

Late Clinical and Echocardiographic Results with the Magna Ease[®] Pericardial Aortic Bioprosthesis



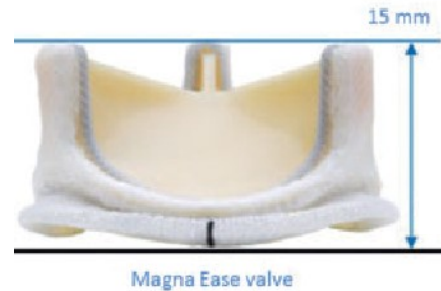
Background / Study Objective

- The introduction of the Perimount Magna Ease[®] bioprosthesis for SAVR (Surgical Aortic Valve Replacement) is relatively recent.
- The current practice is characterized by decreasing average age of candidates to SAVR, thus expanding the importance of late results of bioprostheses.
- We aimed at evaluating the long-term durability and clinical performance of the Perimount Magna Ease[®] bioprosthesis in a large (N=1,017) series with the longest (8.9 yrs median duration among survivors) follow-up so far.



Patients

- All-comers SAVR recipients with the Magna Ease[®] bioprosthesis (2008-2014)



Characteristics: baseline

Age (years)	73.4±9.5
Age <70 years	23.8%
Chronic renal failure	4.4%
Hemodialysis	0.7%
Non-elective	4.9%
Previous cardiac surgery	3.4%
Severe aortic stenosis	59.6%
Severe aortic regurgitation	14.4%
Mixed stenosis and regurgitation	26%
LVEF (%)	60.5±11.2

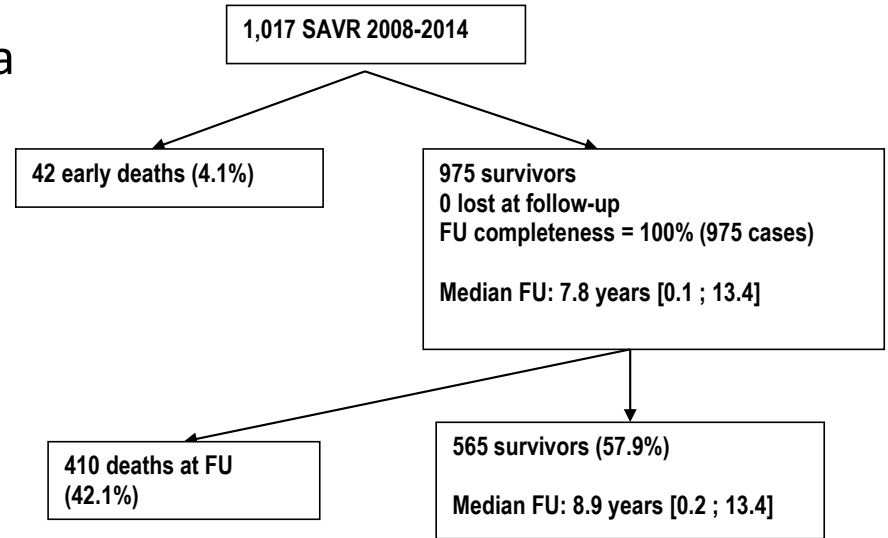
Characteristics: Intraoperative

<u>Associated cardiac procedure</u>	<u>31.1%</u>
- CABG	- 23.1%
- Other valve	- 5.7%
- Thoracic aorta	- 4.9%
- Other	- 2.5%
CPB time (min)	75±36.7
Aortic clamp time (min)	59.9±30.3



Methods

- Single-center investigation
- Prospective collection of in-hospital data
- Systematic follow-up (clinical and echocardiography data)
- Definition of valve-related events: VARC-2
- Time-to-event analyses: Kaplan-Meier and competing risks
- 4.1% early mortality, 975 patients entering follow-up
- No patients lost at follow-up



Results 1

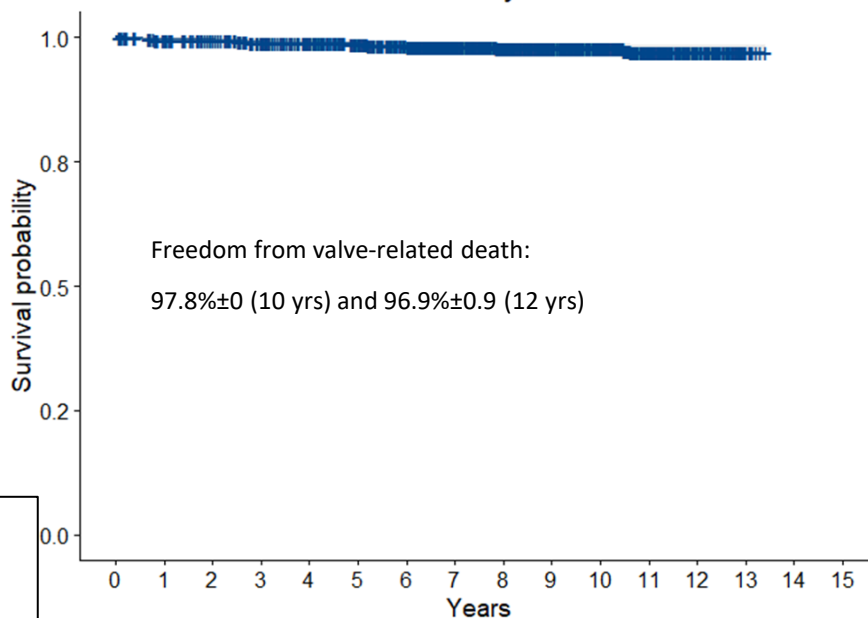
Echocardiography results at discharge

Mean transprosthetic gradient (mmHg)	14±5
Peak transprosthetic gradient (mmHg)	25.7±8.8
EOA (cm ²)	1.67±0.4
<u>Patient/prosthesis Mismatch</u>	
- None (iEOA>0.85 cm ² /m ²)	64.2%
- Moderate (iEOA≤0.85 cm ² /m ²)	29.8%
- Severe (iEOA≤0.65 cm ² /m ²)	6%

FOLLOW-UP RESULTS

- Overall survival: 56.8%±1.8 (10 yrs) and 43.2%±2.3 (12 yrs)
- NYHA I or II: 92.1%
- 20 valve-related deaths
- 28 SVD (Structural Valve Deterioration) after 6.9 yrs ± 3.3
- 10 NSVD (Nonstructural Valve Dysfunction) after 3.4 yrs ± 3.4
- 30 IE (Prosthetic endocarditis) after 3.5 yrs ± 2.8
- 31 Valve-related reinterventions after 4.8 yrs ± 2.9

Valve-Related Survival after 30 days



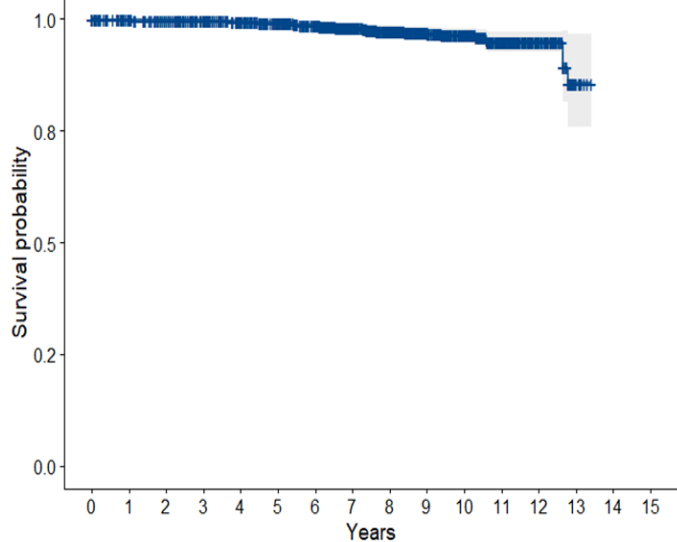
Number at risk

All 975 945 920 884 845 793 725 580 458 359 256 157 75 10 0 0



Results 2

Freedom from SVD (Structural Valve Deterioration)



Number at risk

All 975 939 912 875 836 787 719 574 454 354 252 153 75 10 0 0

	SVD N(%)	TOTAL	Freedom from SVD actuarial and actual (competing risks)				
			5 y	10 y	12 y	13 y	15 y
Pericardial	28 (3.0)	975	99.2±0.3 99.3±0.3	96.3±0.8 97.2±0.6	94.9±1.1 96.5±0.7	85.6±5.2 92.9±2.1	–

N, Number of events; y, years; n, number at risk; SVD, Structural Valvular Deterioration

	Reintervention for SVD N (%)	TOTAL	Freedom from reintervention after day 30 for SVD (actuarial)				
			5 y	10 y	12 y	13 y	
Pericardial	15 (1.5)	975	99.4±0.3 n=789	97.8±0.6 n=255	97.8±0.6 n=75	93.9±3.9 n=10	–

N, Number of events; y, years; SVD, Structural Valvular Deterioration

Echocardiography results at last follow-up

Mean transprosthetic gradient (mmHg)	14.4±7.5
Peak transprosthetic gradient (mmHg)	24.7±10.6
EOA (cm ²)	1.46±0.42
Aortic regurgitation 3 or 4 / 4	0.4%



Conclusion

- The Perimount Magna Ease[®] bioprosthesis in the aortic position shows good durability in the long-term follow-up (10 and 12 years after implantation) (2.9% rate of Structural Valve Deterioration).
- The hemodynamic characteristics are optimal, and are maintained over follow-up.
- The occurrence of valve-related adverse events (NSVD, IE, valve-related death) is generally limited.
- Further evaluation with longer follow-up intervals is required, as bioprostheses are extensively employed in patients with life expectancy higher than 12 years.

