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2-Year Outcomes After Iliofemoral Self-Expanding Transcatheter Aortic Valve Replacement in Patients With Severe Aortic Stenosis Deemed Extreme Risk for Surgery

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ABSTRACT

BACKGROUND We reported favorable 1-year outcomes in patients unsuitable for surgery who underwent self-expanding transcatheter aortic valve replacement (TAVR) compared with an objective performance goal. Longer-term outcomes in these patients are not known.

OBJECTIVES This study sought to evaluate the 2-year safety and efficacy in patients with severe aortic stenosis (AS) at extreme risk of surgery treated with self-expanding TAVR.

METHODS We performed a prospective, multicenter, controlled, nonrandomized investigation of self-expanding TAVR in patients with severe AS and prohibitive surgical risk. We report the 2-year clinical outcomes in these patients.

RESULTS A total of 489 extreme-risk patients were treated transfemorally with a self-expanding aortic bioprosthesis at 41 centers. The rate of all-cause mortality or major stroke was 38.0% at 2 years (all-cause mortality, 36.5%; major stroke, 5.1%). The rates of all-cause mortality, cardiovascular mortality, and major stroke were 36.6%, 26.2%, and 5.1%, respectively, at 2 years. Between 1 and 2 years, the incremental all-cause mortality, cardiovascular mortality, and major stroke rates were 12.3%, 7.9%, and 0.8%, respectively. Multivariable predictors of all-cause mortality at 2 years included the presence of coronary artery disease and admission from an assisted living center. A Society of Thoracic Surgeons score >15% was also predictive of 2-year all-cause mortality. At 2 years, 94% of patients had New York Heart Association functional class I or II symptoms. The frequency of moderate or severe paravalvular regurgitation (4.3% at 1 year; 4.4% at 2 years) was unchanged between the first and second year.

CONCLUSIONS Patients with severe AS at extreme surgical risk treated with self-expanding TAVR continued to show good clinical outcomes and hemodynamic valve performance at 2 years. The presence of comorbid conditions rather than valve performance affected 2-year outcomes in these patients. (Safety and Efficacy Study of the Medtronic CoreValve System in the Treatment of Symptomatic Severe Aortic Stenosis in High Risk and Very High Risk Subjects Who Need Aortic Valve Replacement; NCT01240902) (J Am Coll Cardiol 2015;66:1327–34) © 2015 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

AS = aortic stenosis

NYHA = New York Heart Association

STS-PROM = Society for Thoracic Surgery Predicted Risk of Mortality

TAVR = transcatheter aortic valve replacement

Patients with severe symptomatic aortic stenosis (AS) deemed unsuitable for surgery have an estimated 50.0% mortality at 1 year without valve replacement (1). Transcatheter aortic valve replacement (TAVR) using balloon-expandable (1) and self-expanding (2) bioprostheses has become standard of care in these patients, who often have significant comorbidities, frailties, and disabilities that affect their long-term prognosis (3). Late outcomes after TAVR have been reported (4-7), but there is limited information about late survival in patients deemed to be at extreme risk of surgery (8,9).

SEE PAGE 1335

The CoreValve US Extreme Risk Pivotal Trial evaluated patients deemed unsuitable for surgery by 2 cardiac surgeons and 1 interventional cardiologist (2). A total of 489 patients underwent implantation with self-expanding TAVR by means of an iliofemoral access approach (2). Despite significant concomitant morbidities, the rate of 1-year all-cause mortality and major stroke at 1 year was superior to a rigorously defined objective performance goal (2). The self-expanding aortic bioprosthesis provided sustained improvement in the aortic valve effective orifice area, a reduction in the aortic valve gradient, and an overall improvement in New York Heart Association (NYHA) functional class (2). Our objective in this study was to evaluate the 2-year clinical outcomes in these patients.

TABLE 1 Baseline Clinical Characteristics and Comorbidities (N = 489)

Age, yrs	83.2 ± 8.7
Men, %	47.9 (234/489)
Society of Thoracic Surgeons Predicted Risk of Mortality, %	10.3 ± 5.5
<10	55.6 (272/489)
10–15	27.2 (133/489)
>15	17.2 (84/489)
Logistic euroSCORE, %	22.6 ± 17.1
New York Heart Association functional class III/IV	91.8 (449/489)
Diabetes mellitus	41.5 (203/489)
Insulin controlled	18.4 (90/489)
Cardiac history	
Previous stroke	13.7 (67/488)
Coronary artery disease	81.8 (400/489)
Previous coronary artery bypass graft	39.5 (193/489)
Previous percutaneous coronary intervention	37.0 (181/489)
Previous balloon artic valvuloplasty	20.4 (100/489)
Prohibitive anatomy	
Severe aortic calcification	17.2 (84/488)
Hostile mediastinum	11.9 (58/488)
Comorbidities	
Severe chronic lung disease	23.5 (115/489)
Home oxygen	29.9 (146/489)
Charlson Comorbidity Index	5.3 ± 2.3
Frailty	
Anemia with previous transfusion	22.8 (108/473)
Albumin <3.3 g/dl	18.2 (88/484)
5-m gait speed >6 s	84.2 (283/336)
Disabilities	
Assisted living	27.6 (135/489)
≥2 Katz ADL deficits	20.9 (102/489)
Wheelchair bound	16.6 (81/489)

Values are mean ± SD or frequency, % (n/N).
ADL = activities of daily living; euroSCORE = European System for Cardiac Operative Risk Evaluation.

METHODS

PATIENT ENROLLMENT AND STUDY DESIGN. Detailed patient enrollment criteria, inclusion and exclusion criteria, and study methods have been reported elsewhere (2). In brief, patients with severe symptomatic AS defined as having at least NYHA functional class II symptoms, an aortic valve area ≤0.8 cm^2 (or aortic valve index ≤0.5 cm^2/m^2), and a mean aortic valve gradient >40 mm Hg or a peak aortic

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