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Transcatheter Versus Surgical Aortic Valve Replacement

Propensity-Matched Comparison

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ABSTRACT

BACKGROUND Randomized trials support the use of transcatheter aortic valve replacement (TAVR) for the treatment of aortic stenosis in high- and intermediate-risk patients, but the generalizability of those results in clinical practice has been challenged.

OBJECTIVES The aim of this study was to determine the safety and effectiveness of TAVR versus surgical aortic valve replacement (SAVR), particularly in intermediate- and high-risk patients, in a nationally representative real-world cohort.

METHODS Using data from the Transcatheter Valve Therapy Registry and Society of Thoracic Surgeons National Database linked to Medicare administrative claims for follow-up, 9,464 propensity-matched intermediate- and high-risk (Society of Thoracic Surgeons Predicted Risk of Mortality score ≥3%) U.S. patients who underwent commercial TAVR or SAVR were examined. Death, stroke, and days alive and out of the hospital to 1 year were compared, as well as discharge home, with subgroup analyses by surgical risk, demographics, and comorbidities.

RESULTS In a propensity-matched cohort (median age 82 years, 48% women, median Society of Thoracic Surgeons Predicted Risk of Mortality score 5.6%), TAVR and SAVR patients experienced no difference in 1-year rates of death (17.3% vs. 17.9%; hazard ratio: 0.93; 95% confidence interval [CI]: 0.83 to 1.04) and stroke (4.2% vs. 3.3%; hazard ratio: 1.18; 95% CI: 0.95 to 1.47), and no difference was observed in the proportion of days alive and out of the hospital to 1 year (rate ratio: 1.00; 95% CI: 0.98 to 1.02). However, TAVR patients were more likely to be discharged home after treatment (69.9% vs. 41.2%; odds ratio: 3.19; 95% CI: 2.84 to 3.58). Results were consistent across most subgroups, including among intermediate- and high-risk patients.

CONCLUSIONS Among unselected intermediate- and high-risk patients, TAVR and SAVR resulted in similar rates of death, stroke, and DAOH to 1 year, but TAVR patients were more likely to be discharged home.
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ABBREVIATIONS AND ACRONYMS

CI = confidence interval

DAOH = days alive and out of the hospital

IQR = interquartile range

PROM = Predicted Risk of Mortality

SAVR = surgical aortic valve replacement

STS = Society of Thoracic Surgeons

TAVR = transcatheter aortic valve replacement

Aortic valve disease is the third most common cause of cardiovascular disease in the United States, affecting an estimated 2.5 million adults (5% of those affected are 65 years or older) (1,2). Severe untreated aortic valve stenosis substantially affects life expectancy and quality (3); however, patients with aortic valve disease are often older, with multiple comorbidities, making recovery from open surgical aortic valve replacement (SAVR) challenging (4). Over the past decade, transcatheter aortic valve replacement (TAVR) has emerged as a less invasive alternative to SAVR, thereby offering potential advantages for this older patient cohort (5). TAVR was approved by the U.S. Food and Drug Administration in 2011; since then, >80,000 commercial TAVR procedures have been performed in the United States in patients at intermediate, high, and prohibitive surgical risk (Matthew Brennan, February 4, 2017, personal communication).

SEE PAGE 451

To date, 3 high-quality randomized controlled trials have supported the use of TAVR in intermediate- and high-risk patients (6–8), but these clinical trials excluded important groups of patients with higher risk comorbidities and were conducted at a select group of high-volume valve centers. Consequently, whether these results are applicable to clinical practice has been questioned (9), and concerns regarding the safety and effectiveness of TAVR have been raised (10,11). These concerns are of increasing relevance because TAVR is applied to low- and intermediate-risk patients, in whom the risk of SAVR is less, and its long-term outcomes are well-documented (12).

To address these lingering questions, we used observational data from 2 large U.S. procedural registries to examine the real-world comparative effectiveness of TAVR versus SAVR in a nationally representative real-world cohort of older patients who may have been considered eligible for either TAVR or SAVR.

TABLE 1 Baseline Characteristics of the Aortic Valve Replacement Cohort After Propensity Matching*

	SAVR (n = 4,732)	TAVR (n = 4,732)	Standardized Difference, TAVR vs. SAVR, %
Age, yrs	82 (77-85)	81 (77-85)	−1.01
Female	2,278 (48.1)	2,256 (47.7)	−0.93
Body surface area, m^2	1.9 (1.7-2.1)	1.9 (1.7-2.0)	0.04
Creatinine, mg/dl	1.1 (0.9-1.4)	1.1 (0.9-1.5)	−0.32
Dialysis	186 (3.9)	179 (3.8)	−0.77
LVEF, %	55.0 (45.0-55.0)	55.0 (45.0-55.0)	−1.10
Heart failure symptoms <2 weeks			4.28
None or Class I	447 (9.4)	335 (7.1)	
Class II	947 (20.0)	995 (21.0)	
Class III	2,499 (52.8)	2,509 (53.0)	
Class IV	839 (17.7)	893 (18.9)	
Chronic lung disease			1.62
None	2,793 (59.0)	2,784 (58.8)	
Mild	872 (18.4)	866 (18.3)	
Moderate	564 (11.9)	558 (11.8)	
Severe	503 (10.6)	524 (11.1)	
Home oxygen use	385 (8.1)	378 (8.0)	−0.54
Prior stroke	524 (11.1)	506 (10.7)	−1.22
Peripheral vascular disease	1,138 (24.0)	1,113 (23.5)	−1.24
Pre-operative atrial fibrillation/flutter	1,619 (34.2)	1,572 (33.2)	−2.10
Prior MI			2.21
Recent	161 (3.4)	173 (3.7)	
Old	954 (20.2)	924 (19.5)	
Prior PCI	1,278 (27.0)	1,233 (26.1)	−2.15
CAD: number of diseased vessels			0.95
None	2,292 (48.4)	2,326 (49.2)	
1	770 (16.3)	757 (16.0)	
2	520 (11.0)	512 (10.8)	
3	1,150 (24.3)	1,137 (24.0)	
Prior CV surgery	1,484 (31.4)	1,406 (29.7)	−3.58
Prior aortic valve replacement	219 (4.6)	214 (4.5)	−0.51
Aortic valve mean gradient, mm Hg	42.0 (35.0-52.0)	42.0 (36.0-52.0)	0.46
Aortic insufficiency (moderate/severe)	956 (20.2)	947 (20.0)	−0.47
Mitral insufficiency (moderate/severe)	1,166 (24.6)	1,125 (23.8)	−2.02
PA systolic pressure, mm Hg	41.0 (37.0-46.0)	41.0 (37.0-46.0)	1.09
Pre-operative IABP/inotropes	128 (2.7)	123 (2.6)	−0.66

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METHODS

STUDY DESIGN AND DATA SOURCES. This was a multicenter, nonrandomized analysis of older patients with severe, symptomatic aortic valve stenosis at intermediate or high surgical risk who underwent treatment with TAVR or SAVR in the United States and may have been considered eligible for either treatment (on the basis of available data). Data for this analysis were drawn from 2 U.S. procedural registries: 1) SAVR data were drawn from the Society of Thoracic Surgeons (STS) National Database; and 2) TAVR data were drawn from the STS/American College of Cardiology TVT (Transcatheter Valve Therapy) Registry. The development and application of these registries have been described previously (13,14). More than 90% of cardiac surgery programs in the United States participate in the STS National Database, and participation in the TVT Registry is necessary for Medicare reimbursement. Notably, the involvement of a heart team is also necessary for Medicare reimbursement in the United States. For each registry, participants are required to submit 100% of their case records to the registry for quality

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