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BOLOGNA EARLY-EXPERIENCE WITH THE TRIFECTA PERICARDIAL AORTIC VALVE PROSTHESIS



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Background

The aim of the study was to determine the early postoperative performance and hemodynamic results of the new-generation Trifecta pericardial aortic valve bio-prosthesis (St Jude Medical Inc, St Paul, Minn).



Baseline characteristics	
Age (years, mean ± SD)	76.5± 6.7
Sex male (%)	36 (51.4%)
BSA	1.75± 0.2
Hypertension (%)	59 (84.3%)
COPD	5 (7.14%)
Diabetes (%)	7 (10%)
PAD (%)	9 (12.86%)
Stroke (%)	7 (10%)
NYHA III/IV	39 (55.71%)
Valve Pathology:	
• Stenosis	54 (77.14%)
• Regurgitation	4 (5.71%)
• Mixed lesion	12 (17.14%)
History of AF	8 (11.4%)
Hb (g/dL)	12.7± 1.21
EF %	61.4± 6.7
Maximum aortic gradient (mmHg)	45.9± 16.1

Methods

Between June 2011 and May 2014, we retrospectively reviewed 83 consecutive patients (mean age 76,7 ± 6,51 years) who underwent aortic valve replacement with the Trifecta bio-prosthesis in our institution. Early postoperative hemodynamic performance with Doppler echocardiography at discharge and six months after surgery, were evaluated. At follow-up (mean 6 months) clinical outcomes, freedom from complications and prosthesis performance were also investigated.

Results

Surgical indications were mostly represented by aortic valve stenosis in 64 patients (77,1%), followed by mixed lesions in 12 (14.4%) and aortic insufficiency in 8 (9.6%), respectively. Mean additive EUROscore was 6,95. Associate procedures were performed in 31 patients (37.3%). Preoperative EF was 61,4%, with maximum and mean transvalvular gradient of 74.7 mmHg and 47.01 mmHg, respectively. The highest number of subjects received a 21 mm prosthesis (35 patients, 42.1%) and a 23 mm prosthesis (31 patients, 37.3%). In-hospital mortality was 2,4% (2 patients). At discharge EF was 63.3% and the mean and peak transvalvular gradient was 9,6 mmHg and 18.3 mmHg, respectively. Two months after surgery, 1 patient required reintervention because of severe regurgitation due to structural prosthesis deterioration. At six months follow-up, mortality was 3.6% (3 patients, not cardiac related). Valve area and indexed effective orifice area were 1,74 ± 0,4 cmq and 0,73±0,12 cmq/mq respectively. Mean transvalvular gradient was 9,94 ± 3,5 mmHg. Similar statistical significance was found when data were stratified by valve size. Severe prosthesis-patient mismatch was not detected.

Clinical Outcomes	
In-hospital mortality	2 (2,8%)
Reoperation for bleeding	3 (4.28%)
Perioperative IAO	1 (1,42%)
Post-operative AF	19 (27.14%)
Mean transvalvular gradient (mmHg)	9,1 ± 2,4
Maximum transvalvular gradient (mmHg)	17,19 ± 4,69
Valve area (cmq)	1,81 ± 0.34
Valve area index (cmq/mq)	0,98± 0,18
Intraprothesis regurgitation	1(1,42%)
Paravalvular leak	0
EF % at discharge	62.43± 6.45

Early Echocardiographic Follow-up (six months)	
Follow-up mortality	3 (4,28%)
Mean transvalvular gradient (mmHg)	9,94 ±3,5
Maximum transvalvular gradient (mmHg)	18,01 ± 6,67
Valve area (cmq)	1,74 ± 0.4
Valve area index (cmq/mq)	0,73±0,12
Intraprothesis regurgitation	2 (2,8%)
Paravalvular leak	0
EF %	59.96 ±5.56
Reoperation	1(1,42%)
Endocarditis	0

Conclusions

Early hemodynamic performance and clinical outcomes of the Trifecta bio-prosthesis appear favorable. Additional and longer follow-up is required to have a more complete profile of this prosthesis and to confirm this encouraging clinical outcome.