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Comparison of Transcatheter and Surgical Aortic Valve Replacement in Severe Aortic Stenosis

A Longitudinal Study of Echocardiography Parameters in Cohort A of the PARTNER Trial (Placement of Aortic Transcatheter Valves)

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Objectives This study sought to compare echocardiographic findings in patients with critical aortic stenosis following surgical aortic valve replacement (SAVR) or transcatheter aortic valve replacement (TAVR).

Background The PARTNER (Placement of Aortic Transcatheter Valves) trial randomized patients 1:1 to SAVR or TAVR.

Methods Echocardiograms were obtained at baseline, discharge, 30 days, 6 months, 1 year, and 2 years after the procedure and analyzed in a core laboratory. For the analysis of post-implantation variables, the first interpretable study (≤6 months) was used.

Results Both groups showed a decrease in aortic valve gradients and increase in effective orifice area (EOA) ($p < 0.0001$), which remained stable over 2 years. Compared with SAVR, TAVR resulted in larger indexed EOA ($p = 0.038$), less prosthesis-patient mismatch ($p = 0.019$), and more total and paravalvular aortic regurgitation ($p < 0.0001$). Baseline echocardiographic univariate predictors of death were lower peak transaortic gradient in TAVR patients, and low left ventricular diastolic volume, low stroke volume, and greater severity of mitral regurgitation in SAVR patients. Post-implantation echocardiographic univariate predictors of death were: larger left ventricular diastolic volume, left ventricular systolic volume and EOA, decreased ejection fraction, and greater aortic regurgitation in TAVR patients; and smaller left ventricular systolic and diastolic volumes, low stroke volume, smaller EOA, and prosthesis-patient mismatch in SAVR patients.

Conclusions Patients randomized to either SAVR or TAVR experience enduring, significant reductions in transaortic gradients and increase in EOA. Compared with SAVR, TAVR patients had higher indexed EOA, lower prosthesis-patient mismatch, and more aortic regurgitation. Univariate predictors of death for the TAVR and SAVR groups differed and might allow future refinement in patient selection. (THE PARTNER TRIAL: Placement of AoRTic TraNscathetER Valve Trial; NCT00530894) (J Am Coll Cardiol 2013;61:2514–21) © 2013 by the American College of Cardiology Foundation

Transcatheter aortic valve replacement (TAVR) has emerged as a reasonable alternative to surgical aortic valve replacement (SAVR) (1–4). The PARTNER (Placement of Aortic Transcatheter Valves) trial was the first randomized trial comparing TAVR to standard-of-care therapies in a rigorous fashion. Two-year clinical outcomes in high-risk,

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operable patients with severe aortic stenosis (PARTNER Cohort A) showed TAVR was noninferior to SAVR without significant differences in all-cause mortality or cardiovascular mortality or evidence for structural valve failure.

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Echocardiography is the recommended imaging modality for the assessment of aortic valve stenosis and prosthetic valve function (5–7) and was used for patient selection, valve sizing, and extended follow-up (1,2). In contrast to previous reports relying on site interpretations of images, the trial core laboratory provided rigorous quality control of the image acquisition and analysis process (8). The current investigation reports the complete, centrally analyzed echocardiographic findings from the high-risk, operable patient population (Cohort A).

Methods

Patient selection, study design, and management. Cohort A of the PARTNER trial (2) randomized 699 high-surgical-risk patients (mortality of ≥15%) with severe, symptomatic aortic stenosis, between SAVR and TAVR with the Edwards Sapien valve (Edwards Lifesciences, Irvine, California) (in a 1:1 ratio) (Fig. 1). All patients enrolled had site-determined, severe native tricuspid aortic stenosis defined by echocardiographically determined aortic valve area of ≤0.8 cm^2 plus either a peak velocity ≥4 m/s or a mean gradient ≥40 mm Hg at rest or during dobutamine infusion. Study design and complete inclusion and exclusion criteria are presented in a previous publication (2).

Randomization to SAVR or TAVR was stratified by feasibility of transapical or transfemoral access. Echocardiograms were obtained at baseline, and at 7 days, 30 days, 6 months, 1 year, and 2 years after the procedure.

Echocardiography core laboratory analysis. All echocardiograms were analyzed at an independent core lab that followed the American Society of Echocardiography standards for echocardiography core laboratories (9). Image acquisition quality was ensured by use of a detailed acquisition protocol, site qualification and training with quality feedback at regular intervals, and retraining of sites with unacceptable image quality. Image analysis quality was ensured by reader qualification, detailed analysis instructions, group and individual training, regular intra- and interobserver variability testing, retraining, and coaching when indicated (9). All measurements and analyses were performed without knowledge of clinical or other laboratory data including previous echocardiography results, group assignment, and timing of the assessment.

Reproducibility was determined on 649 to 1,360 pairwise comparisons among readers for each of 8 critical variables on 30 echocardiograms (total number of comparisons = 8,031). Intraclass correlation coefficients were 0.92 to 0.99 for physician over-readers and 0.89 to 0.97 for sonographers. Kappa statistics for agreement for categorical variables calculated for physician over-readers were 0.56 to 0.85.

Ventricular size and function and valvular function were measured according to previously published guidelines (6,7,10). An integrative, semiquantitative approach was used to assess the severity of valvular regurgitation. Both qualitative (visual) and quantitative (biplane Simpson method of disks) approaches were used to report ejection fraction. Relative wall thickness (RWT) was calculated as 2× posterior wall thickness/left ventricular end-diastolic dimensions (LVED) (RWTp) and also using the posterior wall thickness plus septal wall thickness as (septal wall thickness + posterior wall thickness)/LVED, or RWTm. Site-reported systolic annulus diameters were derived from long-axis views. The effective orifice area (EOA) is calculated as the Doppler stroke volume/aortic velocity time integral. The cover index was determined as (11): [prosthesis diameter − annular diameter]/prosthesis diameter. The severity of prosthesis-patient mismatch was graded using EOA indexed to body surface area (6) with absence defined as >0.85 cm^2/m^2, moderate ≥0.65 and ≤0.85 cm^2/m^2, and <0.65 cm^2/m^2.

Paravalvular regurgitation after TAVR/SAVR was graded in accordance with the ASE recommendations for native

Abbreviations and Acronyms

CI = confidence interval(s)
EOA = effective orifice area
HR = hazard ratio(s)
ITT = intention-to-treat analysis
LV = left ventricular
LVDV = left ventricular diastolic volume
LVED = left ventricular end-diastolic dimensions
LVES = left ventricular end-systolic dimensions
LVSV = left ventricular systolic volume
RWT = relative wall thickness
RWTm = relative wall thickness: the septal and posterior wall thickness
RWTp = relative wall thickness: using formula twice the posterior wall thickness
SAVR = surgical aortic valve replacement
TAVR = transcatheter aortic valve replacement

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