanical valve replacement or minimally invasive alternatives remains crucial.[13]

Institutional and regional series have reported excellent long-term outcomes and survival following SAVR,[15] however, data from large national cohorts is lacking. The existing PARTNER 3 and Evolut Low Risk trial results are expected to be released in 2023, and it should be parenthetically noted that the SAVR arm in these trials was not a direct “apples to apples” comparison as multivessel CABG was performed in nearly 14% and other concomitant operations in 5%.[4-7] Some have raised concerns of potential bias in randomized clinical trials comparing TAVR and SAVR, and further concerns with the Evolut Low Risk trial in particular.[16,17] Therefore, the goal of the current study was to provide real-world long-term survival following isolated SAVR through comprehensive linkage of the NDI and the STS

ACSD with a study cohort closely matched to the inclusion and exclusion criteria of the existing low risk trials[4-7] so as to serve as a benchmark to interpret future trial outcome reporting.

The claims of non-inferiority or superiority of TAVR versus SAVR hinges on the outcomes of the robustness of each technique. In the PARTNER 3 trial, there was similar mortality between surgery and TAVR at one (TAVR: 1.0% vs SAVR: 2.5%, p=0.08) and two years (TAVR: 2.4% and SAVR: 3.2%, p=0.47).[5,6] The SAVR mortality in that study is similar to the mortality seen in the current series (1 year: 2.5%, and 2 year: 3.2%, Figure 1). In the Evolut Low Risk trial, unfortunately, the SAVR mortality has continued to rise at an accelerated rate compared to the current series from the STS ACSD (2.7% at 1 year, 4.4% at 2 years, and 8.3% at 3 years).[8] This near doubling of mortality from year 2 to 3 in the Evolut Low Risk trial is concerning and potentially questionable as this was not consistent with the national cohort from the STS ACSD (2 year: 3.5% and 3 year: 4.5%). Consequently, the rapid increase in the SAVR mortality fairs significantly worse than the TAVR mortality in the Evolut Low Risk arm (1 year: 2.1%, 4.4%, and 6.3%); giving the potentially inappropriate impression of superiority of TAVR. With anticipated results of the 5-year PARTNER 3 and the 4-year Evolut Low Risk data expected in late 2023, it will be very important to weigh the robustness of this future evidence based on a SAVR cohort of less than 345 and 537 patients, respectively, several with concomitant operations, with the results of over 42,000 real-world isolated low risk SAVR patients in the current national study.

This study has several limitations. While the STS ACSD captures 97% of operations in the United States to provide the most comprehensive assessment and remains the gold standard for clinical outcomes, the retrospective nature of all registry data limits demonstration of

causality. Furthermore, the STS ACSD does not currently provide frailty information or detailed postoperative echocardiographic information.

The results of the current national cohort study with an age and STS PROM equivalency to existing low risk trials[4-7], confirm that the long-term survival following SAVR remains excellent at over 87% at 8 years. When closely examining subcohorts of patients of age less than 75, and STS PROM < 1%, the 8-year survival is over 90%. It is the hope that these contemporary longitudinal data serve to aid in the balanced interpretation of current and future trials comparing SAVR and TAVR and assist in the clinical decision-making process when recommending the optimal treatment for patients of lower risk requiring aortic valve replacement.

Acknowledgement: The authors thank The Society of Thoracic Surgeons Research and Analytic Center for providing the statistical analysis.

References:

1. Mack MJ, Leon MB, Smith CR, et al. 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. Lancet. 2015;385:2477-84.
2. Makkar RR, Thourani VH, Mack MJ, et al. Five-Year Outcomes of Transcatheter or Surgical Aortic-Valve Replacement. N Engl J Med. 2020;382:799-809.
3. Leon MB, Smith CR, Mack MJ, et al. Transcatheter or surgical aortic valve replacement in intermediate-risk patients. N Engl J Med. 2016;374:1609-1620.
4. Popma JJ, Deeb GM, Yakubov SJ, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. N Engl J Med. 2019;380:1706-1715.
5. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. N Engl J Med. 2019;380:1695-1705.
6. Leon MB, Mack MJ, Hahn RT, et al. Outcomes 2 Years After Transcatheter Aortic Valve Replacement in Patients at Low Surgical Risk. J Am Coll Cardiol. 2021;77:1149-1161.
7. Forrest JK, Deeb GM, Yakubov SJ, et al. 2-Year Outcomes After Transcatheter Versus Surgical Aortic Valve Replacement in Low-Risk Patients. J Am Coll Cardiol. 2022;79:882-896.
8. Forrest JK, Deeb GM, Yakubov SJ, et al. 3-Year Outcomes After Transcatheter or Surgical Aortic Valve Replacement in Low-Risk Patients With Aortic Stenosis. J Am Coll Cardiol. 2023;81:1663-1674.
9. Bowdish ME, D'Agostino RS, Thourani VH, et al. STS Adult Cardiac Surgery Database: 2021 Update on Outcomes, Quality, and Research. Ann Thorac Surg. 2021;11:1770-1780.
10. Marcu G, Qiu F, Manoragavan R, et al. Temporal Trends and Drivers of Heart Team Utilization in Transcatheter Aortic Valve Replacement: A Population-Based Study in Ontario, Canada. J Am Heart Assoc. 2021;10:e020741. doi: 10.1161/JAHA.120.020741. Epub 2021 Jun 22.
11. Fukuhara S, Nguyen CTN, Yang B, et al. Cardiac Reoperations in Patients With Transcatheter Aortic Bioprosthesis. Ann Thorac Surg. 2023;116:69-76.
12. Zaid S, Hirji SA, Bapat VN, et al. Surgical Explantation of Failed Transcatheter Aortic Valve Replacement. Ann Thorac Surg. 2023 Jun 22:S0003-4975(23)00612-4. doi: 10.1016/j.athoracsur.2023.05.036. Online ahead of print.
13. Mesnier J, Ternacle J, Cheema A, et al. Cardiac Death After Transcatheter Aortic Valve Replacement With Contemporary Devices. J Am Coll Cardiol Intv 2023;16:2277–2290.
14. Wei LM, Cook CC, Hayanga JWA, et al. Robotic Aortic Valve Replacement: First 50 Cases. Ann Thorac Surg. 2022;114:720-726.
15. Celik M, Durko AP, Bekkers JA, et al. Outcomes of surgical aortic valve replacement over three decades. J Thorac Cardiovasc Surg. 2022;164:1742-1751.
16. Barili F, Brophy JM, Ronco D, et al, for the International Evidence Grading Research Initiative Targeting Transparency and Quality (INTEGRITTY). Risk of bias in

randomized clinical trials comparing transcatheter and surgical aortic valve replacement: a systematic review and meta-analysis. JAMA Netw Open. 2023;6:e2249321.

17. Barili F, Anselmi A, Boden WE, et al. Concerns Regarding the Report of 3-Year Outcomes of the Evolut Low Risk Trial. J Am Coll Cardiol. 2023;82:e101.

FIGURE LEGENDS

Figure 1. CONSORT diagram. AVR, aortic valve replacement; PROM, predicted risk of mortality; AR, aortic regurgitation; MR, mitral regurgitation; TR, tricuspid regurgitation; MI, myocardial infarction; CVA, cerebrovascular accident; ESRD, end stage renal disease; CAD, coronary artery disease.

Figure 2. Kaplan Meier Time to Event All-Cause Mortality

Figure 3. Kaplan Meier Survival by STS Predicted Risk of Mortality, Age, and Ejection Fraction. A – Survival by STS PROM; B – Survival by Preoperative Age at Operation; C – Survival by Preoperative EF at Operation

Table 1. Baseline Demographics and Patient Characteristics

Patient Factor	Low Risk SAVR Cohort (2011-2019; N=42,586)*		
	Value	**N**	**Column N %**
Female	Yes	18,841	44.2%
PROM Group	STS PROM <1%	5,127	12.0%
	STS PROM 1%-2%	20,289	47.6%
	STS PROM 2%-3%	11,596	27.2%
	STS PROM 3%-4%	5,574	13.1%
Age Group	Age 65-74 yrs	10,349	24.3%
	Age 75-84 yrs	23,574	55.4%
	Age >= 85 yrs	8,584	20.2%
Diabetes	Insulin	2,646	6.2%
	Oral Control	8,455	19.9%
Kidney Function	eGFR >= 60	31,475	73.9%
	eGFR 45-59.9	8,278	19.4%
	eGFR 30-44.9	2,833	6.7%
Chronic Lung Disease	No	34,887	81.9%
	Mild	4,765	11.2%
	Moderate	1,527	3.6%
	Severity Unknown	1,309	3.1%
Peripheral Vascular Disease	Yes	2,973	7.0%
Cerebrovascular Disease	Yes	5,084	11.9%
Cerebrovascular Accident (>30 days)	Yes	1,006	2.4%
Congestive Heart Failure	Yes	10,655	25.0%
NYHA Class I-III	Yes	11,017	25.9%
NYHA Class IV	Yes	460	1.1%
Moderate AR	Yes	7,126	16.7%
Moderate MR	Yes	3,728	8.8%
Moderate TR	Yes	2,179	5.1%
Previous CABG	Yes	819	1.9%
Prior PCI	Yes	4,773	11.2%
Preoperative Pacemaker	Yes	1,455	3.4%
Preoperative Atrial Fibrillation	Yes	3,111	7.3%
Aortic Valve Implant	Bioprosthesis	41,659	97.8%
	Mechanical	927	2.2%
Annular/Root Enlargement Performed	Yes	1,262	3.0%
Continuous Variables	**Value**	**Mean**	**Std. Dev.**
STS PROM	%	1.92	0.83
Age	Years	74.3	5.7
BMI	Kg/m^2	30.4	6.1

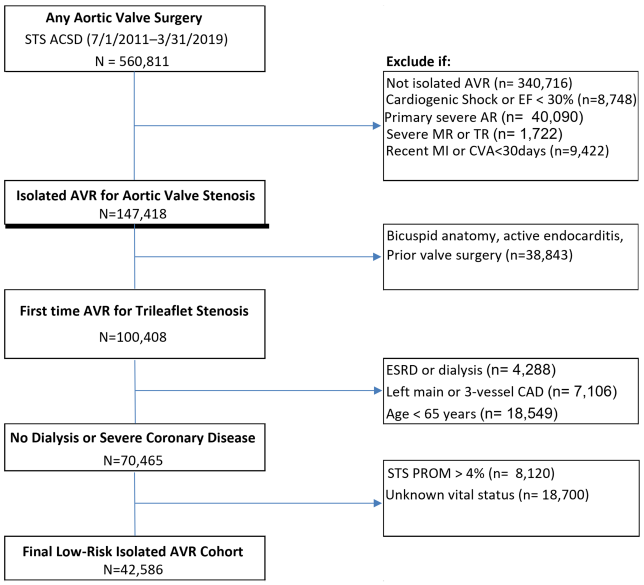
Estimated GFR	mL/min/1.73m^2	71.4	16.3
Preoperative Creatinine	mg/dL	0.96	0.26
Ejection Fraction	%	60.1	8.2

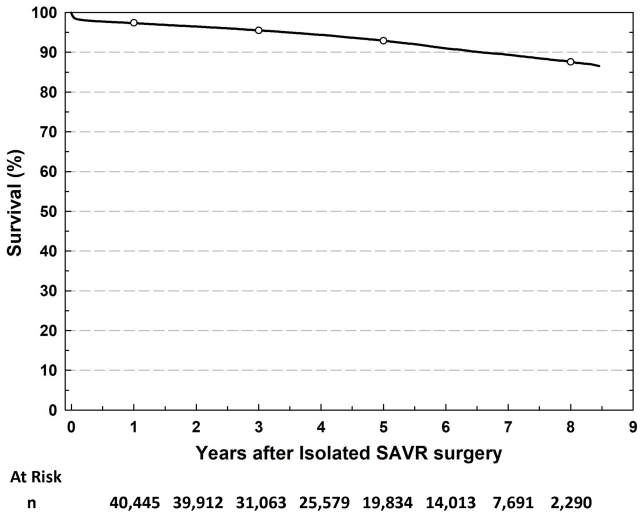
PROM – predicted risk of mortality; NYHA – New York Heart Association; AR – aortic regurgitation; MR – mitral regurgitation; TR – tricuspid regurgitation; eGFR – estimated glomerular filtration rate; PCI – percutaneous coronary intervention; CABG – coronary artery bypass grafting; BMI – body mass index.

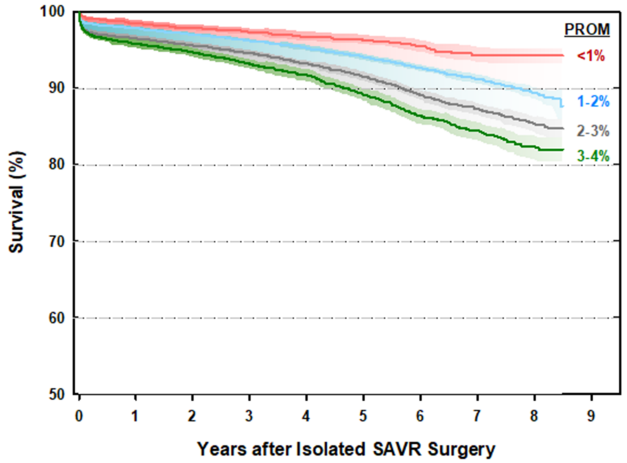
Table 2. STS Benchmark Mortality Comparison to Contemporary Low Risk Trials

Years after Implant	LR-SAVR Mortality			LR-TAVR Mortality	
	STS SAVR Benchmark	PARTNER 3	Evolut LR	PARTNER 3	Evolut LR
1	**2.6%**	2.5%	2.7%	1.0%	2.1%
2	**3.5%**	3.2%	4.4%	2.4%	4.4%
3	**4.5%**	N/A	8.3%	N/A	6.3%
4	**5.6%**	N/A	N/A	N/A	N/A
5	**7.1%**	N/A	N/A	N/A	N/A
6	**9.0%**	N/A	N/A	N/A	N/A
7	**10.6%**	N/A	N/A	N/A	N/A
8	**12.4%**	N/A	N/A	N/A	N/A

LR – low risk; SAVR – surgical aortic valve replacement; TAVR – transcatheter aortic valve replacement.

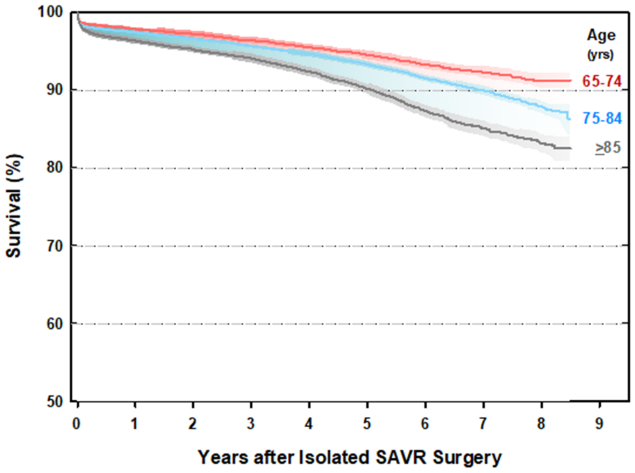




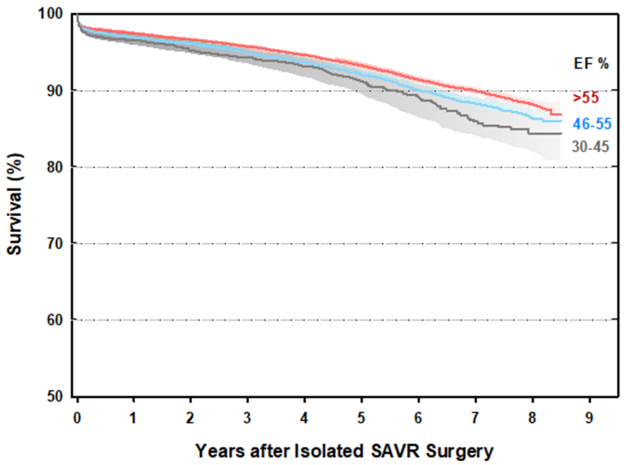


Patients at Risk (n)	1-yr	3-yr	5-yr	8-yr
PROM <1% (N=5,127)	4,758	2,692	1,744	219
PROM 1-2% (N=20,289)	19,338	14,480	9,079	1,062
PROM 2-3% (N=11,596)	11,045	9,226	5,877	708
PROM 3-4% (N=5,574)	5,313	4,705	3,128	332

Survival (%)	1-yr	3-yr	5-yr	8-yr
PROM <1%	98.5%	97.5%	96.4%	94.3%
PROM 1-2%	97.9%	96.2%	94.1%	89.4%
PROM 2-3%	96.6%	94.7%	91.6%	85.4%
PROM 3-4%	95.9%	93.2%	89.2%	82.5%



Patients at Risk (n)	1-yr	3-yr	5-yr	8-yr
Age 65-74 yrs (N=10,428)	9,837	7,270	4,654	566
Age 75-84 yrs (N=23,574)	22,380	16,787	10,508	1,230
Age > 85 yrs (N=8,584)	8,162	6,977	4,618	518
Survival (%)	**1-yr**	**3-yr**	**5-yr**	**8-yr**
Age 65-74 yrs	97.9%	96.4%	94.6%	91.3%
Age 75-84 yrs	97.5%	95.7%	93.3%	88.0%
Age > 85 yrs	96.4%	94.1%	90.2%	83.3%



Patients at Risk (n)	1-yr	3-yr	5-yr	8-yr
EF > 55% (N=31,079)	29,508	22,246	13,838	1,577
EF 46-55% (N=9,005)	8,590	6,980	4,737	608
EF 30-45% (N=2,502)	2,356	1,877	1,253	136

Survival (%)	1-yr	3-yr	5-yr	8-yr
EF > 55%	97.5%	95.8%	93.3%	88.4%
EF 46-55%	97.0%	95.0%	92.1%	86.4%
EF 30-45%	96.6%	94.4%	91.2%	84.4%

Declaration of interests

☐ The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

☒ The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

All Authors reports statistical analysis was provided by The Society of Thoracic Surgeons. Vinod H. Thourani, MD reports a relationship with Abbott, Boston Scientific, Cryolife, Edwards, Jenavalve, Medtronic, Shockwave that includes: consulting or advisory. Dr. Thourani discloses consulting fees from Abbott, Boston Scientific, Cryolife, Edwards Lifesciences, Jenavalve, Medtronic, and Shockwave. Dr. Szeto discloses consulting fees from Edwards Lifesciences, Medtronic, Artivion, Terumo, and Abbott. Dr Sabik discloses consulting fees from Medtronic. No other authors have relevant disclosures.