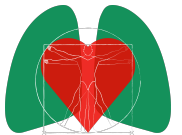


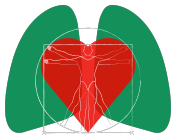
- 000262

5-years hemodynamic performance of three aortic bioprostheses. A randomized clinical trial



Background / Study Objective

- Aortic valve replacement is one of the most frequently performed cardiac surgical procedures.
- Carpentier Perimount Magna Ease™, Crown PRT™, and Trifecta™ bovine pericardial valves have been widely used worldwide.
- Nevertheless, there are few studies properly designed to compare the hemodynamic performance of these three bioprostheses.



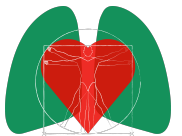
Patients

- “BEST-VALVE” (Comparison of three contemporary cardiac **bioprosthesis**: mid-term **valve** hemodynamic performance) was a single-center randomized phase IV clinical trial, with observer-blind analysis, prospective and longitudinal, comparing three bovine pericardial aortic bioprostheses: Carpentier Perimount Magna Ease™, Crown PRT™, and Trifecta™.
- The study enrolled consecutive patients undergoing AVR candidates for aortic bioprosthesis between 2014 and 2017 at a single institution.
- Patients were randomly assigned to receive any of the 3 prostheses (1:1:1). There was no cross-overs nor drop outs.



Methods

- The primary endpoint was to compare the hemodynamic performance (mean and peak aortic gradients, peak aortic velocity and effective orifice area) quantified by *in-vivo* echocardiogram of three biological aortic prostheses.
- We used using a two-tailed Wilcoxon rank-sum test, at a 0.05 alpha level.
- This analysis accommodated nonignorable missing outcomes owing to the death of patients by assigning deceased patients the worst ranks in order on the basis of the time of death.



Results 1 • N=154. CP ME™ n=48, Crown PRT™ n=51, Trifecta™ n=55.

ECHOCARDIOGRAPHIC FINDINGS 5-YEARS AFTER SURGERY

	Magna Ease™ (n=43)	Crown PRT™ (n=47)	Trifecta™ (n=52)	Global (N=142)	p-value	P-value*		
						Crown vs. Magna Ease	Trifecta vs. Magna Ease	Trifecta vs. Crown
Peak aortic gradient (mmHg)	23.6 (IQR 15.4 – 31.1)	30 (IQR 18.6 – 57)	30.8 (IQR 17 – 86)	26.6 (IQR 17.7 – 42)	0.016	0.018	0.010	0.436
Mean aortic gradient (mmHg)	12.3 (IQR 7.8 – 17.5)	15 (IQR 10.8 – 31.9)	14.7 (IQR 8.2 – 55)	13.9 (IQR 8.9 – 27)	0.044	0.016	0.067	0.485
Peak aortic velocity (cm/s)	239.5 (IQR 196.2 – 287.7)	266.3 (IQR 214 – 551.1)	245.7 (IQR 198.3 – 460)	243.4 (IQR 202 – 399.6)	0.039	0.025	0.045	0.288
Effective orifice area (cm ²)	1.3 (IQR 1.1 – 1.7)	0.68 (IQR 0.7 – 1.6)	0.5 (IQR 0.5 – 1.2)	1.1 (IQR 0.7 – 1.5)	0.001	0.030	0.001	0.023

*Wilcoxon Rank Sum adjusted by Bonferroni

FACTORS ASSOCIATED TO 5 YEARS GRADIENTS (LINEAR MIXED MODEL)

Covariate	Coef (95% Confidence Interval)	p Value
Mean aortic gradient pre-surgery (mmHg)	0.06 (- 0.57 – 0.18)	0.307
Mean aortic gradient 1 month after surgery (mmHg)	- 0.16 (- 0.58 – 0.25)	0.447
Mean aortic gradient 1 year after surgery (mmHg)	0.72 (0.34 – 1.10)	0.001

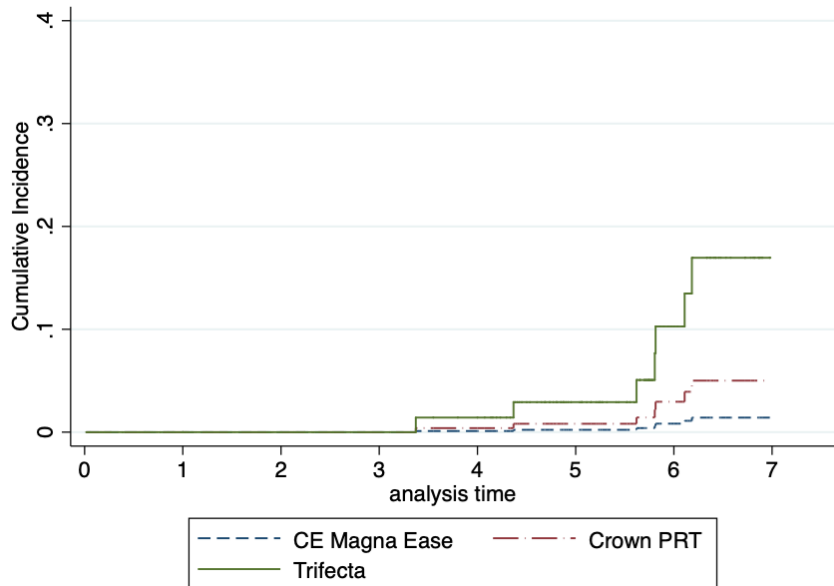
SERIOUS ADVENT EVENTS AT 5 YEARS.

	Magna Ease™ (n=48)	Crown PRT™ (n=51)	Trifecta™ (n=55)	Global (N=154)	P
Myocardial infarction	0 (0.00%)	5 (9.8%)	5 (9.1%)	10 (6.5%)	0.088
Cerebrovascular event	5 (10.4%)	4 (7.8%)	4 (7.3%)	13 (8.4%)	0.834
Thromboembolic complications	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	-
Structural valve deterioration (VARC-II definition)	0 (0.00%)	2 (3.9%)	6 (10.9%)	8 (5.2%)	0.040
Endocarditis	4 (8.3%)	4 (7.8%)	5 (9.1%)	13 (8.4%)	0.973
Reintervention	1 (2.1%)	3 (5.9%)	5 (9.1%)	9 (5.8%)	0.319

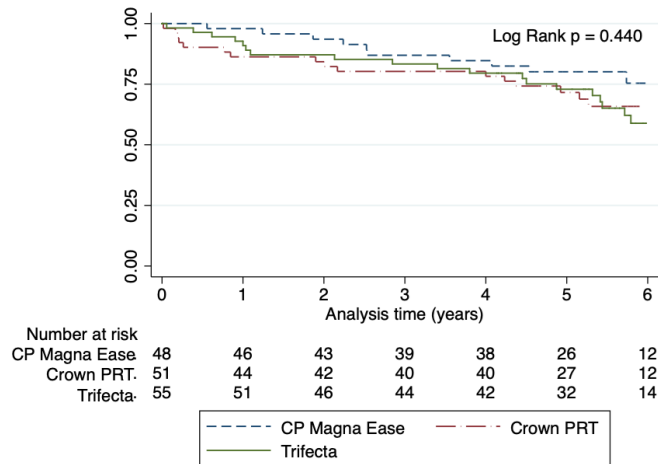


Results 2

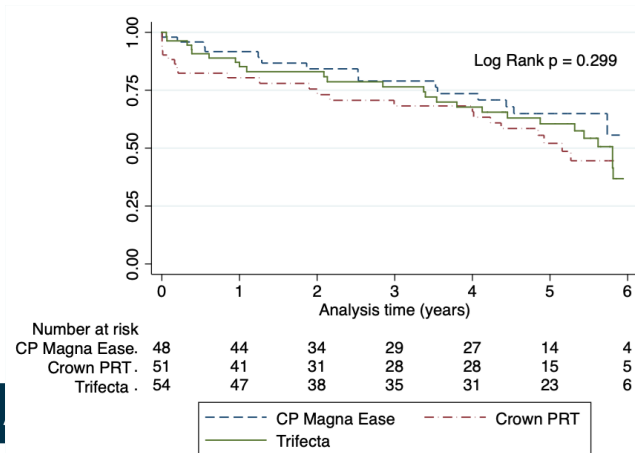
COMPETING RISK ANALYSIS FOR STRUCTURAL VALVE DETERIORATION



GLOBAL KAPLAN-MEIER SURVIVAL



GLOBAL EVENT-FREE KAPLAN-MEIER SURVIVAL



Conclusion

- There were significant differences in the hemodynamic performance between *Carpentier Perimount Magna Ease*[™] and *Crown PRT*[™], and also between *Carpentier Perimount Magna Ease*[™] and *Trifecta*[™]. *CP Magna Ease*[™] showed the best hemodynamic performance at 5 years follow-up.
- The mean aortic gradient at 1-year after surgery was related with the mean aortic gradient at 5-years after surgery.
- The *Trifecta*[™] prosthesis presented a higher incidence of structural valve deterioration during the follow-up.

