



Early and One-year Outcomes of Aortic Root Surgery in Marfan Syndrome Patients

A Prospective, Multi-Center, Comparative Study

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Outcomes in Marfan Patients
study group**

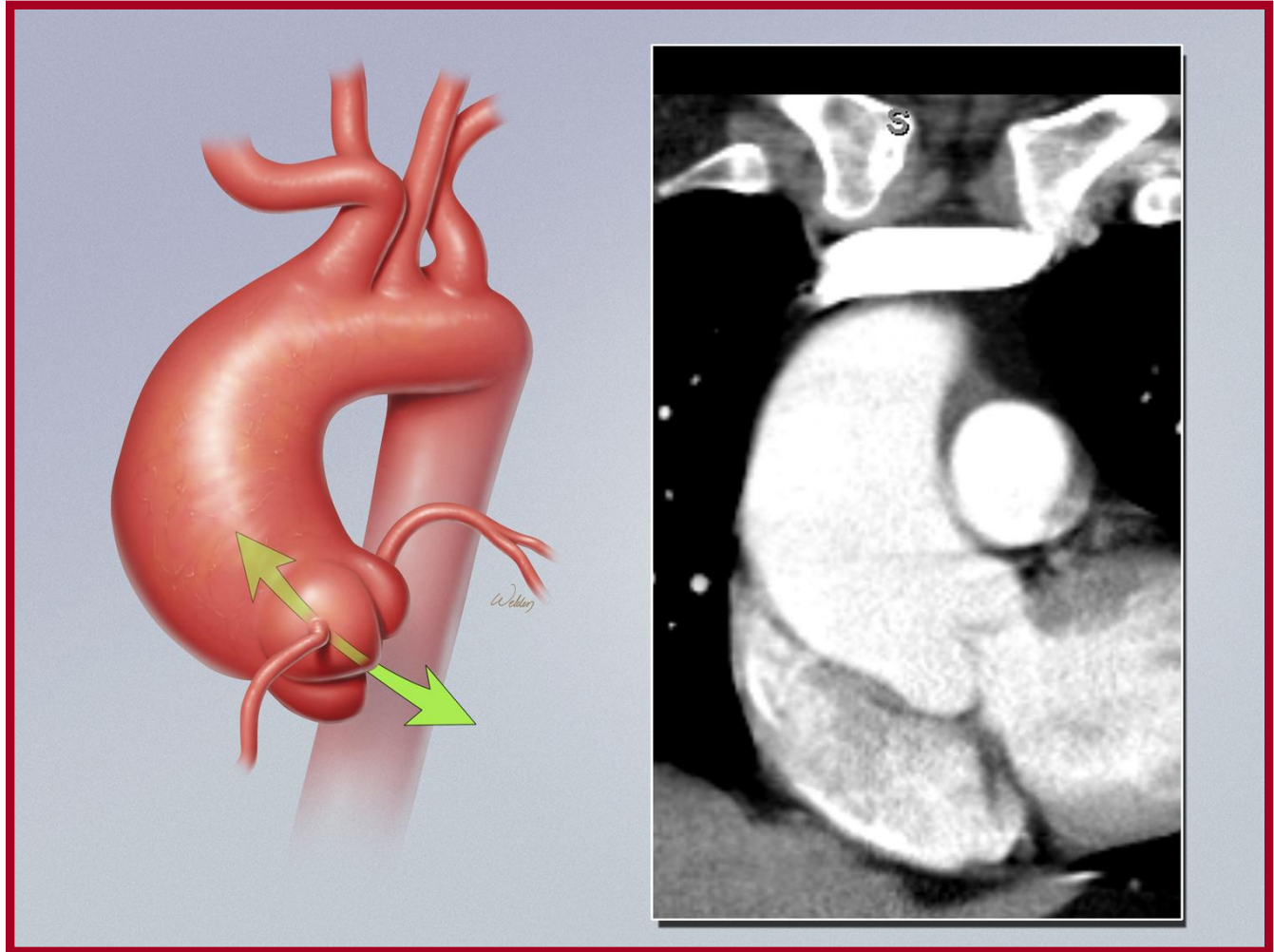


Disclosures

- Coselli** **St. Jude Medical, Inc. (speaker, research support)**
Vascutek Terumo (educational grant, consultant, royalties)
Medtronic, Inc. (research support , speaker , Steering Committee)
- LeMaire** **Medtronic, Inc. (consultant/advisory board)**
- Miller** **Medtronic , Inc. (consultant)**
Edwards LifeSciences (consultant, research grant)
- No disclosures: Connolly, Dietz, Hartzell, Milewicz, Minard, Stephens, Sundt, Volguina, Vricella**

Ascending Aorta in Marfan Patients

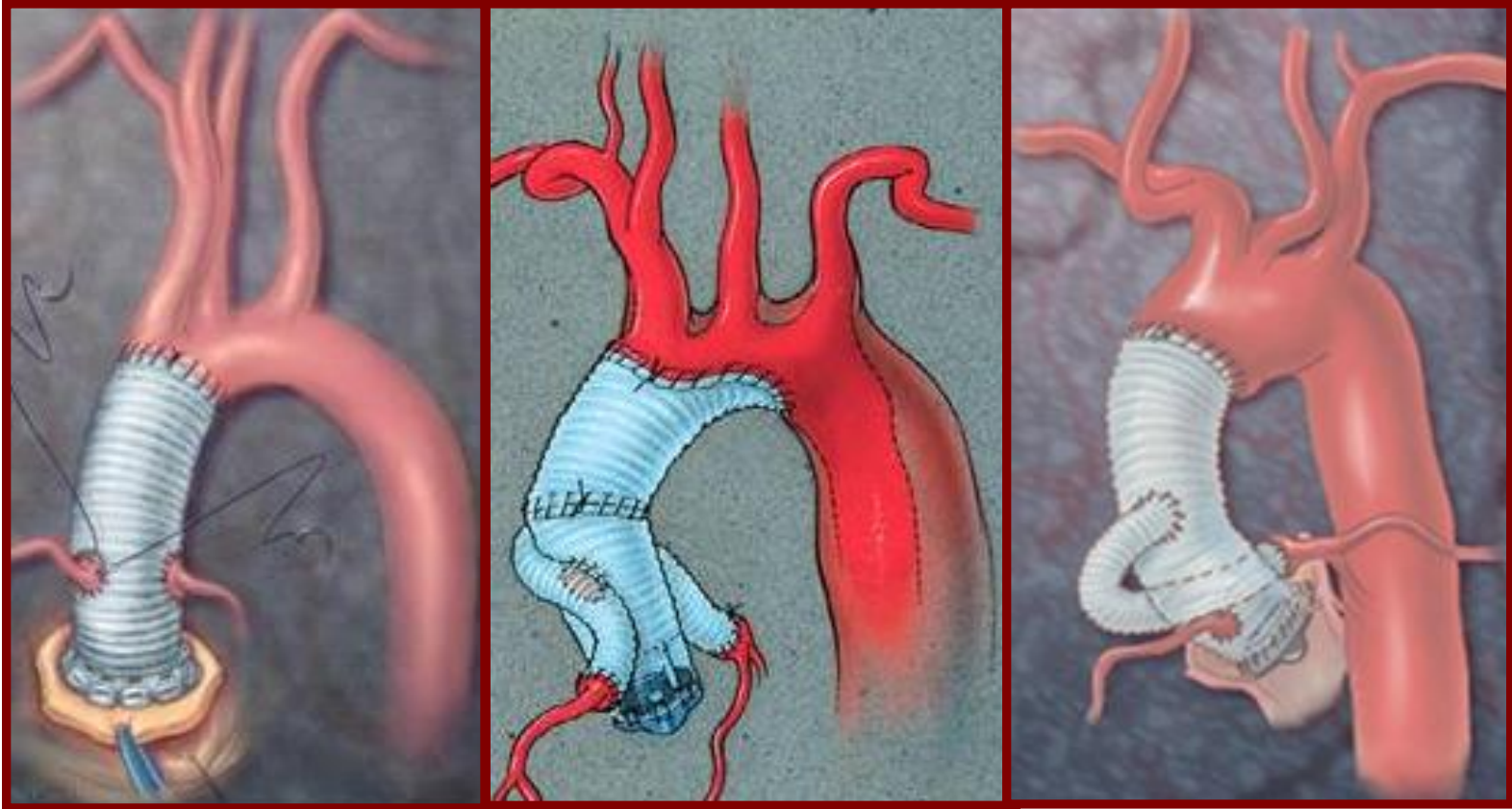
Aortic Valve Operative
Outcomes in Marfan Patients





Aortic Root Replacement: Valve-replacing Technique (AVR)

Modified Bentall Procedure

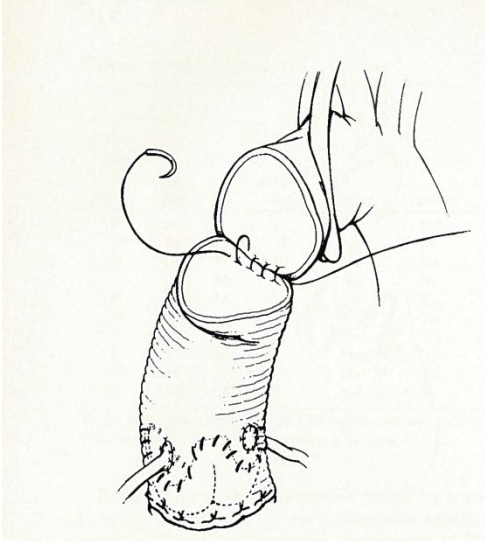
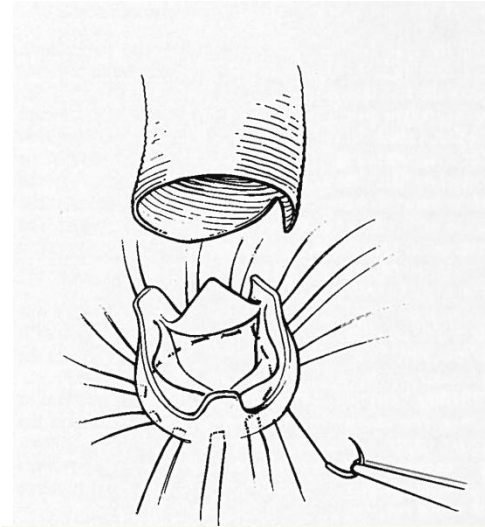
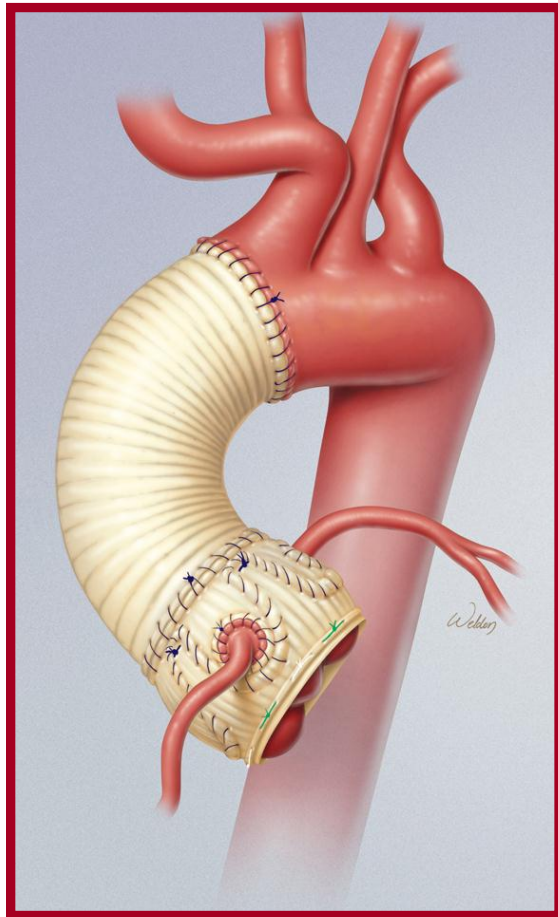


Aortic Valve Operative
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Aortic Root Replacement: Valve-sparing Technique (AVS)

David V Procedure



David & Feindel
JTCVS 1992;103:617-22
Original David procedure
10 patients; 5 with MFS



Aortic Valve Operative Outcomes in Marfan Patients (AVOOMP)

- **Prospective, multicenter, international registry study**
- **Goal: Compare the outcomes of AVS and AVR root replacement**
- **Enrollment: March 2005 – Nov 2010**
- **316 subjects enrolled**
- **Primary endpoint:
Major adverse valve-related events**

Aortic Valve Operative Outcomes in Marfan Patients



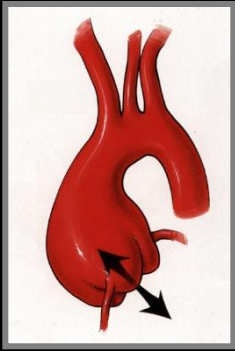
- **Enrollment criteria**
 - **Marfan syndrome diagnosis based on 1996 Ghent criteria** (De Paepe et al, *Am J Med Genet*)
 - **In need of aortic root replacement**
 - **Observational registry**
- **Treatment not assigned – type of operation determined by clinical factors and on surgeon and patient preference**
- **Follow-up at 6 months and at 1, 2, and 3 years**
- **Clinical follow-up: 98% complete at 1+ years**
- **Imaging follow-up: 93% complete at 1+ years**

Enrolling Sites



**Aortic Valve Operative
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Institution	PI	Enrolled Subjects
Mayo Clinic, Rochester	Sundt / Schaff	55
Stanford University	Miller	49
Johns Hopkins Hospital	Gott / Vricella	32
New York Presbyterian-Cornell Hospital	Girardi	29
University of Pennsylvania	Bavaria	28
International sites	6 sites	70
Baylor College of Medicine	Coselli	15
Washington University	Moon	14
Other US sites	6 sites	24

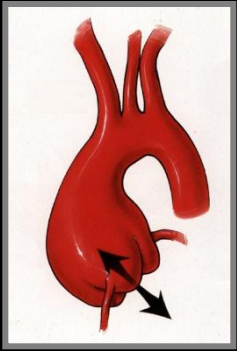


Definitions

- **Major adverse valve-related events (MAVRE), 2008 guidelines**

Akins et al. - JTCVS 2008

- **Valve-related mortality**
- **Valve-related morbidity**
- **Need for new permanent pacemaker or defibrillator within 14 days after operation**

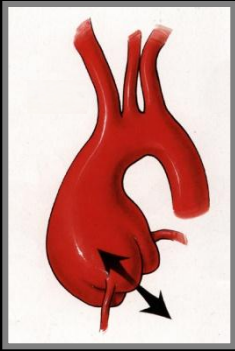


Definitions

Valve-related **mortality**

- Death caused by
 - valve-related morbid event
 - reintervention on operated valve
- Sudden unexplained death

Akins et al. - JTCVS 2008



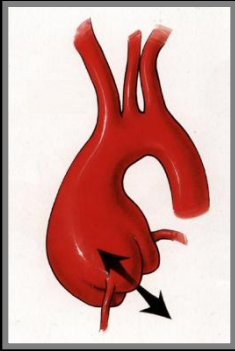
Definitions

Valve-related **morbidity**

- **Structural valve deterioration (SVD)**
- **Nonstructural dysfunction (NSD)**
- **Operated valve endocarditis**
- **Valve thrombosis**
- **Embolism**
- **Bleeding after discharge**

Aortic regurgitation $\geq 2+$ \rightarrow SVD/NSD

Akins et al. - JTCVS 2008



Analysis

- **Analysis based on “intent-to-treat” principles**
- **Univariate analysis for group comparisons**
 - **Student *t* and Mann-Whitney *U* tests for continuous variables**
 - **Chi-square and Fisher exact tests for categorical variables**
- **Cox regression analysis to determine whether type of operation was a risk factor for valve-related complications**



316 Patients

Age, y	35 ± 13 (range, 4-70)
Male sex	203 (64%)
Acute dissection	13 (4%)
Chronic dissection	17 (5%)
Rupture	1
Endocarditis	2

**Aortic Valve Operative
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316 Patients

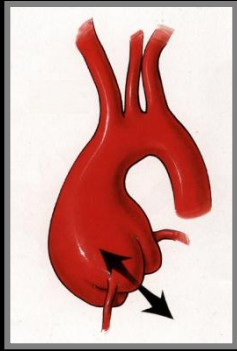
Preoperative Characteristics	AVR (n = 77)	AVS (n = 239)	P Value
Age, y	39 ± 14	33 ± 13	<0.01
Male sex	55 (71%)	148 (62%)	0.1
Sinuses of Valsalva, mm	53	49	<0.01
LV ejection fraction, %	60	60	0.6
Acute dissection	7 (9%)	6 (3%)	<0.01
Chronic dissection	11 (12%)	6 (3%)	<0.01
Previous CV surgery	17 (14%)	12 (5%)	<0.01

Aortic Valve Operative Outcomes in Marfan Patients



Procedures

Operative Details	AVR (n = 77)	AVS (n = 239)	P Value
Emergent or urgent surgery	18 (23%)	10 (4%)	<0.01
Circulatory arrest	22 (29%)	48 (20%)	0.1
CPB time, m	152	195	<0.01
Aortic clamp time, m	115	156	<0.01
Concomitant arch	20 (26%)	46 (20%)	0.2
Elephant trunk arch	5 (6%)	4 (2%)	0.03
Concomitant MV replacement	5 (6%)	1 (<1%)	<0.01
Concomitant CABG	4 (5%)	9 (4%)	0.6



Procedures

- **Final decision to perform AVR or AVS was made intraoperatively in 140 patients (46%)**
- **AVR was considered the only suitable option in 55 patients (17%)**



Early Outcomes

30-day Outcomes	AVR (n = 77)	AVS (n = 239)	P Value
Ventilator support time, h	12	8	<0.01
Time in ICU, h	46	26	0.02
Length of hospital stay, d	7	6	0.04
LV ejection fraction, %	55	60	0.05



Early Outcomes

30-day Complications	No. Patients (n = 316)
Death	2 (1%)
Stroke	0
Cardiac complications*	40 (13%)
Pulmonary complications	26 (8%)
Re-exploration for bleeding	18 (6%)
Major adverse valve-related event	21 (7%)

** 40 with arrhythmia, 10 with pericardial effusion, 8 with cardiac failure*



Two Early Deaths

Repair	POD	Comment
AVS	1	4-year old girl Bleeding Not valve-related
AVR	7	30-year old man Cardiac failure, multiple organ failure Not valve-related



Early Outcomes

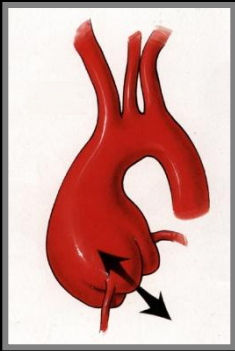
30-day Outcomes	AVR (n = 77)	AVS (n = 239)	<i>P</i> Value
Major valve-related adverse event	6 (8%)	15 (5%)	0.4
Nonstructural dysfunction	1 (1%)	7 (2%)	1.0
Embolism	1 (1%)	3 (1%)	1.0
Bleeding	2 (3%)	3 (1%)	0.6
Permanent pacemaker / 14 days after operation	2 (3%)	3 (1%)	0.6

No valve-related deaths, reinterventions, valve thrombosis, endocarditis



Non-structural Valve Dysfunction

- ***Six patients with significant postprocedure TEE underwent intraoperative conversion***
 - Homograft root (2005) → stented bioprosthetic AVR
 - David I (2005)
 - Yacoub remodeling (2006)
 - David V (2008)
 - David IV (2009)
 - David V (2010)
- } Mechanical AVR
- ***One patient with coronary artery kinking*** after Florida sleeve procedure required same-day reintervention
 - ***One patient with coronary pseudoaneurysm*** after David V procedure required reintervention on POD 6

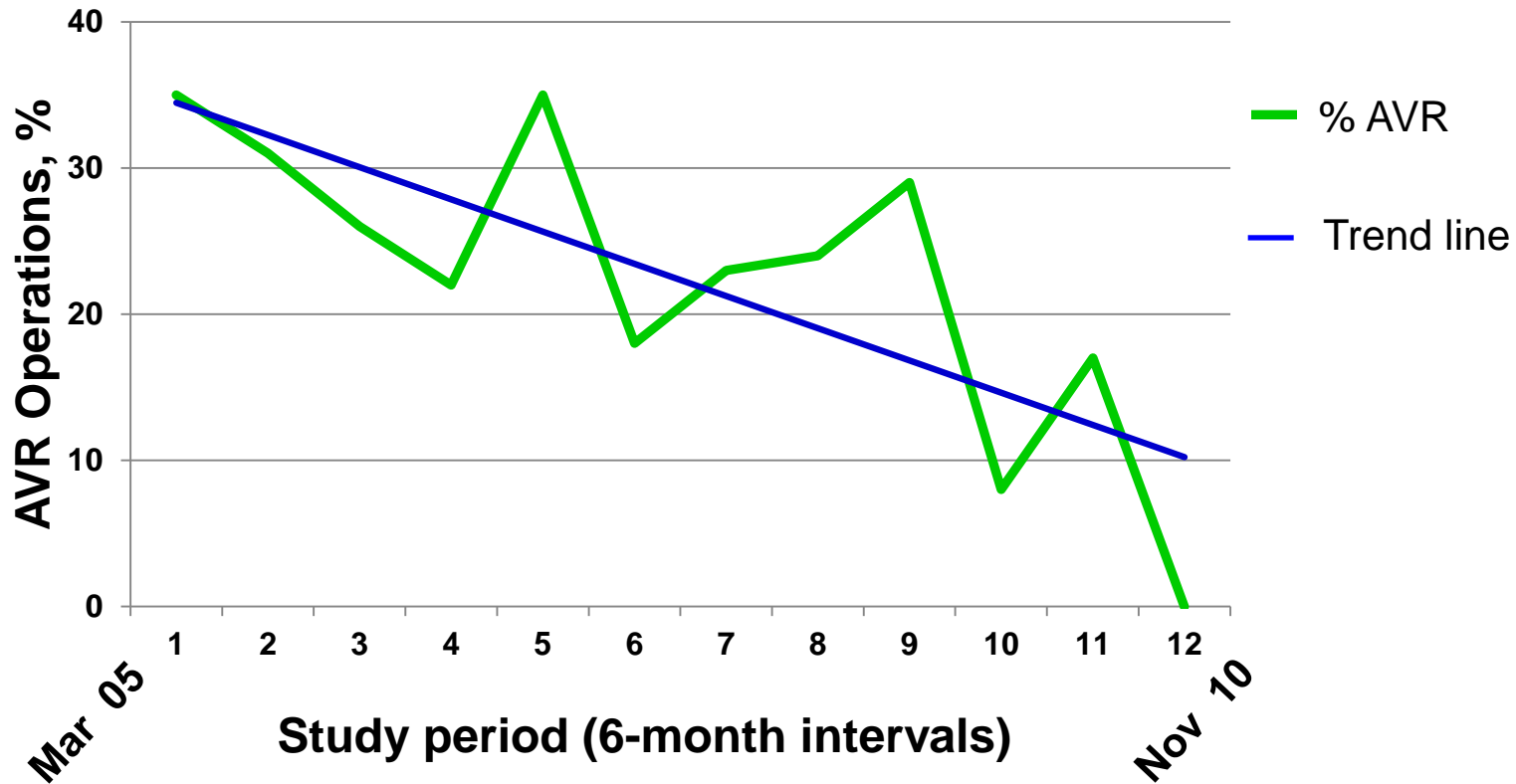


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One-year Outcomes

Proportion of AVR and AVS

Small and declining proportion of AVR operations (24% of all surgeries)



One-year Outcomes



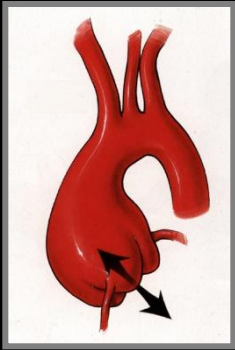
Aortic Valve Operative Outcomes in Marfan Patients

Major Adverse Valve-related Events	AVR patients (n=8)	AVS patients (n=35)	P-value
MAVRE	8	35	0.5
NSD/SVD	1 (13%)	23 (66%)	0.04
Embolism	2 (25%)	4 (11%)	0.6
Bleeding	5 (63%)	3 (9%)	0.01
Permanent pacemaker by POD 14	2 (25%)	3 (9%)	0.6
Endocarditis	1 (13%)	0	0.1
Reintervention	0	1 (3%)	0.6
Valve-related death	1 (13%)	2 (6%)	0.7



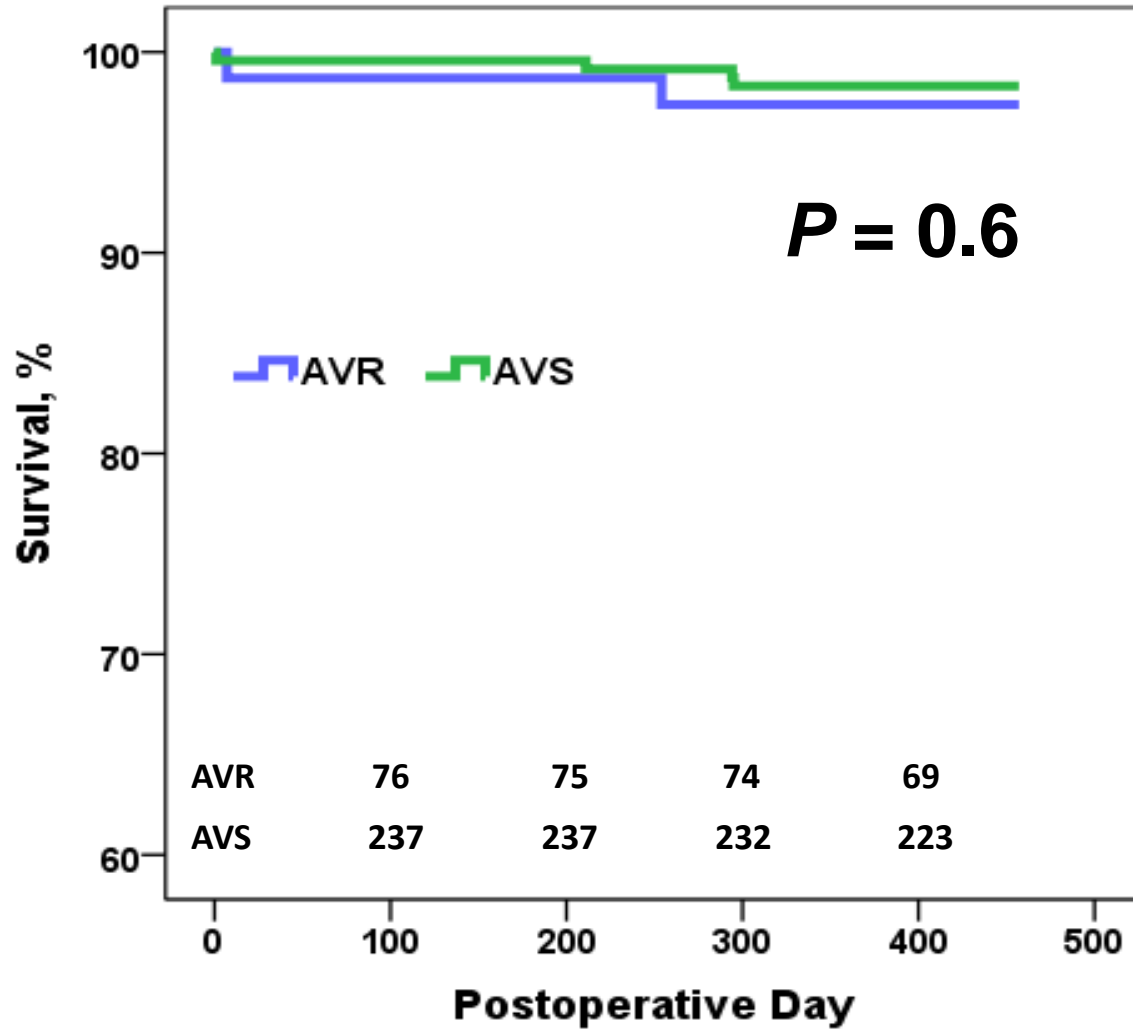
One-year Deaths

Repair	POD	Comment
AVS	211	64 year-old man Cause unknown Valve related
AVR	254	44 year-old woman Intracranial hemorrhage, sepsis Valve related
AVS	294	28 year-old man Drowning Not valve related
AVS	295	15 year-old girl Cause unknown Valve related



Aortic Valve Operative Outcomes in Marfan Patients

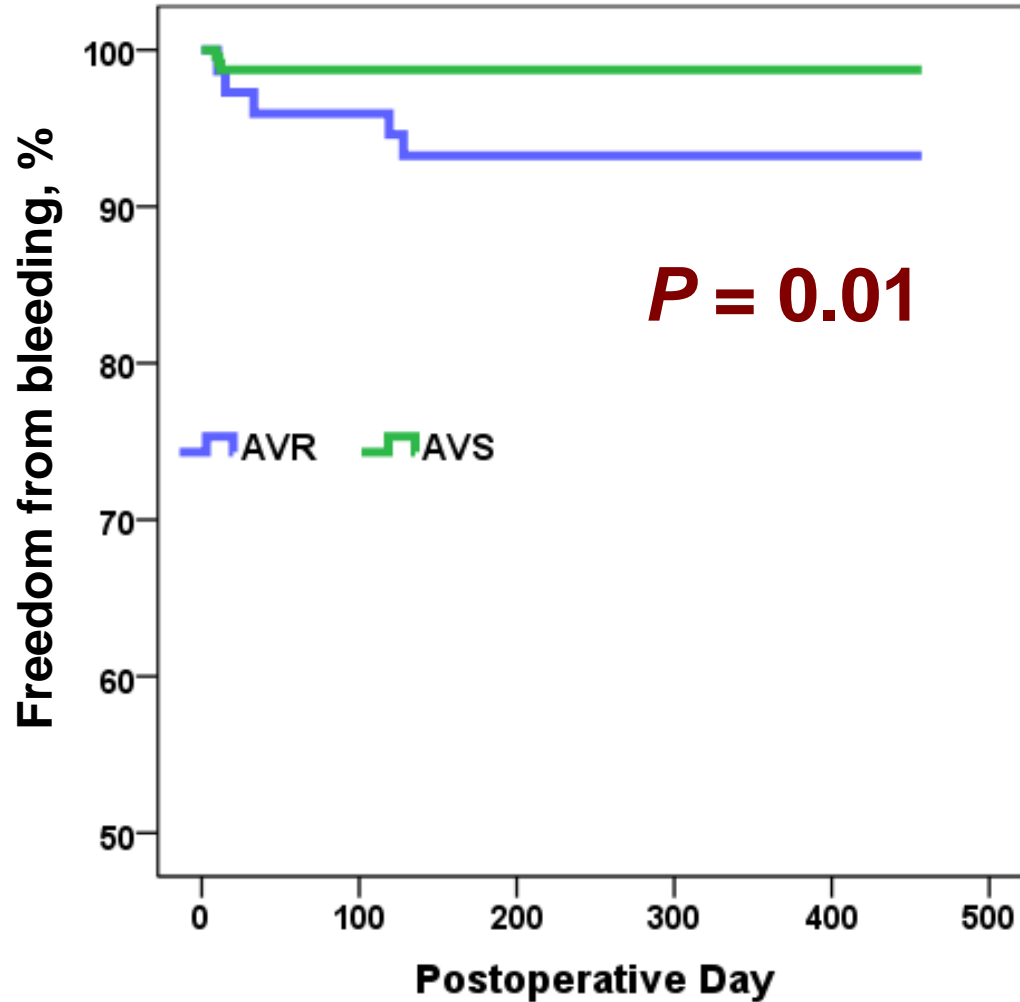
One-year Overall Survival



Aortic Valve Operative Outcomes in Marfan Patients



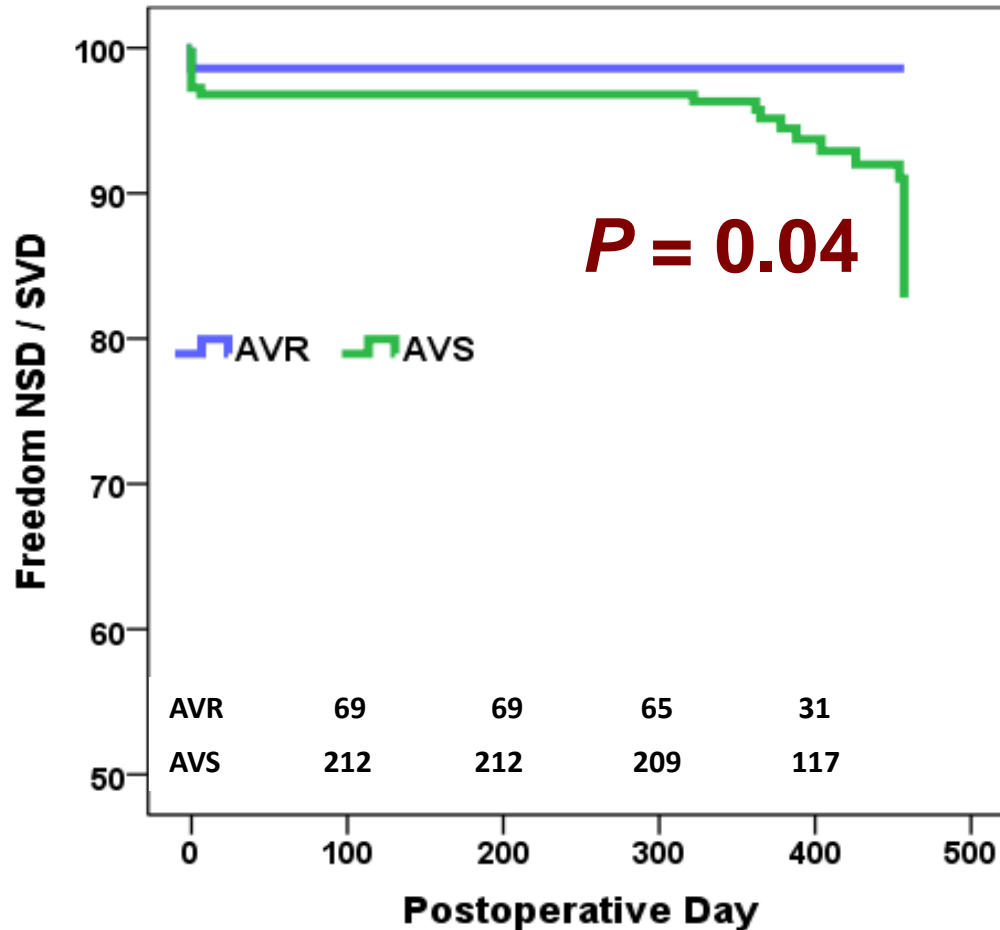
One-year Freedom from Bleeding



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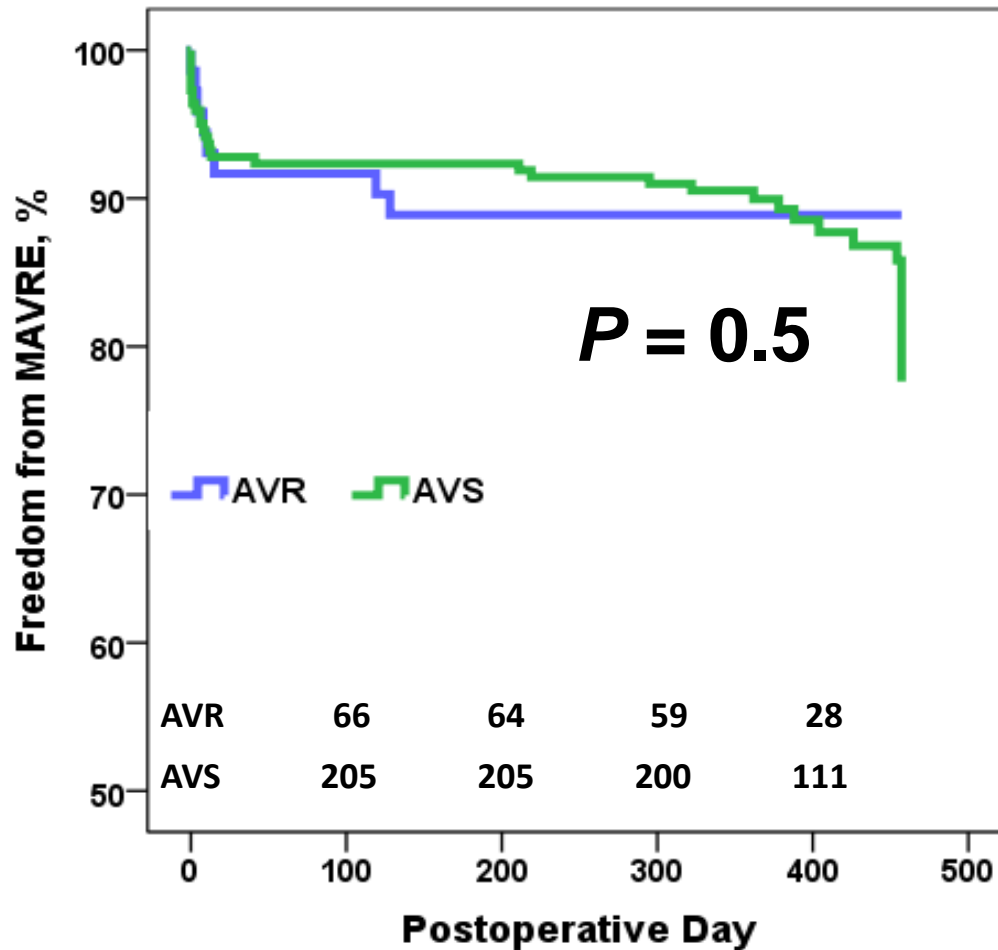


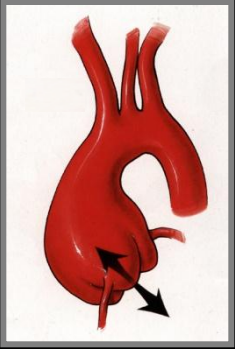
One-year Freedom from Nonstructural Dysfunction / Structural Valve Deterioration



One-year Freedom from Major Adverse Valve-related Events

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Other valve-related complications

At 1 year, no difference between AVS and AVR groups in freedom from

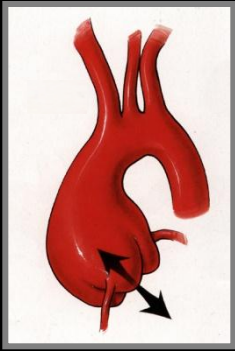
- **Valve-related death (1 AVR, 2 AVS)**
- **Embolism (2 AVR, 4 AVS)**
- **Reintervention (0 AVR, 1 AVS)**
- **Endocarditis (1 AVR, 0 AVS)**
- **Valve thrombosis (0 AVR, 0 AVS)**
- **Valve-related morbidity (7 AVR, 28 AVS)**



Cox Regression, 1-year

Type of surgery was not associated with

- **overall survival**
- **MAVRE (HR=0.66, 95% CI: 0.3-1.5)**
- **any other valve-related outcome**



Conclusions

- **AVR and AVS – similar early outcomes**
- **At 1 year, no differences in survival or MAVRE**
- **Increased AR $\geq 2+$ in AVS group at 1 year vs. no AR $\geq 2+$ in AVR group**
- **Follow-up should be continued for 5-10 years**

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Thank you!