TAVR Decreases Mortality When Compared With Surgery in High-Risk Patients

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A large, prospective, randomized trial was conducted at 45 sites in the United States to compare the safety and efficacy of transcatheter aortic valve replacement (TAVR) with the CoreValve self-expanding prosthesis with surgical aortic-valve replacement (SAVR) in patients with severe aortic stenosis at high risk for cardiac surgery. Results from the cohort of patients who were not surgical candidates and underwent TAVR with CoreValve were recently reported [Popma JJ et al. *J Am Coll Cardiol* 2014]. David H. Adams, MD, Mount Sinai Medical Center, New York, New York, USA, presented the results from the patients in the high-risk cohort who were randomized to either CoreValve or surgery [Adams DH et al. *N Engl J Med* 2014].

To participate in the trial, patients had to have NYHA Functional Class ≥II, severe aortic stenosis, mortality risk with surgery ≥15%, and risk of death or irreversible complications within 30 days <50%. Surgical risk was determined by using the Society of Thoracic Surgeons (STS) Predicted Risk of Mortality Calculator in conjunction with other key risk factors. Key exclusion criteria included recent active gastrointestinal bleed, stroke, myocardial infarction, or recent procedures with bare-metal or drug-eluting stents. Patients with significant untreated coronary artery disease, a left ventricular ejection fraction <20%, creatinine clearance <20 mL/min, or a life expectancy <1 year were also excluded. Patients meeting entry criteria were randomized 1:1 to TAVR by any route or SAVR. Patients will be followed for a total 5 years, but the primary endpoint was all-cause mortality at 1 year.

Of the 795 patients randomized, 390 underwent TAVR and 357 underwent SAVR. The mean STS predicted risk of mortality score was 7.3% ± 3.0 for TAVR compared with 7.5% ± 3.4 for SAVR. The proportion of patients with severe chronic lung disease was 13.3% for TAVR versus 9.0% in the SAVR group. Approximately 98% of TAVR patients and 94% of SAVR patients completed the 1-year follow-up assessments.

One-year mortality was lower in the TAVR arm (14.2%) compared with the SAVR arm (19.1%; p<0.001 for noninferiority and p=0.04 for superiority). The TAVR survival advantage was also evident in all subgroups. At 1 year, TAVR patients had higher rates of major vascular complications and pacemaker implants, but lower rates of bleeding, new onset or worsening atrial fibrillation, and acute kidney injury compared with SAVR (Table 1). SAVR patients had significantly lower paravalvular regurgitation at each time point (p<0.001). Dr. Adams noted that additional analyses will be reported in the future including long-term outcomes.

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Table 1. Procedural Outcomes at 1 Year

Outcome	TAVR (n=390)	SAVR (n=357)	p Value
Death	55 (14.2)	67 (19.1)	0.04*
Stroke	33 (8.8)	42 (12.6)	0.10
Major vascular complication	24 (6.2)	7 (2.0)	0.004
Pacemaker implants	85 (22.3)	38 (11.3)	<0.001
Life-threatening or disabling bleeding	64 (16.6)	136 (38.4)	<0.001
Major bleeding	114 (29.5)	130 (36.7)	0.03
New-onset or worsening atrial fibrillation	60 (15.9)	115 (32.7)	<0.001
Acute kidney injury	23 (6.0)	54 (15.1)	<0.001

Additional analyses of the follow-up data will be reported, which is important given the mortality benefit is statistically fragile—if mortality had been different by just one patient the results would not have been significant—and higher major vascular complication rates and pacemaker use have unclear long-term consequences at present.