Hemodynamic Performance during Exercise of the New St Jude Trifecta Aortic Bioprosthesis: Results from a French Multicenter Study

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Background: Initial experience with the new St Jude Trifecta pericardial aortic stented bioprosthesis shows an excellent resting hemodynamic profile. Little is known about changes in the hemodynamic profile of the Trifecta valve during exercise.

Methods: Between February 2011 and November 2012, 85 patients (49 men; mean age, 76 ± 7 years) with severe symptomatic aortic stenosis who underwent aortic valve replacement with the Trifecta bioprosthesis at three centers in France (Amiens, Rennes, and Angers) underwent quantitative Doppler echocardiographic at rest, during low-level exercise (25 W), and during peak exercise (68 ± 21 W), 6 months after aortic valve replacement.

Results: Mean peak transvalvular aortic velocity, mean transvalvular gradient, and mean left ventricular ejection fraction for all valve sizes were 211 ± 35 cm/sec, 10 ± 3 mm Hg, and 62 ± 10% at rest; 237 ± 48 cm/sec, 13 ± 4 mm Hg, and 64 ± 10% during low-level exercise; and 248 ± 70 cm/sec, 15 ± 5 mm Hg, and 67 ± 10% during peak exercise, respectively. Mean effective orifice area was 1.84 ± 0.42 cm^2 at rest, 1.86 ± 0.84 cm^2 (P = .92) during low-level exercise, and 1.95 ± 0.62 cm^2 (P = .49) during peak exercise. The prevalence of prosthesis-patient mismatch was low in the overall series (23%) and increased to 30% for the smallest valve sizes (19 and 21 mm).

Conclusions: The new Trifecta bioprosthesis provides an excellent hemodynamic profile both at rest and during exercise. This type of valve could be an appropriate choice in patients with small aortic annular diameters, to avoid prosthesis-patient mismatch. (J Am Soc Echocardiogr 2014;■:■-■.)

Keywords: Bioprosthesis, Exercise, Echocardiography

Aortic stenosis is the most common form of acquired valvular heart disease in Western countries. Despite ongoing improvements in prosthesis performance, aortic valve replacement (AVR) still does not provide an ideal substitute for the native valve. Bioprosthetic valves are now increasingly used in aging Western populations. However, several issues remain unresolved concerning implantability, durability, and, most important, hemodynamic performance. For example, high residual transprosthetic gradients, especially in small prostheses, may lead to prosthesis-patient mismatch (PPM) associated with suboptimal clinical outcome and less regression of left ventricular (LV) hypertrophy after AVR.[1,2] In recent decades, stentless bioprostheses have provided excellent hemodynamic performances, but their surgical implantation is often more challenging. The new St Jude Trifecta pericardial supra-annular aortic valve (St Jude Medical, St Paul, MN), designed with a single pericardial sheet externally mounted on a high-strength titanium stent and a small sewing ring, is expected to provide increased effective orifice area (EOA).[3] Initial clinical experience with the Trifecta valve demonstrated promising resting hemodynamic profiles.[3,4] However, little is known about changes in the hemodynamic profile of this aortic bioprosthesis during exercise. Moreover, no data are available on the exercise capacity and Doppler hemodynamic profiles of patients with PPM. This French multicenter study was therefore designed to assess the hemodynamic performance of the novel Trifecta aortic stented bioprosthesis during standardized semisupine exercise echocardiography after AVR for aortic stenosis.

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METHODS

Study Population

Between February 2011 and September 2012, a total of 162 patients with severe symptomatic aortic stenosis (area < 1 cm^2)

Abbreviations

AVR = Aortic valve replacement

EOA = Effective orifice area

LV = Left ventricular

LVOT = Left ventricular outflow tract

PASP = Pulmonary artery systolic pressure

PPM = Prosthesis-patient mismatch

TVG = Transvalvular gradient

TVI = Time-velocity integral

underwent AVR with the new St Jude Trifecta bioprosthesis at three university hospitals in France (Amiens, Rennes, and Angers). Seventy-seven patients were not included, because of their inability or refusal to perform sufficient exercise or because of an insufficient degree of echogenicity at rest. Thus, the final study group consisted of 85 patients (49 men; mean age, 76 ± 7 years) who all underwent comprehensive resting echocardiography immediately followed by exercise echocardiography ≥6 months after AVR.

Exercise Protocol

All patients completed a bicycle exercise test in the semisupine (45°) position on a tilting exercise table. The same position was maintained throughout the examination period to minimize the influence of venous return. After an initial workload of 25 W, maintained for 3 min, the workload was increased every 2 min by 25 W.[5] Blood pressure and a 12-lead electrocardiogram were recorded every 2 min. Patients were allowed to take their usual medications, including β-blockers, on the day of exercise echocardiography.

Echocardiographic Measurements at Rest and during Exercise

Echocardiographic and Doppler data were obtained at rest, during low-level exercise (25 W), and during peak exercise and stored digitally for offline analysis. Using Doppler echocardiography from apical views during semisupine exercise test, LV outflow tract (LVOT) time-velocity integral (TVI), maximal transvalvular gradient (TVG) and velocity, and mean TVG were estimated at rest, during low-level exercise, and during peak exercise in all patients. Pulmonary artery systolic pressure (PASP) was estimated at rest and during exercise, on tricuspid regurgitation using the simplified Bernoulli equation, adding an assumed right atrial pressure of 5 mm Hg.[5] LV ejection fraction was estimated according to Simpson's rule.[6,7] Stroke volume was determined as the product of LVOT TVI and the cross-sectional area of the aortic annulus using LVOT diameter measured in a parasternal long-axis view.[8] Cardiac output was calculated as the product of stroke volume and heart rate. TVGs were calculated using the simplified Bernoulli equation.[9] EOA was calculated using the continuity equation.[10] For each Doppler measurement, three to five cycles were averaged, avoiding postextrasystolic beats, both at rest and during exercise. LVOT diameter was assumed to remain constant during exercise.

PPM

PPM was classically defined according to indexed EOA (EOAi) at rest. Severe mismatch was defined as EOAi ≤ 0.65 cm^2/m^2, moderate mismatch as EOAi ≤ 0.85 cm^2/m^2, and absence of mismatch as EOAi > 0.85 cm^2/m^2.[11]

Coronary Angiography

Preoperative coronary angiography was performed in all patients. Reduction of the normal diameter ≥ 50% was considered to define significant coronary artery stenosis in the left main coronary artery. A cutoff value of 70% diameter narrowing was used for the right coronary, left anterior descending coronary, and circumflex coronary arteries. Coronary artery disease was defined as significant stenosis in at least one vessel.

Statistical Analysis

Data for the study population and echocardiographic measurements are presented as number (percentage) or mean ± SD after testing for a normal distribution (Kolmogorov-Smirnov test). Echocardiographic measurements at rest and during exercise were compared using Student's *t* tests. Interobserver and intraobserver variability was examined for LVOT and TVI at rest and during low-level and peak exercise. Measurements were performed in a group of 10 randomly selected patients by one observer and repeated offline on 2 separate days by two independent observers who were blinded to each other's measurements and to the study time point. Data are presented as means of absolute differences and mean percentage errors between measurements and using correlation coefficients (r). P values < .05 were considered significant.

RESULTS

Clinical Characteristics of the Study Population

Preoperative clinical, echocardiographic, and angiographic data from the 85 patients of the study are presented in Table 1. Concomitant coronary artery bypass grafting was performed in 25 of 85 patients (29%): one graft in 21 patients (25%), two grafts in 2 patients (1%), and three grafts in 2 patients (1%). Mean cardiopulmonary bypass time was 61 ± 22 min, and mean aortic cross-clamp time was 40 ± 12 min. The mean prosthesis size was 22 ± 2 mm, and 21-mm and 23-mm diameter valves were predominantly implanted (42% and 36%, respectively; Figure 1). None of the patients had any valve-related postoperative complications.

Echocardiographic Results at Rest

In the overall population, mean TVG, EOA, and EOAi at rest were 10 ± 3 mm Hg, 1.84 ± 0.42 cm^2, and 1.01 ± 0.21 cm^2/m^2, respectively. Complete resting hemodynamic results are presented by prosthesis size in Tables 2 and 3. In our series, 22% of the patients (19 of 85) had low-flow states at rest, defined as a stroke volume index < 35 mL/m^2. In this subgroup of patients, EOAs were significantly lower than in patients with stroke volume indices ≥ 35 mL/m^2 (1.61 ± 0.47 and 1.91 ± 0.41 cm^2, respectively, P = .004). All patients had mean TVGs < 20 mm Hg at rest, and 53% (45 of 85) had mean TVGs ≤ 10 mm Hg. Five patients (6%) had mild paravalvular leaks, and no patients had moderate or severe paravalvular leaks. The mean LV ejection fraction was 62 ± 11%, the mean E/e′ ratio was 12 ± 6, and the mean resting PASP was 27 ± 10 mm Hg.

Echocardiographic Results during Exercise

Hemodynamic data during exercise are presented by valve size in Tables 2 to 4 and Figure 2. Maximal exercise capacity was 71 ± 27 W (range, 25–150 W). No subjects had exercise-induced myocardial ischemia or significant mitral regurgitation. Heart rate, systolic blood pressure, diastolic blood pressure, tricuspid regurgitation velocity, LV ejection fraction, and cardiac output increased with increasing