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Trifecta Aortic Valve Replacement in Elderly and Polymorbid Patients: Clinical and Echocardiographic Follow-Up

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ABSTRACT

Objectives: We sought to evaluate the hemodynamic performance and clinical outcome of the St. Jude Medical Trifecta aortic bioprosthesis in a large single-center series of consecutive polymorbid, moderate-to-high surgical risk elderly patients.

Methods: Between January 2014 and January 2015, 250 consecutive patients undergoing aortic valve replacement at Careggi University Hospital, Florence, received a Trifecta aortic bioprosthesis. 202 patients (46.4% females, mean age 79.9±4 years) were enrolled in the present follow up study. Clinical and echocardiographic data were collected preoperatively and at one year after surgery.

Results: the most prevalent indication for aortic valve replacement was stenosis (51.5%), followed by mixed pathology (29.7%), regurgitation (14.4%), prosthetic valve degeneration (3.5%) and endocarditis (1%). Preoperative functional class was NYHA III in 67.8% and NYHA IV in 12.4 %; logistic EuroSCORE was moderately high (13.5±6.4). Most patients (73%) underwent concomitant surgical procedures. Global mortality was 9.6% (24 patients), early mortality being 1.6% (4 patients). Adverse events included five thromboembolic events and four prosthetic valve endocarditis; early prosthetic valve degeneration occurred in one. At one-year follow-up, mean gradients ranged from 6.0±2.7 and 12.1±8.6 for the 27 and 19 mm valve, respectively. Indexed effective prosthesis area ranged from 0.73 to 1.16 cm2/m2 for the 19 and 25 mm valve, respectively.

Conclusion: St. Jude Medical Trifecta aortic bioprosthesis confirmed excellent hemodynamic profile and achieved good clinical results when offered to elderly patients with high incidence of co-morbidities and moderately high preoperative risk, who underwent concomitant surgical procedures in high percentage of cases.

KEYWORDS

Aortic Valve Replacement; Aortic Bioprosthesis; Doppler Echocardiography; Octuagenarians; Polymorbidity.

INTRODUCTION

The Trifecta aortic valve (St. Jude Medical, Inc., St. Paul, MN, USA) is a third-generation three-leaflet stented bioprosthesis consisting of bovine pericardium tissue leaflets mounted on a titanium stent covered with swine pericardium, and is specifically designed for the supra-annular aortic position [1]. Since its arrival on the market in April 2011, several studies on the hemodynamic performance and durability of this device have yielded promising results, showing overall optimal trans-prosthetic gradients and low percentages of severe patient-prosthesis mismatch, even in subjects with a small aortic annulus in relation to body size [2]. Other studies have demonstrated that its near-physiologic, hemodynamic profile is superior to that of some of its principal competitors [3-8]. However, the studies conducted so far have often been relatively small and

have had a limited period of follow-up; moreover, the populations analysed have been quite heterogeneous in terms of age and indication for aortic valve replacement.

The present study sought to analyse the hemodynamic performance of the St. Jude Trifecta aortic bioprosthesis in a population of polymorbid, moderate- to high-risk, octogenarian patients, mainly suffering from severe aortic valve stenosis.

MATERIALS AND METHODS

Patient selection

Between January 2014 and January 2015, 250 consecutive patients underwent aortic valve replacement with the St. Jude Trifecta aortic bioprosthesis at Careggi University Hospital, Florence. Patients submitted to multiple combined surgical procedures were not excluded from the study. Written informed consent was obtained from all patients and institutional review board approval was granted by the local ethics committee.

Surgical technique

All patients underwent midline sternotomy and cardiopulmonary bypass; myocardial protection was implemented through moderate hypothermia and cardioplegic arrest. After aortic annulus decalcification, the appropriate prosthesis size was determined by the surgeon with the specific manufacturer-supplied replica sizer. Prostheses were implanted by means of three linear sutures. Immediately after weaning from cardiopulmonary bypass, correct bioprosthetic positioning and function were checked by trans-oesophageal echocardiography. None of the patients required an aortic root enlargement procedure.

Patient follow-up

Upon hospital discharge, each patient was scheduled for a one-year follow-up visit, consisting of clinical examination, ECG and a thorough echocardiographic exam. Of the 226 surviving patients, a total of 202 attended the follow-up visit and were enrolled in the present study. Deceased patients' medical records were obtained from the patients' relatives or from their general practitioners. Standardized definitions from the Society of Thoracic Surgeons/American Association for Thoracic Surgery, specified in the ''Guidelines for Reporting Morbidity and Mortality and Cardiac Valvular Operations'' [9], were used to classify adverse events. Early events were defined as those occurring within 30 days of surgery, medium-term events were defined as those occurring between 30 days and 6 months after surgery, while late events were classified as those occurring between 6 months and one year after prosthesis implantation.

Echocardiographic examination

Preoperative and one-year postoperative data from bi-dimensional and Doppler transthoracic echocardiographic examinations (EPIQ, X5-1 transducer, Philips Healthcare, Andover, Massachusetts) of all the patients enrolled in the study were acquired in a single core laboratory and stored in an ad hoc database. Standard prosthetic valve measurements were collected according to the American Society of Echocardiography (ASE) guidelines [10]. Each measure was repeated three times and averaged. Peak and mean systolic gradients were obtained automatically through the modified Bernoulli equation, by integrating the continuous-wave Doppler spectral envelope of flow, sampled where the transducer position could yield maximum velocity across the aortic valve or bioprosthesis. Effective orifice area (EOA) was calculated as (CSA_{LVOT} x TVI_{LVOT})/TVI_{AO}, where CSA_{LVOT} represents the cross-sectional area of the left ventricular outflow tract (LVOT), while TVI_{LVOT} and TVI_{AO} represent the time-velocity integrals (TVI) derived from the pulsed-wave Doppler of LVOT and the continuous-wave Doppler of the aortic valve/prosthesis, respectively. Finally, mild-to-moderate patient-prosthesis mismatch (PPM) was defined as any value of EOAi (EOA indexed by patient's body surface area) between 0.85 cm^2/m^2 and 0.65 cm^2/m^2, while severe PPM was defined as any EOAi value below 0.65 cm^2/m^2 [11-13]. Left ventricular mass (LVM) was indexed by body surface area (BSA), calculated by means of the Dubois and Dubois formula [14].

Statistical analysis of data

Statistical analysis was carried out by means of SPSS, release 22.0 for Windows (IBM SPSS, Inc., Chicago, IL, USA). All data are presented as mean ± standard deviation or as percentages (continuous and categorical variables, respectively). The Kolmogorov–Smirnoff test was used to verify the normality of data distribution. Student's paired t-test was used to compare continuous variables. Dichotomous variables were compared by means of Fisher's exact test or χ^2, as appropriate. Gender differences were analysed by using two-way analysis of variance. $P < 0.05$ was considered statistically significant.

RESULTS

Patients' and operative data

The mean age of the 202 enrolled patients at the moment of implantation was 79.9 ± 4 years (range 65-89 years); 188 (93%) patients were 75 years old or older, and 116 (46.4%) were females. Preoperatively, the majority of patients were in NYHA functional class III or IV; no patient was in NYHA I class. Preoperative risk, as assessed by means of the logistic EuroSCORE, was moderately high (13.5 ± 6.4). Indications for aortic

valve replacement were: aortic valve stenosis in 104 (51.5%) patients, aortic valve regurgitation in 29 (14.4%), and mixed valve pathology in 60 (29.7%). Seven (3.5%) patients underwent aortic valve replacement because of previous prosthetic aortic valve degeneration, and 2 (1%) because of aortic prosthetic valve endocarditis. A total of 12 (5.9%) patients had previously undergone aortic valve replacement. Degenerative calcific stenosis of a three-leaflet valve was present in 164 (81.1%) patients, while a rheumatic aetiology was reported in only 2 (1%) cases. Aortic bicuspidy was observed in 2 (1%) patients. Preoperative baseline characteristics are summarized in Table 1.

Table 1: Preoperative baseline characteristics.

Variables	All implants (N = 202)
Age, years	79.98 ± 4.07
Female sex	116 (46.4%)
Weight, kg	70.82 ± 12.61
Height, cm	165.2 ± 8.59
BSA (Dubois), m2	1.77 ± 0.18
BMI, kg/m2	25.86 ± 3.86
eGFR (Cocroft-Gault), mL/min	59.87 ± 20.37
eGFR (MDRD), mL/min	73.15 ± 14.47
eGFR (CKD-EPI), mL/min	64.81 ± 12.82
Serum creatinine, mg/dL	0.99 ± 0.39
Clinical History	
Known CAD	42 (20.79%)
Hypertension	154 (76.2%)
Dyslipidaemia	72 (35.6%)
Diabetes	40 (19.8%)
Smoking	71 (35%)
Family history of CAD	33 (16.3%)
Mean left ventricular ejection fraction	57.4 ± 10.6
Low left ventricular ejection fraction (<45%)	21 (10.4%)
Aortic bicuspidy	2 (0.9%)
Carotid artery disease	28 (13.8%)
Aortic valve replacement indication	
Aortic stenosis (pure)	104 (51.5 %)
Aortic mixed valve pathology (prevalent stenosis)	60 (29.7%)
Aortic regurgitation (prevalent regurgitation)	29 (14.4%)
Previous prosthesis degeneration	7 (3.5%)
Prosthesis endocarditis	2 (1%)
Predominant heart rhythm	
Sinus rhythm	162 (80.2%)
Atrial fibrillation	27 (13.3%)
Pacemaker	13 (6.4%)
Preoperative NYHA class	
I	0
II	40 (19.8%)
III	137 (67.8%)
IV	25 (12.4%)
Logistic EuroSCORE	13.53 ± 6.40

Values are expressed as mean ± standard deviation or numbers (%).

Table 2 shows a list of surgical procedures performed concurrently with aortic valve replacement with the Trifecta bioprosthetic aortic valve in 146 patients (72.3%).

Implanted prostheses ranged in size from 19 mm to 27 mm; no patient received a prosthesis with a nominal size of 29 mm. Figure 1 shows the size distribution of the Trifecta aortic valves implanted, on follow-up examination.

Table 2: Surgical procedures concomitant with aortic valve replacement with Trifecta bioprosthetic valve and adverse events.

Procedures	All implants (N = 202)
CABG	92 (45%)
Mitral valvuloplasty	21 (10.4%)
Mitral valve replacement	24 (11.9%)
Tricuspid valvuloplasty	25 (12.4%)
MAZE	22 (10.9%)
Morrow's Myectomy	5 (2.5%)
Ascending aorta repair/replacement	16 (7.9%)
Adverse events	
Endocarditis	4 (1.98%)
Prosthetic valve detachment (perivalvular abscess)	2 (0.99%)
Subacute endocarditis	2 (0.99%)
Irreversible advanced or complete atrioventricular heart block	15 (7.42%)
Thromboembolic events	5 (2.47%)
TIA	4 (1.98%)
Ischaemic stroke	1 (0.49%)
Haemorrhagic stroke	0
Prosthetic valve regurgitation/perivalvular leaks	
Absent	193 (95.5%)
Mild degree	8 (3.9%)
Moderate degree	1 (0.5%)
Severe degree	0
Re-hospitalization for congestive heart failure	6 (2.97%)
Mortality	
Overall mortality	24 (9.6 %)
Early (within 30 days of implantation)	4 (1.6 %)

Medium-term (between 30 days and 6 months after AVR)	14 (6.9 %)
Late (between 6 and 12 months after AVR)	6 (2.9 %)
Cause of death	
Acute heart failure	10 (4.9%)
Ischaemic stroke	4 (1.6%)
Septic shock	1 (0.5%)
Neoplasia	1 (0.5%)
Sudden death	8 (3.2%)

Values are expressed as mean ± standard deviation or numbers (%).

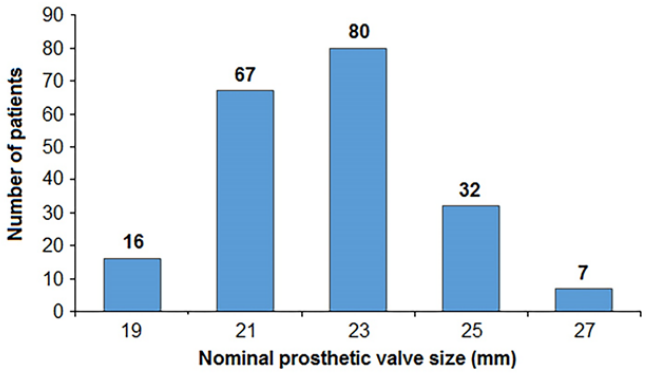

Figure 1: Size distribution of Trifecta valves implanted, on follow-up examination. N = 202.

CLINICAL EVENTS

A total of 24 (9.6%) patients died. Early mortality occurred in 4 (1.6%) patients. In the immediate postoperative period, 5 (2.47%) patients suffered thromboembolic events: 4 (1%) transient ischemic attacks (TIA) and 1 (0.49%) ischemic stroke; none of these patients had a previous known history of atrial fibrillation. Two (1%) patients underwent postoperative thoracic revision for sternal wound dehiscence. No major bleeding occurred in the postoperative period or during follow-up. There were 4 (1.9%) cases of prosthetic valve endocarditis. Two (1%) patients suffered early prosthetic valve detachment and root abscesses, and needed immediate re-operation. Another 2 (1%) adverse events were incidentally detected during the scheduled one-year follow-up echocardiographic examination; these took the form of subacute endocarditis with sessile vegetation protruding into the prosthesis orifice: after careful re-evaluation by means of trans-esophageal echocardiography, an indication for re-operation was established in both cases. Freedom from prosthetic valve endocarditis was 98% at one year. There were no cases of prosthetic valve thrombosis or significant hemolysis. A *de novo*, irreversible, advanced or complete atrio-ventricular heart block needing permanent ventricular pacing occurred in 15 (6%) patients. A total of 6 (2.9%) patients underwent re-hospitalization for congestive heart failure during the follow-up period (Table 2).

Clinical and functional evaluation

At the one-year follow-up examination, all patients displayed good adherence to optimal medical therapy (Table 3). Arterial blood pressure control was generally satisfactory (143±20/71±10 mmHg). Fifty-four (26.7%) patients were in NYHA functional class I, 117 (57.9%) were in NYHA II and 31 (15.3%) in NYHA III. No patient was in NYHA functional class IV. As already stated, only 6 (2.9%) patients in NYHA III underwent re-hospitalization for an episode of decompensation. The distributions of patients' pre-operative and follow-up NYHA functional classes are shown in Figure 2.

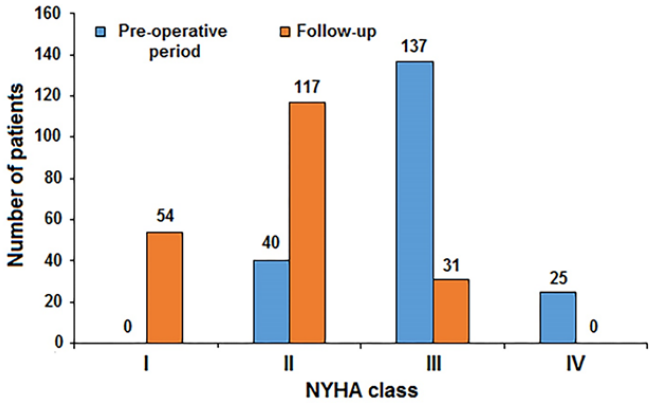

Figure 2: Distribution of NYHA classes before surgery and on follow-up examination. N = 202.

Table 3: Patients' therapy.

Medications	All implants (N = 202)
Beta-blockers	141 (69.8%)
ACE-inhibitors	118 (58.48%)
Sartans	7 (3.5%)
Diuretics	183 (90.6%)
Ca-agonists	12 (5.9%)
Digoxin	19 (9.4%)
ASA	143 (70.8%
Statins	122 (60.4%)
Amiodarone	66 (32.7%)

Values are expressed as mean ± standard deviation or numbers (%).

HAEMODYNAMIC RESULTS

Haemodynamic results on one-year follow-up examination are reported in Table 4 and in Figure 3. Peak gradients ranged from 8.14 mmHg for the 27 mm valve to 16 mmHg for the 19 mm valve, while mean gradients ranged from 6 mmHg for the 27 mm valve to 12.06 mmHg for the 19 mm valve. Average EOA ranged from 1.18 cm2 for the 19 mm valve to 2.16 cm^2 for the 27 mm valve, while EOAi ranged from 0.73 cm^2/m^2 for the 19 mm size to 1.16 cm^2/m^2 for 25 mm size. Mild-to-moderate PPM was present in 59 (29.2%) patients, while severe PPM

occurred in 21 (10.4%) patients. In the early post-operative period and on hospital discharge, no case of moderate or severe prosthetic valve regurgitation/peri-valvular leak was observed. On one-year follow-up examination, 95.5% of patients had no valvular regurgitation or peri-valvular leaks; only 1 (0.5%) case of moderate valve regurgitation was recorded; in this case, early signs of prosthetic aortic valve degeneration were detected (thickening of one of the cusps) (Table 2, Figure 4). On one-year follow-up examination, average LVEF was 58.3% ± 9.1%. A low LVEF< 45% was present in 16 (7.9%) patients. Left ventricular diastolic dysfunction, defined according to the latest definition by the ASE [15], was observed in 57.6% of patients and did not differ significantly between the two genders (females = 63.3%, males = 50.6%, *p* = ns), though a more severe degree of dysfunction was present in females. Mean left ventricular mass index (LVMi) decreased from 155.41 ± 38.95 g/m^2, pre-operatively, to 114.78 ± 28.83 g/m^2 one-year follow-up examination (paired t-test, p < 0.001), with no differences between genders (*p* = ns). Complete left ventricular hypertrophy (LVH) regression, which occurred in 57.9% of patients, was also substantially similar in both sexes (*p* = ns).

Table 4: Haemodynamic characteristics of implanted prosthesis, N =202.

Variables	Nominal size of prosthesis				
	19	**21**	**23**	**25**	**27**
Number of prosthesis	16	67	80	32	7
Peak gradient, mmHg	16.00±7.68	13.09±6.17	12.54±5.55	12.44±4.87	8.14±2.04
Mean gradient, mmHg	12.06±8.61	10.87±6.39	8.9±5.11	8.22±3.73	6.00±2.71
EOA, cm2	1.18±0.38	1.59±0.32	1.79±0.47	2.16±0.59	2.16±0.56
EOAi, cm2/m2	0.73±0.23	0.94±0.31	1.00±0.29	1.16±0.37	1.09±0.26
PPM					
> 0.85 cm2/m2	2 (0.9%)	37 (18.3%)	50 (24.7%)	27 (13.4%)	6 (2.9%)
< 0.85 >0.65 cm2/m2	8 (3.6%)	20 (9.9%)	25 (12.3%)	5 (2.5%)	1 (0.5%)
< 0.65 cm2/m2	6 (2.9%)	10 (4.9%)	5 (2.5%)	0	0

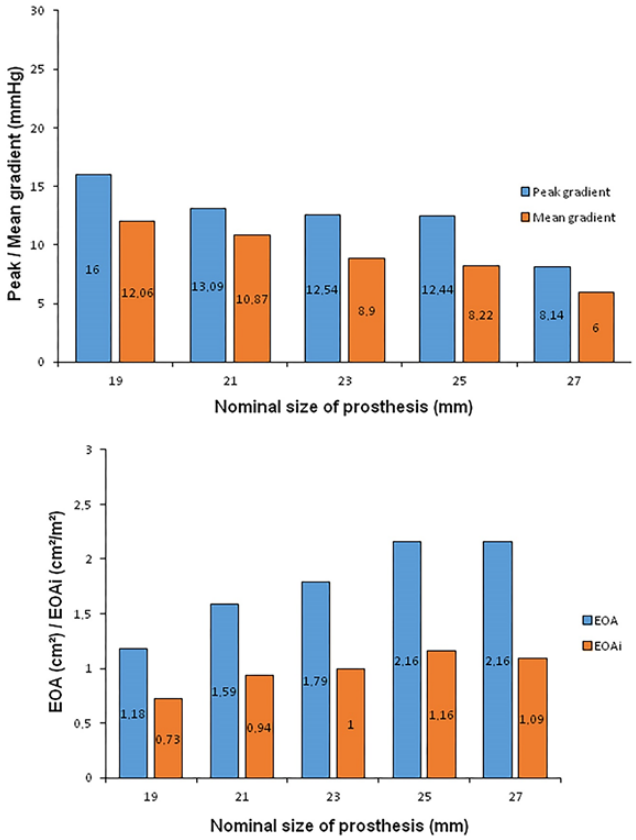

Figure 3: Top: distribution of average Peak and Mean gradients of implanted Trifecta valves by size, on follow-up examination. **Bottom:** Distribution of average EOA and EOAi of implanted Trifecta valves by size, on follow-up examination. N = 202.

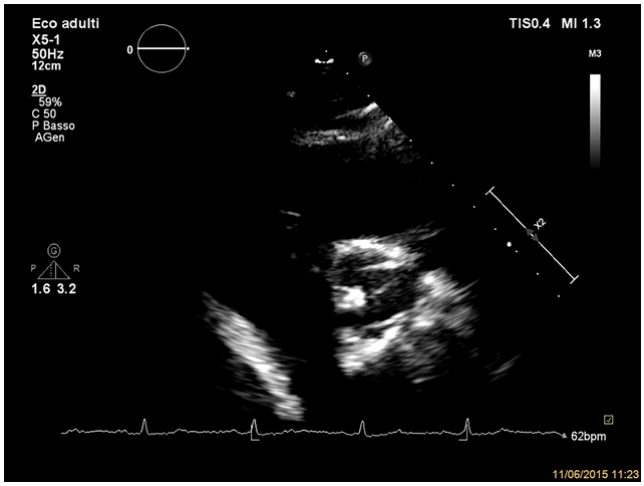

Figure 4: Short-axis parasternal view of Trifecta valve showing the thickening of cusps.

DISCUSSION

The results of the present prospective study confirm the optimal haemodynamic profile of the Trifecta aortic bio-prosthesis, first described in the pilot study by Bavaria and Colleagues [1]. Very low trans-valvular gradients and larger EOAs endow this valve with one of the highest performance levels among currently available pericardial bio-prostheses [3-8]. These features have also been observed in patients with small annuli, relative to body size [2], in whom haemodynamic results have

even proved to be comparable to those of stentless bio-prostheses[16].

While several studies have tested the haemodynamic performance of the Trifecta aortic valve and evaluated its durability over variable periods of follow-up [17], very few have reported haemodynamic data collected after one year or longer [1,18,19]; our follow-up data are consistent with their results. The considerable reduction in LVMi and the complete LVH regression attained in more than half of the patient population confirm the excellent haemodynamics of this prosthesis. Our data assume even greater importance if we consider the advanced age, higher number of comorbidities, higher average preoperative risk and elevated number of concomitant procedures of the patients enrolled in the present study.

To our knowledge, our population is the oldest one ever to undergo aortic valve replacement with the Trifecta aortic bioprosthesis. Our patients had more comorbidities and relatively higher preoperative risk profiles: nevertheless, mortality was comparable to that expected in a healthy population within the same age-group. Severe PPM, which has been demonstrated to negatively affect patient prognosis [18-21], had a low incidence, occurring in only 21 (10.4%) patients; these were mainly women with little body surface area and small aortic annuli. Diastolic dysfunction, although present in more than half of the population, did not affect the global clinical outcome of patients, probably because of the reported good adherence to optimal medical therapy.

Study limitations

Our study reflects the annual experience of a single primary center. While the fact that all procedures were carried out by the same surgical team using standard surgical techniques could be an advantage in reducing confounders, the limited size of our population could constitute a limitation to the study. Moreover, although we could document good valve durability on one-year follow-up examination, with only one case of early deterioration, early post-operative and discharge data were not available for comparison, making it impossible to evaluate the temporal trend in the performance of the prosthesis.

CONCLUSION

The current study confirmed the already known optimal haemodynamic profile of the Trifecta aortic bio-prosthesis and demonstrated its good durability on one-year follow-up examination in a population of polymorbid, moderate- to high-risk octogenarian patients undergoing AVR and multiple concomitant surgical procedures.

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