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Structural valve degeneration after ten-years from aortic valve replacement with pericardial prosthesis in non-elderly adults



Background / Study Objective

- Structural valve degeneration (SVD) remains the «*Achille heel*» of biological prostheses and younger age at implantation is reported to accelerate the degeneration process
- Previous studies on the topic are usually conducted without a standardized definition of SVD, and reoperation is often considered the proxy variable of SVD
- Perimount Magna Ease (PME) has been launched on the market in 2008 and it is currently one of the most implanted valve worldwide
- Despite that, few studies reported long-term outcome of PME in non-elderly adults
- It is the aim of this study to analyze the incidence of SVD in non-elderly patients at long-term follow-up, with the standardized definition of SVD currently accepted in the literature



Patients

- January 2010 - December 2012: 871 consecutive patients implanted with Perimount Magna Ease (PME) at a single Cardiac Surgery Institution.
- *Inclusion criteria*: isolated and combined aortic valve replacement (AVR)
- *Exclusion criteria*: age <18 years (n28), AVR with any concomitant aortic annular enlargement (n13), implantation of PME only in different positions (i.e. mitral/pulmonary valve, n 141).
- Final study population: 689 patients who underwent AVR with PME valve:
 - Patients aged ≤ 70 years (n260, 37.7%) were more likely to be affected by bicuspid aortic valve disease (22.4% vs 4.8%, $p < 001$), ascending aorta aneurism (24.1% vs 3.8% $p < 001$), chronic kidney disease requiring dialysis (1.9% vs 0.2%, $p 0.02$) and to have had a prior cardiac surgery operation (8.5% vs 2.8%, $p < 001$)
 - Patients aged >70 years (n429, 62.3%) were more likely to be affected by multiple comorbidities (diabetes mellitus, hypertension, dyslipidemia, coronary artery disease) and reported higher EuroSCORE II (2.7% vs 4.09%, $p < 001$)

Methods

- Complete ten-year clinical and echocardiographic follow-up was obtained in all patients
- Logistic regression was used to calculate the propensity score with adjustment for confounding baseline variables, in order to select pairs of ≤ 70 vs > 70 aged patients having similar preoperative risk profile. Descriptive statistics with univariate analyses were used to assess differences between groups.
- Kaplan-Meier survival estimation were performed to assess ten-year freedom from moderate-to severe structural valve degeneration (SVD), redo, endocarditis and cardiovascular mortality
- A sub-analysis of patients aged ≤ 70 years old was performed. Three age-based categories (*≤ 50 years vs 51-60 years vs 61-70 years*) were compared in terms of freedom from SVD, redo, endocarditis and cardiovascular mortality. Cox regression analysis was performed to assess risk factors for the development of moderate-to severe SVD.
- Statistical analysis was performed with SPSS for Windows (Version 27.0, SPSS Inc., Chicago, IL, USA). A p value < 0.05 was considered for statistical significance.

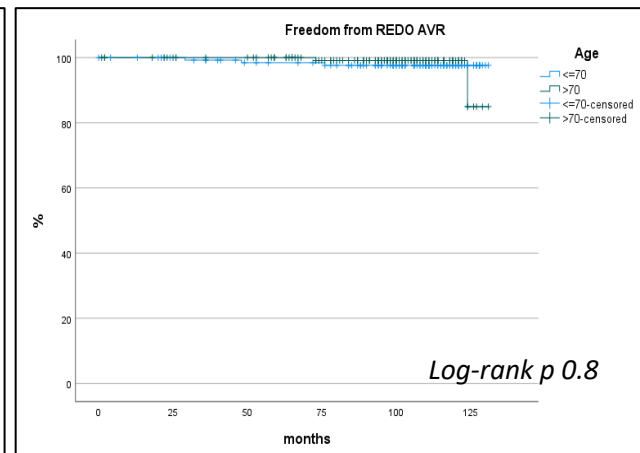
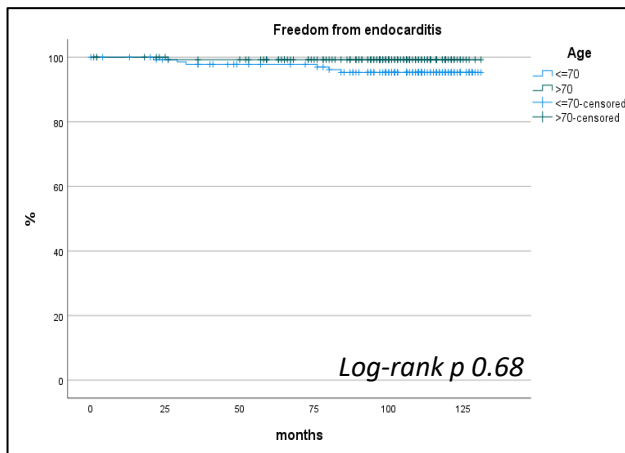
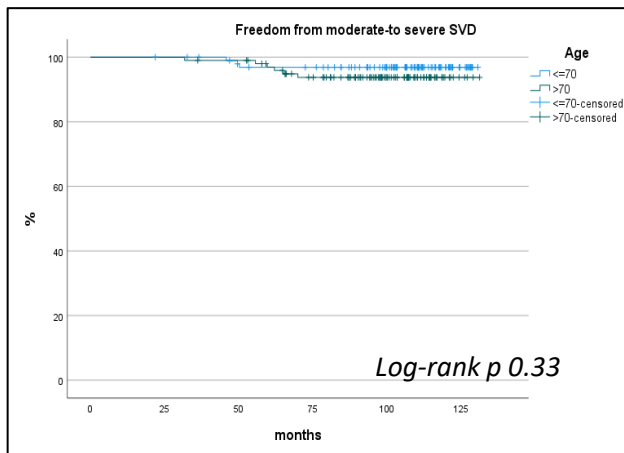


Results 1

PS matched population (n282: 141 pairs)

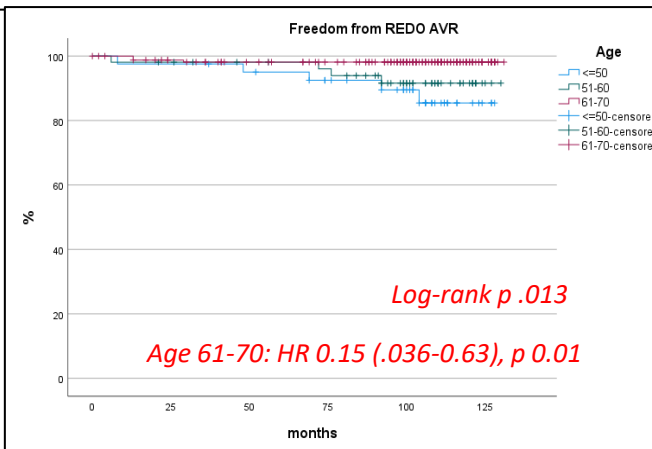
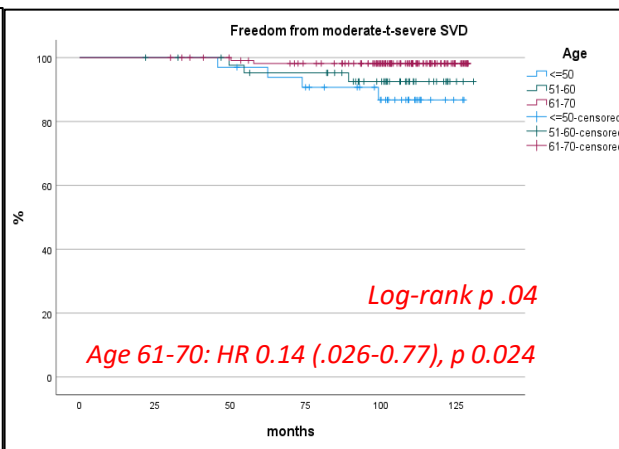
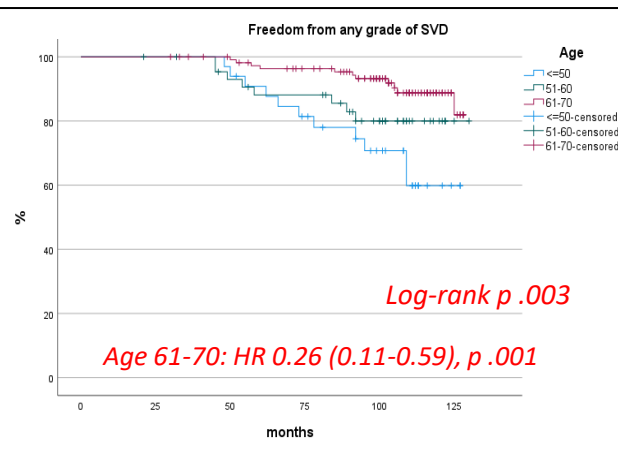
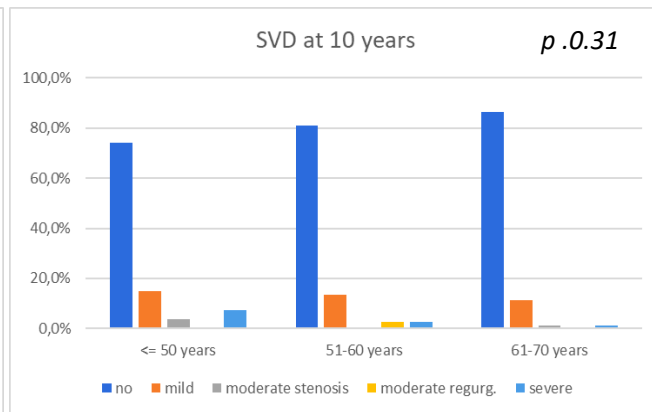
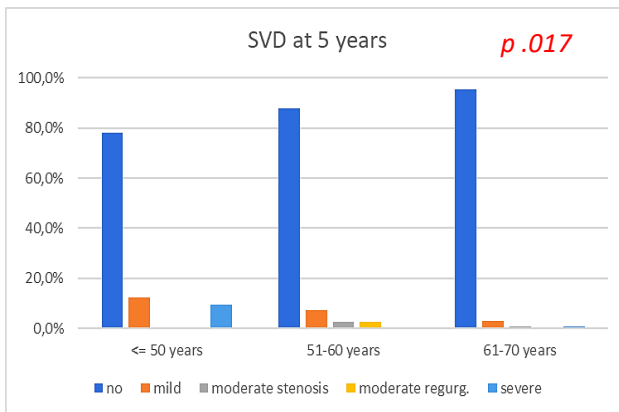
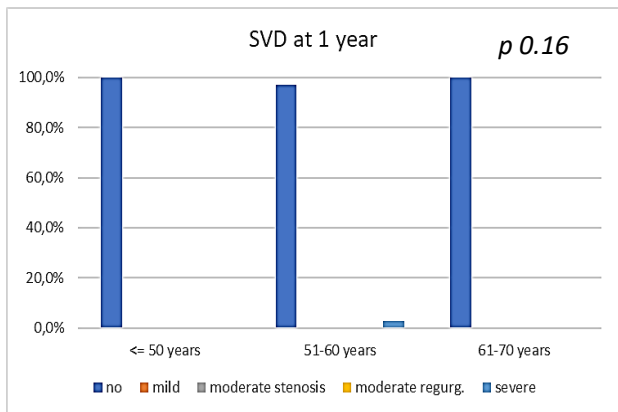
- No differences in hospital death and major post-operative outcome between the two groups (Tables)
- No statistical differences in freedom from moderate-to-severe SVD, REDO AVR and endocarditis (Graphs)
- Freedom from cardiovascular mortality was similar between the two groups (92.7% vs 85.8% at 10y in ≤ 70 vs >70 years old; p 0.78)

Intraoperative characteristics n(%)	≤ 70 years old (n 141)	>70 years old (n 141)	p	Postoperative outcome	≤ 70 years old	>70 years old	p
				n(%); m(SD)	(n 141)	(n 141)	
				In-hospital mortality	1 (0.7)	0	0.32
Isoltatad AVR	81 (46.6)	93 (53.4)	0.14	Bleeding requiring surgical revision	8 (5.7)	5 (3.5)	0.3
AVR + MVR	13 (9.2)	8 (5.7)	0.26	Sepsis	0	3 (2.1)	0.08
AVR+ CABG	22 (51.2)	21 (48.8)	0.87	Acute kidney injury reuring dialysis	0	1 (0.7)	0.8
AVR+ Asc.Ao	18(54.5)	15 (10.6)	0.58	Prolonged ventiation	14 (9.9)	14 (9.9)	0.9
CPB time	101.9	93.02	0.06	Pacemaker implantation	3 (2.1)	4 (2.8)	0.7
Aortic clamp time	80.2	71.14	0.01	Stroke	2 (1.4)	3 (2.1)	0.65
Prosthetic size				Perioperative myocardial infarction	1 (0.7)	0	0.32
19-21-23mm	86 (61)	92 (65.2)	0.46	New onset atrial fibrillation	38 (26.9)	46 (32.6)	0.42
25-27-29mm	55 (39)	49 (34.8)		ICU days	2.75 (6.7)	2.87 (5.9)	0.89



Results 2

Sub-analysis in Patients ≤ 70 years old



- No statistical difference in ten-year freedom from cardiovascular mortality (94.8% vs 96.2% vs 93.9% in ≤ 50 vs 51-60 vs 61-70 years; *p* 0.9) and from endocarditis (95.5% vs 99.3% vs 95% at 10 y % in ≤ 50 vs 51-60 vs 61-70 years; *p* 0.18) between the three age categories

Conclusion

- Perimount Magna Ease bioprostheses confirmed excellent short to long-term outcome in both patients aged ≤ 70 years and > 70 years old, without significant difference in freedom from moderate-to-severe SVD, REDO and endocarditis
- However, when patients aged ≤ 70 years old were considered, SVD seems to begin already at five years after surgery
- Patients younger than 50 years old and patients between 51-60 years showed a significantly higher incidence of any SVD, moderate-to-severe SVD and REDO
- Age > 60 years resulted to be «protective» for SVD, therefore 60 years should be considered as the real cut-off for accelerated SVD, possibly mandating the use of new generation bioprostheses with the potential for delaying SVD

