Title
Evolution of Surgical Aortic Valve Replacement in the Era of Transcatheter Valve Technology

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RESEARCH LETTER

Evolution of Surgical Aortic Valve Replacement in the Era of Transcatheter Valve Technology

Transcatheter aortic valve replacement (TAVR) has shown similar clinical benefit and symptomatic recovery to surgical aortic valve replacement (SAVR) for high- and intermediate-risk patients with severe aortic stenosis in the PARTNER I and II trials.[1,2] We hypothesized the adoption of TAVR would have significantly impacted resource use and postoperative outcomes after SAVR.

Methods | A total of 173 108 adult patients undergoing isolated aortic valve replacement between January 1, 2004, and December 31, 2013, were identified from the National Inpatient Sample's Healthcare Cost and Utilization Project using the *International Classification of Diseases, Ninth Revision* procedural codes for SAVR (35.21 and 35.22) and TAVR (35.05 and 35.06). The National Inpatient Sample is a 20% stratified sample of discharges from more than 4000 community hospitals modeling over 35 million US hospitalizations annually. Patients undergoing redo or concomitant cardiac operations were excluded. This study was exempted from review by the institutional review board at the University of California, Los Angeles because the National Inpatient Sample is a publicly available deidentified database sponsored by the Agency for Healthcare Research and Quality. A data use agreement with the Healthcare Cost and Utilization Project was completed.

Cost, length of stay, and mortality were estimated using Healthcare Cost and Utilization Project survey weights. Costs were standardized to the 2013 US gross domestic product using US Department of Commerce consumer price indices and adjusted for diagnosis related group-based severity. The Elixhauser Comorbidity Index, which identifies 31 common comorbidities, was used to estimate disease severity. Cardiovascular comorbidities and complications were further identified using peer-reviewed *International Classification of Diseases, Ninth Revision* codes for cardiac surgery.[3] Mortality, length of stay, and log-transformed costs were modeled using hierarchical multivariable logistic, Poisson distribution, and linear distribution, respectively, controlling for patient demographics, comorbidities, complications, and hospital characteristics. A piecewise multivariable regression model was used to compare trends in SAVR cost before and after 2011. Statistical analyses were performed using Stata version 14 (StataCorp LLC), with $P < .001$ considered significant after Bonferroni correction.

Results | Demographics, comorbidities, and outcomes were estimated for each of the 3 cohorts of patients undergoing isolated SAVR from 2004 to 2010 (early cohort), SAVR from 2011 to 2013 (late cohort), and TAVR from 2011 to 2013 (**Table**).

Although the mean unadjusted cost of the late cohort was $3093 greater than that of the early cohort (95% CI, 730-5456; $P < .001$), the annual cost of SAVR has decreased by 4.92% (95% CI, 3.26-6.54; $P < .001$) since 2011. In SAVR patients, the Elixhauser Comorbidity Index was significantly associated with increased cost ($\beta = 0.066$ [95% CI, 0.062-0.070]; $P < .001$) and stabilized after the advent of TAVR (**Figure**). Complications associated with increased cost and length of stay, including infection and stroke, also remained stable after 2011. Mortality after SAVR decreased throughout the decade (odds ratio, 0.75; 95% CI, 0.63-0.89; $P < .001$).

Since US Food and Drug Administration approval, use of TAVR has rapidly increased from 1164 to 13 525 cases annually. The mean cost of TAVR has risen from $51 008 to $55 136 ($P < .001$) despite no significant change in Elixhauser Comorbidity Index score, proportions of individual comorbidities, or rates of postoperative complications. There was no difference in adjusted mortality (odds ratio, 0.81; 95% CI, 0.62-1.05; $P = .11$) or rate of postoperative neurologic complications (odds ratio, 0.90; 95% CI, 0.55-1.47; $P = .68$) between TAVR and late cohort SAVR patients. Yet, TAVR was 8.38% (95% CI, 5.98-10.84; $P < .001$) more expensive than SAVR after multivariable adjustment.

Discussion | Our study demonstrates the impact of newly introduced TAVR technology on resource use in SAVR. The reduction in cost of SAVR and stabilization of disease severity reflect more efficient allocation of resources between SAVR and TAVR. However, the cost of TAVR is increasing. Previous analyses have recommended reductions in the initial cost of TAVR to ensure its cost-effectiveness in practice and implicated the higher fixed cost of the valve.[4,5] Our data show that this discrepancy remains despite the development of new generations of valves and increased competition in transcatheter technology.[6] Further research is necessary to elucidate whether this increase reflects a learning curve as TAVR programs

Table. Demographic Characteristics, Comorbidities, and Outcomes After Isolated Aortic Valve Replacement by Modality, 2004 to 2013[a,b]

Characteristic	SAVR Early Cohort (n = 101 031)	SAVR Late Cohort (n = 50 078)	*P* Value	TAVR (n = 21 999)
Age (IQR), y	61 (50-72)	62 (52-73)	.05	83 (77-88)
Male	62 792 (62)	31 153 (62)	.97	11 194 (51)
Race/ethnicity				
White	61 173 (79)	36 305 (79)	.41	17 703 (86)
Black	5116 (7)	3358 (7)		741 (4)
Hispanic	6449 (8)	3974 (9)		756 (4)
Asian/Pacific Islander/other	4427 (6)	2471 (5)		1303 (6)
Insurance				
Medicare	43 039 (43)	22 781 (46)	<.001	19 771 (90)
Medicaid	6787 (7)	3757 (8)		204 (1)
Private insurance	44 591 (44)	19 749 (39)		1561 (7)
Self-pay	3132 (3)	2147 (4)		85 (<1)
Other	3111 (3)	1620 (3)		334 (2)
Hospital bed size				
Small	6032 (6)	3046 (6)	.99	815 (4)
Medium	17 595 (18)	8631 (17)		3287 (15)
Large	76 686 (76)	38 296 (77)		17 898 (81)
Location/teaching status				
Rural	3426 (3)	1103 (2)	.003	180 (1)
Urban, nonacademic	33 484 (33)	13 539 (27)		2558 (12)
Urban, academic	63 403 (64)	35 331 (71)		19 262 (87)
Comorbidities				
Elixhauser Comorbidity Index score (IQR)	4 (3-5)	5 (3-6)	<.001	6 (5-7)
Prior stroke	1545 (2)	886 (2)	.13	440 (2)
Hypertension	50 448 (50)	27 355 (55)	<.001	9952 (45)
Hyperlipidemia	34 802 (34)	23 721 (47)	<.001	13 718 (63)
Angina	3172 (3)	1175 (2)	<.001	622 (3)
Coronary artery disease	7478 (7)	4760 (9)	<.001	7647 (35)
Congestive heart failure	31 946 (32)	17 134 (34)	.007	15 823 (72)
Cardiogenic shock	2244 (2)	1954 (4)	<.001	848 (4)
Endocarditis	19 333 (19)	9512 (19)	.81	4159 (19)
Pacemaker	1980 (2)	1482 (3)	<.001	2256 (10)
Prior CABG	4952 (5)	2717 (5)	.11	5626 (26)
Prior PCI	2766 (3)	2383 (5)	<.001	3969 (18)
Chronic lung disease	11 957 (12)	6377 (13)	.07	6123 (28)
Peripheral vascular disease	22 711 (22)	12 246 (24)	.01	4931 (22)
Chronic renal failure	6257 (6)	6383 (12)	<.001	8147 (37)
Hemodialysis	358 (<1)	499 (1)	<.001	414 (2)
Chronic liver disease	763 (1)	568 (1)	<.001	456 (2)
Diabetes	2136 (2)	1761 (4)	<.001	793 (4)
Anemia	30 380 (30)	27 066 (54)	<.001	11 035 (50)
Coagulopathy	14 473 (14)	11 412 (23)	<.001	4566 (21)
Obesity	11 580 (11)	9723 (19)	<.001	2859 (13)
Clinical outcomes				
Mortality	3803 (4)	1468 (3)	<.001	974 (4)
Length of stay (IQR), d	7 (5-11)	7 (5-11)	.79	6 (4-10)
Cost (IQR), $	37 795 (29 041-52 861)	39 739 (30 586-56 019)	<.001	49 601 (39 313-64 589)

(continued)

Table. Demographic Characteristics, Comorbidities, and Outcomes After Isolated Aortic Valve Replacement by Modality, 2004 to 2013[a,b] (continued)

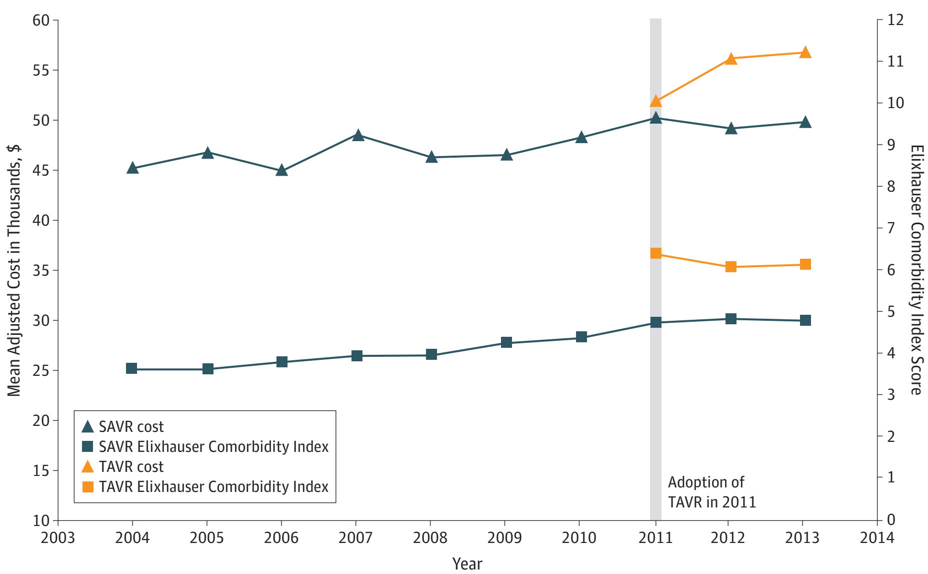
Characteristic	SAVR Early Cohort (n = 101 031)	SAVR Late Cohort (n = 50 078)	*P* Value	TAVR (n = 21 999)
Discharge status				
Routine	49 220 (49)	22 530 (45)	.003	6598 (30)
Short-term hospital	955 (1)	411(1)		218 (1)
SNF/IC facility	15 772 (16)	9235 (18)		7094 (32)
Home health care	31 180 (31)	16 390 (33)		7107 (32)
Complications				
Valve-related	5215 (5)	3108 (6)	.004	813 (4)
Puncture	1265 (1)	569 (1)	.41	539 (2)
Hemorrhage	6839 (7)	2920 (6)	.005	1824 (8)
Stroke	1308 (1)	545 (1)	.14	328 (1)
Supraventricular arrhythmia	34 678 (34)	19 341 (39)	<.001	10 166 (46)
Atrioventricular block	7335 (7)	4443 (9)	<.001	2895 (13)
Postoperative shock	5596 (6)	2774 (6)	>.99	1162 (5)
Myocardial infarction	3211 (3)	1728 (3)	.24	748 (3)
Deep venous thrombosis	1050 (1)	267 (1)	<.001	200 (1)
Respiratory failure	11 337 (11)	8112 (16)	<.001	2335 (11)
Postoperative infection	12 277 (12)	6154 (12)	.81	3465 (16)

Abbreviations: CABG, coronary artery bypass grafting; IC, intermediate care; IQR, interquartile range; PCI, percutaneous coronary intervention; SAVR, surgical aortic valve replacement; SNF, skilled nursing facility; TAVR, transcatheter aortic valve replacement.

[a] Data are presented as No. (%) unless otherwise indicated.

[b] Totals may not add up to 100% because the data collected by the Healthcare Cost and Utilization Project may not be complete.

Figure. Inpatient Cost and Comorbidity Index of Patients Undergoing Isolated Aortic Valve Replacement, 2011 to 2013



SAVR indicates surgical aortic valve replacement; TAVR, transcatheter surgical aortic valve replacement.

become established. As the indication for TAVR expands to medium- and low-risk cohorts, legislation may be necessary to ensure its cost-effectiveness.

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Role of Preventability in Redefining Failure to Rescue Among Major Trauma Patients

Failure to rescue (FTR) is defined as death after a major complication[1] and has been adopted as a measure of quality in surgical patients. Current definitions of FTR are limited because they do not account for the influence of preventability on mortality. The aim of this study was to examine the association of preventability with rates of FTR among patients with major trauma.

Methods | This 6-year, retrospective cohort study was performed at a university-affiliated level I trauma center. We identified all adult patients with neck, torso, and peripheral vascular injuries (n = 802) who were taken directly from the emergency department to the operating room for emergency surgery. Institutional review board approval and waiver for patient consent were obtained from the John F. Wolf, MD, Human Subjects Committee, Los Angeles Biomedical Research Institute.

Patients whose outcomes were classified as FTR were compared with those in the non-FTR group. Variables analyzed were demographic characteristics, Injury Severity Score (higher scores indicate more severe injuries), Glasgow Coma Scale score (higher scores indicate less neurologic impairment), transfusion requirements, presence of a head injury, location of the injury (chest, abdomen, or extremity), toxicology screen results, insurance status, and hypotension on admission (defined as systolic blood pressure ≤90 mm Hg). Complications were categorized as either medical or surgical.

We then completed an in-depth analysis of divisional and departmental peer review proceedings to identify the final adjudication of FTR as preventable, potentially preventable, or not preventable. The Pearson χ^2 test and a paired t test were performed for univariate analysis and a logistic regression for multivariate analysis using Stata, version 12.0 (StataCorp). P values were 1-sided, and statistical significance was defined as $P < .05$.

Results | Of the 802 patients who underwent emergency surgery, 682 (85.0%) were men and 120 (15.0%) were women, with a mean (SD) age of 33.8 (14.7) years. Of these, 172 patients (21.4%) developed a complication. We found that 78 patients (45.4%) had a medical complication and 94 (54.6%) had a surgical complication.The most common complication was pneumonia (24 patients), and the incidence of FTR was 30.8% (53 patients). On univariate analysis, age, sex, and type of complication were similar between patients in the FTR and non-FTR groups. The FTR group had more patients with a blunt mechanism of injury, hypotension, a higher Injury Severity Score, a lower Glasgow Coma Scale score, and a shorter length of stay. Binary variables were assigned a value of 0 if the variable was absent and 1 if present. Variables with $P < .20$ were included in the multivariate analysis. On multivariate analysis, factors associated with FTR were insurance status

Table. Multivariate Analysis of Factors Associated With Failure to Rescue

Factor	Risk of Failure to Rescue, OR (95% CI)	*P* Value
Insurance coverage	0.26 (0.09-0.73)	.01
Age per 1-y increase	1.02 (0.99-1.05)	.14
Penetrating mechanism of injury	0.84 (0.33-2.12)	.71
Hypotension on admission to ED[a]	3.35 (1.35-8.30)	.01
Higher Injury Severity Score[b]	1.07 (1.03-1.11)	<.001
Higher Glasgow Coma Scale score on admission to ED[c]	0.95 (0.86-1.05)	.33

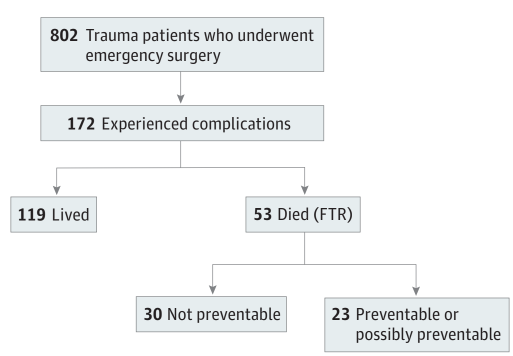
Abbreviations: ED, emergency department; FTR, failure to rescue; OR, odds ratio.

[a] Defined as a systolic blood pressure of 90 mm Hg or lower.

[b] Higher scores indicate more severe injuries.

[c] Higher scores indicate less neurologic impairment.

Figure. Dispersion of Trauma Patients Who Underwent Emergency Surgery



Preventable and possibly preventable cases represent only a few of the cases designated as failure to rescue (FTR).