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Effect of SAPIEN 3 Transcatheter Valve Implantation on Health Status in Patients With Severe Aortic Stenosis at Intermediate Surgical Risk

Results From the PARTNER S3i Trial

Suzanne J. Baron, MD, MSc, Vinod H. Thourani, MD, Susheel Kodali, MD, Suzanne V. Arnold, MD, MHA, Kaijun Wang, PhD, Elizabeth A. Magnuson, ScD, Augusto D. Pichard, MD, Vasilis Babaliaros, MD, Isaac George, MD, D. Craig Miller, MD, Murat Tuzcu, MD, Kevin Greason, MD, Howard C. Herrmann, MD, Craig R. Smith, MD, Martin B. Leon, MD, David J. Cohen, MD, MSc, on behalf of the PARTNER 2 Investigators

ABSTRACT

OBJECTIVES The aim of this study was to evaluate whether transcatheter aortic valve replacement (TAVR) with the SAPIEN 3 valve (S3-TAVR) results in improved quality of life (QoL) compared with previous-generation TAVR devices or surgical aortic valve replacement (SAVR).

BACKGROUND In patients with severe aortic stenosis at intermediate surgical risk, TAVR using the SAPIEN XT valve (XT-TAVR) results in similar QoL compared with SAVR. Compared with SAPIEN XT, the SAPIEN 3 valve offers a lower delivery profile and modifications to reduce paravalvular regurgitation.

METHODS Between February and December 2014, 1,078 patients at intermediate surgical risk with severe aortic stenosis were treated with S3-TAVR in the PARTNER (Placement of Aortic Transcatheter Valve) S3i trial. QoL was assessed at baseline, 1 month, and 1 year using the Kansas City Cardiomyopathy Questionnaire, Medical Outcomes Study Short Form-36, and EQ-5D. QoL outcomes of S3-TAVR patients were compared with those in the SAVR and XT-TAVR arms of the PARTNER 2A trial using propensity score stratification to adjust for differences between the treatment groups.

RESULTS Over 1 year, S3-TAVR was associated with substantial improvements in QoL compared with baseline. At 1 month, S3-TAVR was associated with better QoL than either SAVR or XT-TAVR (adjusted differences in Kansas City Cardiomyopathy Questionnaire overall summary score 15.6 and 3.7 points, respectively, $p < 0.001$). At 1 year, the differences in QoL between S3-TAVR and both SAVR and XT-TAVR were reduced but remained statistically significant (adjusted differences 2.0 and 2.2 points, respectively, $p < 0.05$). Similar results were seen for generic QoL outcomes.

CONCLUSIONS Among patients at intermediate surgical risk with severe aortic stenosis, S3-TAVR resulted in improved QoL at both 1 month and 1 year compared with both XT-TAVR and SAVR. (J Am Coll Cardiol Intv 2018;■:■–■) © 2018 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

AS = aortic stenosis

CI = confidence interval

KCCQ = Kansas City Cardiomyopathy Questionnaire

KCCQ-OS = Kansas City Cardiomyopathy Questionnaire overall summary

S3-TAVR = transcatheter aortic valve replacement using the SAPIEN 3 valve

SAVR = surgical aortic valve replacement

SF-36 = Medical Outcomes Study Short Form-36

STS = Society of Thoracic Surgeons

TAVR = transcatheter aortic valve replacement

XT-TAVR = transcatheter aortic valve replacement using the SAPIEN XT valve

Over the past decade, multiple trials have demonstrated that transcatheter aortic valve replacement (TAVR) is associated with comparable survival and quality-of-life outcomes compared with surgical aortic valve replacement (SAVR) in patients with severe, symptomatic aortic stenosis (AS) at high surgical risk (1-4). As TAVR has been embraced by the cardiology community, the use of these devices has expanded to lower risk patients with promising results. Recently, the PARTNER (Placement of Aortic Transcatheter Valve) 2A trial demonstrated similar rates of death or disabling stroke as well as similar quality of life at 2 years in patients at intermediate surgical risk treated with either SAVR or TAVR using the second-generation SAPIEN XT valve (Edwards Lifesciences, Irvine, California) (XT-TAVR) (5,6).

While the PARTNER 2A trial was under way, a third-generation balloon-expandable TAVR system, SAPIEN 3 (Edwards Lifesciences), was developed. Compared with SAPIEN XT, SAPIEN 3 offers a lower profile delivery system as well as an outer skirt, designed to reduce paravalvular regurgitation. When TAVR using the SAPIEN 3 valve (S3-TAVR) was compared with SAVR in a propensity-adjusted analysis of intermediate-risk patients, S3-TAVR was found to be associated with reduced rates of death and stroke at 1 year (7). However, many elderly patients who are candidates for TAVR care at least as much about quality of life as they do about duration of life (8). As such, it is important to understand whether differences in clinical outcomes as well as differences in procedure-related complications (such as paravalvular regurgitation, bleeding, atrial fibrillation, or permanent pacemaker implantation) might lead to differences in health status between alternative valve replacement procedures. To address this gap in knowledge, we used data from the PARTNER 2A randomized trial and SAPIEN 3 intermediate-risk registry (PARTNER S3i) to compare health status outcomes among patients with severe AS at intermediate surgical risk treated with S3-TAVR versus either SAVR or XT-TAVR.

METHODS

STUDY DESIGN AND POPULATION. The design of the PARTNER 2A randomized trial and the SAPIEN 3 intermediate-risk registry, including inclusion and exclusion criteria (which were identical for the 2 trials), study procedures, and follow-up protocols, has been described previously (5,7). Briefly, these studies enrolled patients with severe, symptomatic AS at intermediate surgical risk (defined as a predicted risk for 30-day mortality between 4% and 8%, on the basis of either the Society of Thoracic Surgeons [STS] mortality risk score or clinical assessment by a multidisciplinary heart team). In the PARTNER 2A trial, patients were stratified according to available access route (transfemoral vs. transthoracic) and randomized 1:1 to undergo either XT-TAVR or SAVR. In PARTNER S3i, patients underwent S3-TAVR via either a transfemoral or a transthoracic approach, as appropriate. Both the PARTNER 2A trial and PARTNER S3i registry were approved by the Institutional Review Board at each site, and written informed consent was obtained from all patients.

MEASUREMENT OF HEALTH STATUS. Health status was evaluated at baseline, 1 month, and 12 months. Both disease-specific and generic health status measures were used, because disease-specific instruments allow a more sensitive assessment of changes in health status in a particular patient population. Disease-specific health status was assessed using the Kansas City Cardiomyopathy Questionnaire (KCCQ). The KCCQ capture 5 key domains of health status in patients with heart failure (physical function, social function, symptoms, self-efficacy and knowledge, and quality of life [defined as the discrepancy between a desired state of health and actual state of health]) and is scored from 0 to 100, with higher scores indicating better health status (9). The individual scales of the KCCQ may be converted into a single overall summary score (KCCQ-OS), which has been shown to correlate with important clinical outcomes including hospitalization, health care costs, and death in heart failure populations (10,11). Among patients with heart failure, small, moderate, and large clinical improvements correspond to changes in the KCCQ-OS of approximately 5, 10, and 20 points,

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