INSTITUT CARDIOVASCULAIRE PARIS SUD

Update of New TAVI Indications

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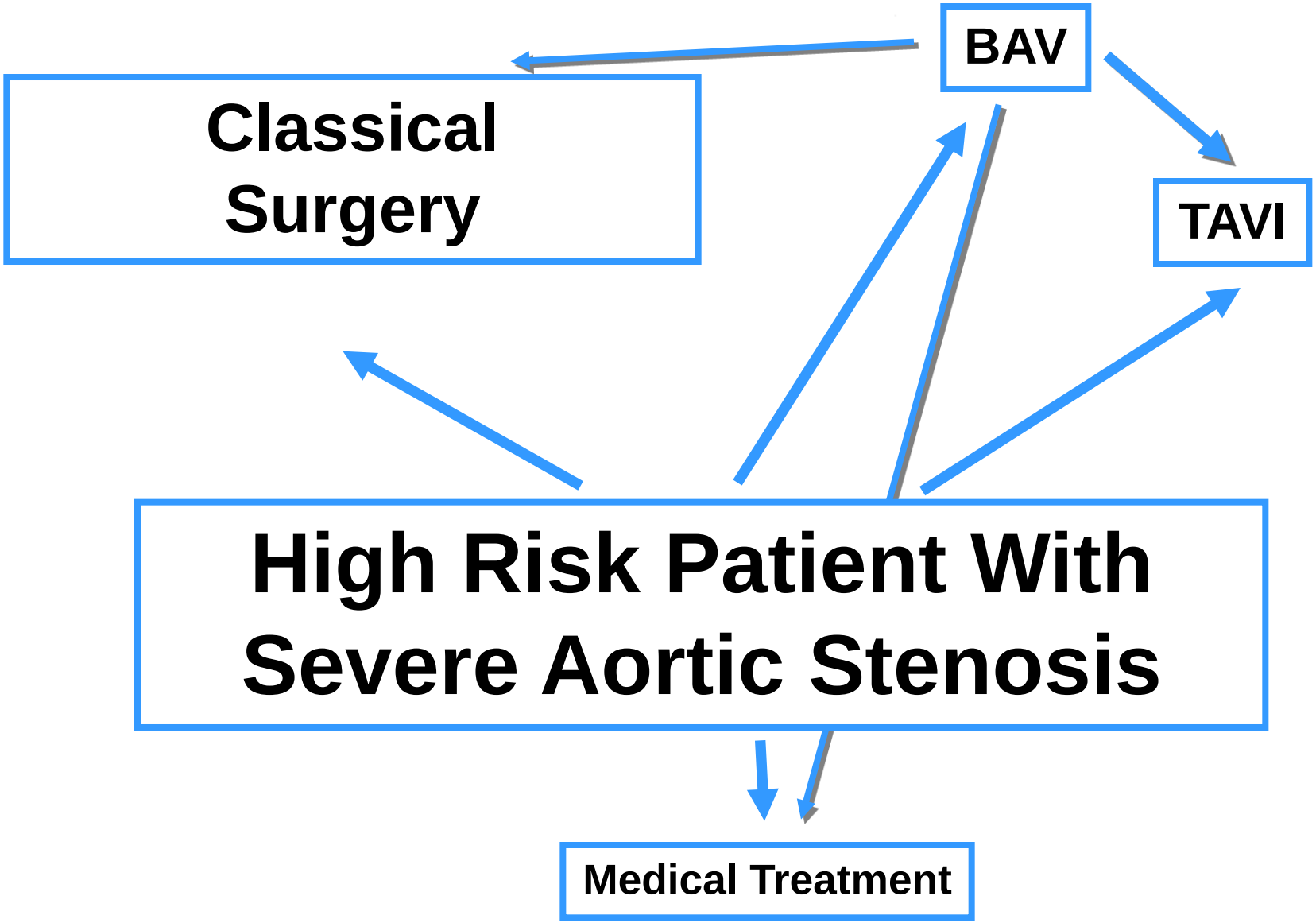
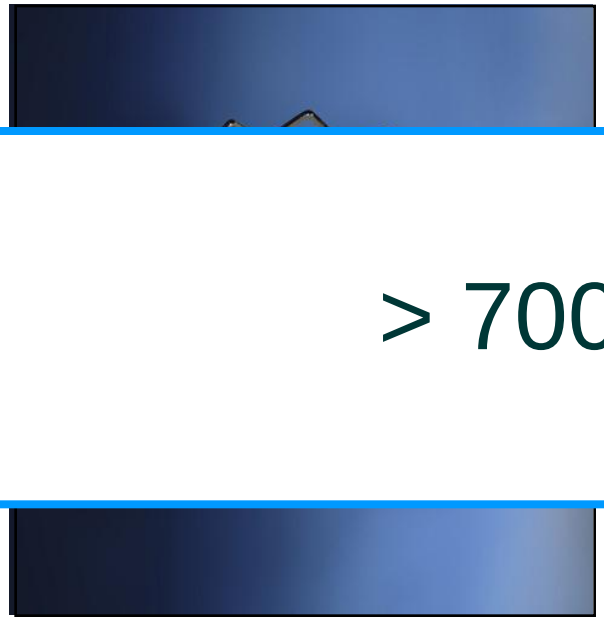
CARDIOVASCULAR SUMMIT TCTAP 2013

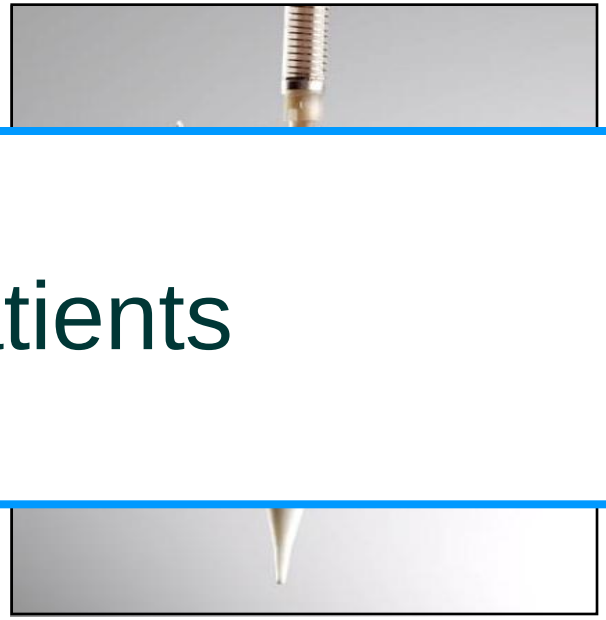
Conflict of Interest to Disclose

- ✓ Consulting (Symetis)
- ✓ Proctoring (Edwards)
- ✓ French PI of the Reprise II study
- ✓ Co PI of the Discover study
- ✓ Co PI of the Bravo II study


BAV
Classical Surgery
TAVI
High Risk Patient With Severe Aortic Stenosis
Medical Treatment

First Valves Generation





> 70000 Patients

Edwards
> 35000 patients

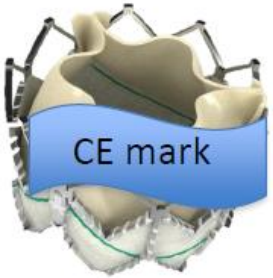
CoreValve
> 35000 patients

« Now this is not the end.

It is not even the beginning of the end.

But it is, perhaps, the end of the beginning. »

Sir Winston Churchill, Novembre 1942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Emerging Indications

- ✓ Valve in Valve
- ✓ Pure Aortic Regurgitation
- ✓ Combined CAD
- ✓ Bicuspid Aortic Valves

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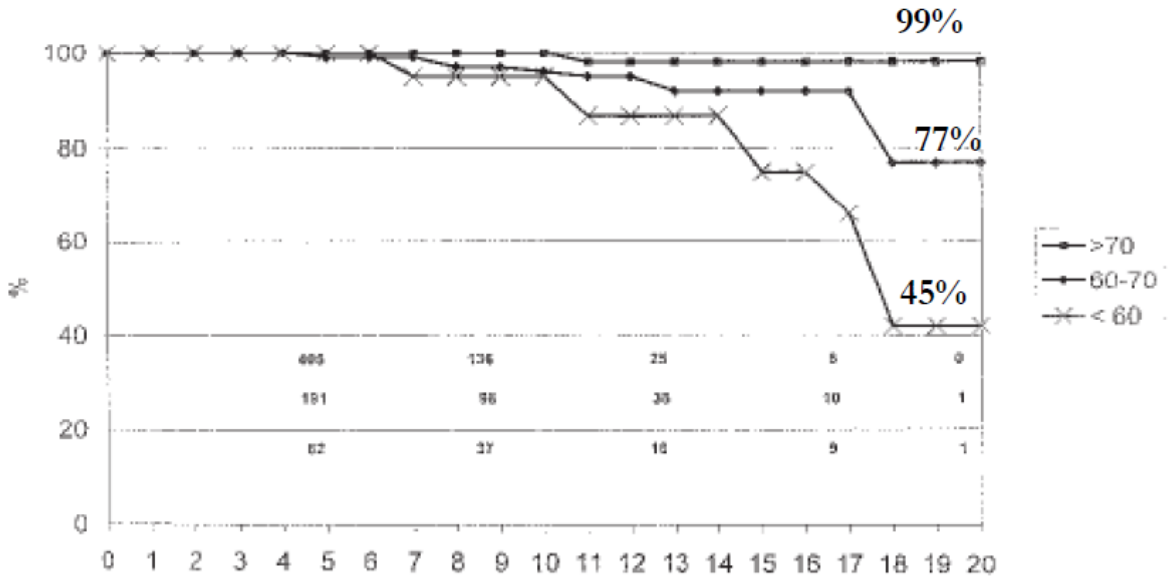
Structural bioprosthesis failure

1,133 pts (mean age 72.6 yrs) – undergoing AVR using the **Perimount** valve between 1984-2003 @Trousseau Hospital, F. Rabelais University, Tours France



Actuarial freedom from structural valve failure

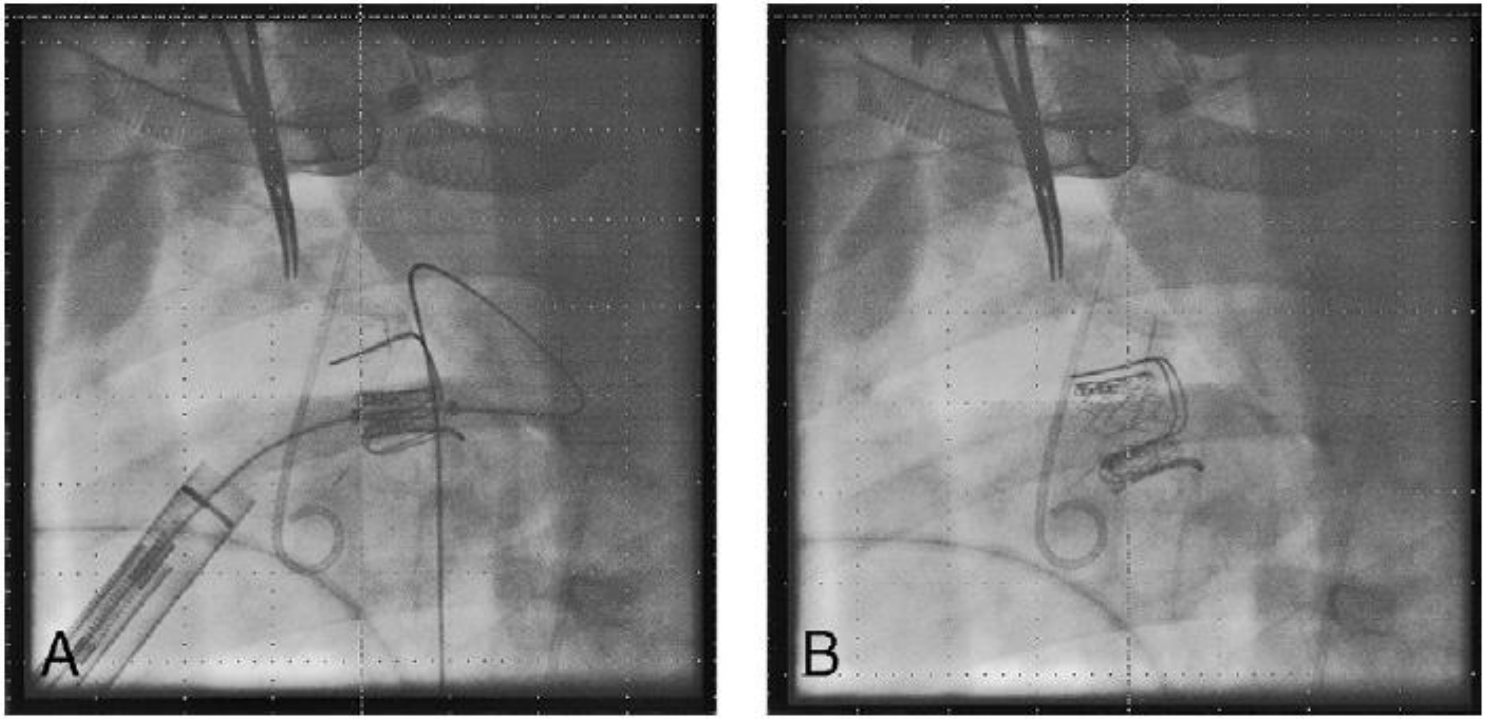
Aupart MR et al. J Heart Valve Dis 2006;768-75

Xenograft Degeneration

The risk of reoperative surgery may be significantly increased, up to 6% to 15%, mostly because of advanced age, additional risk factors, and an increased technical difficulty caused by adhesions.

PRECLINICAL STUDIES

Valve-in-a-Valve Concept for Transcatheter Minimally Invasive Repeat Xenograft Implantation



Walter et al. JACC 2007;50:56–60

Transcatheter Valve-in-Valve Implantation for Failed Bioprosthetic Heart Valves

John G. Webb, MD; David A. Wood, MD; Jian Ye, MD; Ronen Gurvitch, MD; Jean-Bernard Masson, MD; Josep Rodés-Cabau, MD; Mark Osten, MD; Eric Horlick, MD; O. Wendler, MD; Eric Dumont, MD; Ronald G. Carere, MD; Namal Wijesinghe, MD; Fabian Nietlispach, MD; Mark Johnson, MD; Chrisopher R. Thompson, MD; Robert Moss, MD; Jonathon Leipsic, MD; Brad Munt, MD; Samuel V. Lichtenstein, MD, PhD; Anson Cheung, MD

Background—The majority of prosthetic heart valves currently implanted are tissue valves that can be expected to degenerate with time and eventually fail. Repeat cardiac surgery to replace these valves is associated with significant morbidity and mortality. Transcatheter heart valve implantation within a failed bioprosthesis, a "valve-in-valve" procedure, may offer a less invasive alternative.

Methods and Results—Valve-in-valve implantations were performed in 24 high-risk patients. Failed valves were aortic (n=10), mitral (n=7), pulmonary (n=6), or tricuspid (n=1) bioprostheses. Implantation was successful with immediate restoration of satisfactory valve function in all but 1 patient. No patient had more than mild regurgitation after implantation. No patients died during the procedure. Thirty-day mortality was 4.2%. Mortality was related primarily to learning-curve issues early in this high-risk experience. At baseline, 88% of patients were in New York Heart Association functional class III or IV; at the last follow-up, 88% of patients were in class I or II. At a median follow-up of 135 days (interquartile range, 46 to 254 days) and a maximum follow-up of 1045 days, 91.7% of patients remained alive with satisfactory valve function.

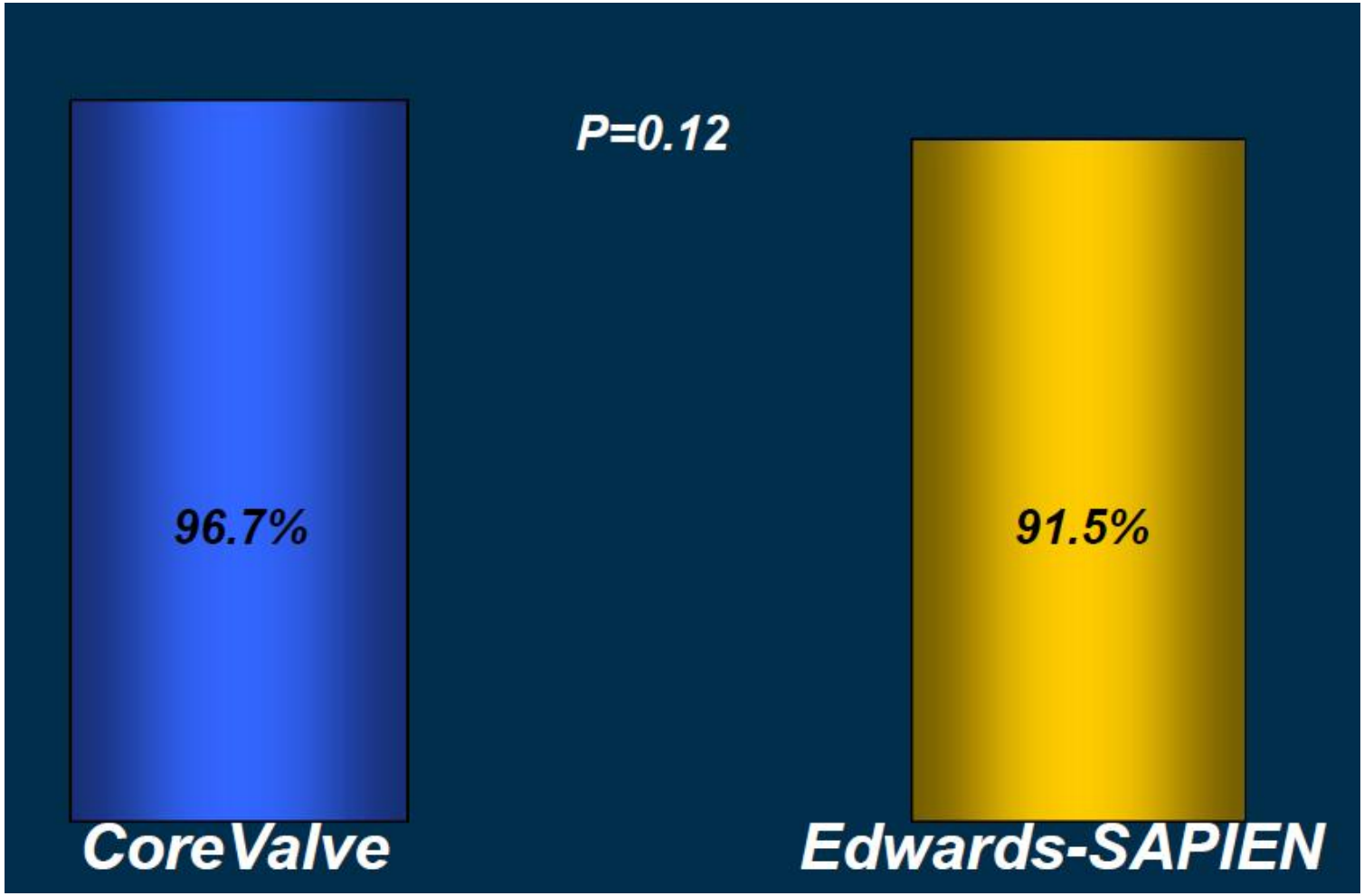
Conclusions—Transcatheter valve-in-valve implantation is a reproducible option for the management of bioprosthetic valve failure. Aortic, pulmonary, mitral, and tricuspid tissue valves were amenable to this approach. This finding may have important implications with regard to valve replacement in high-risk patients. (***Circulation***. **2010;121:1848-1857.**)

Webb et al. Circulation 2010;121:1848-1857

Valve in Valve

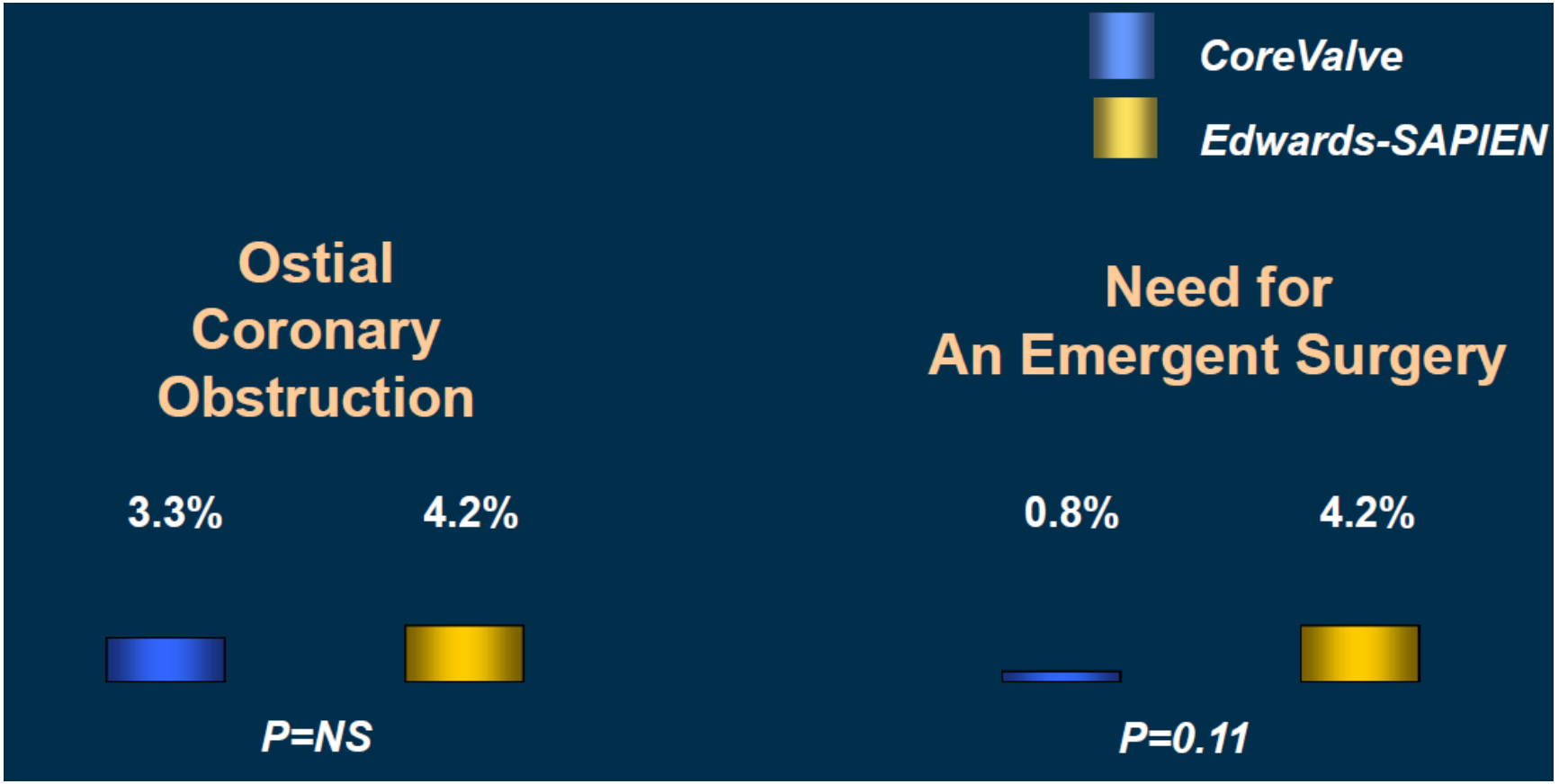
What Have we learned ?

Valve in Valve International Registry



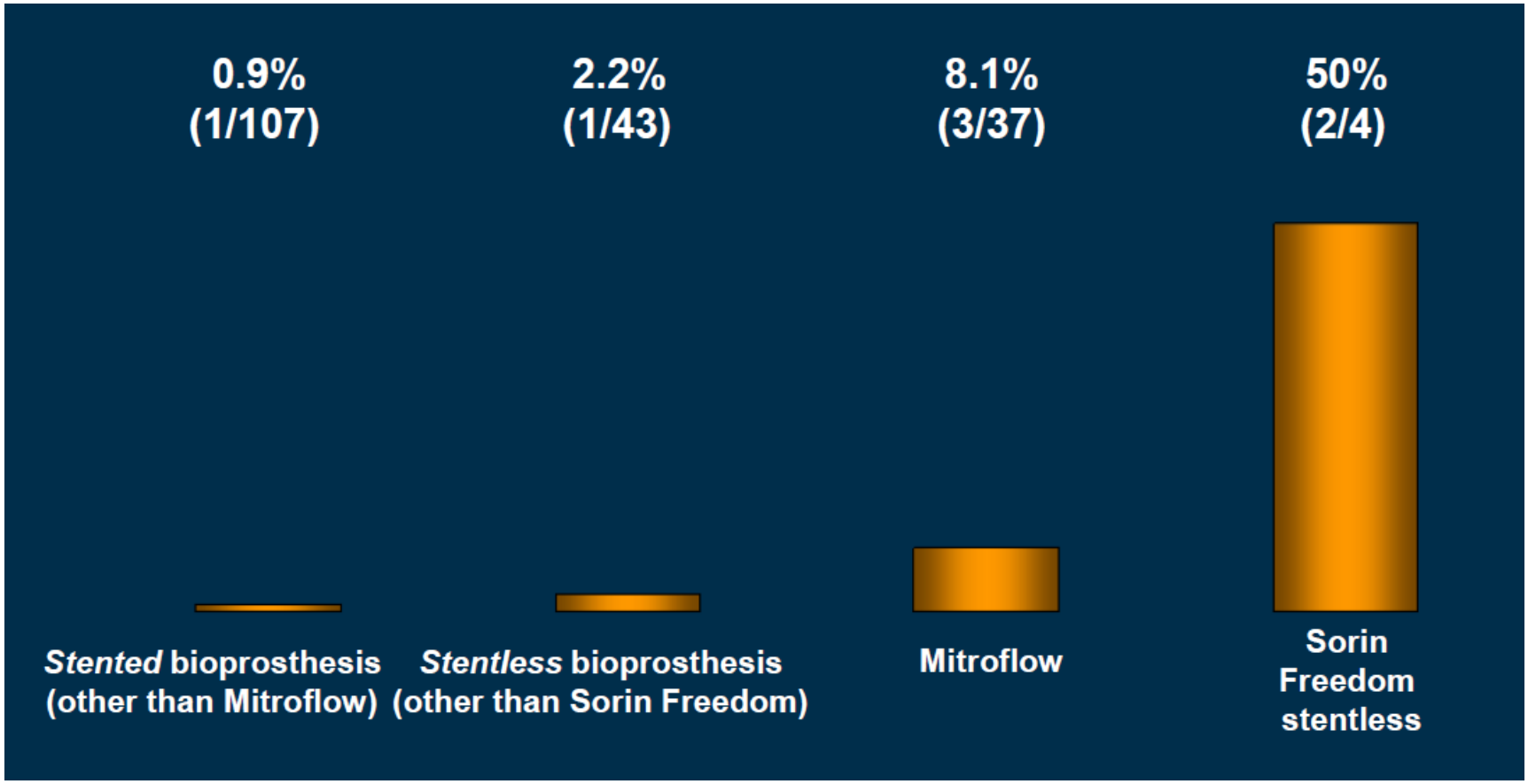
DVIR et al. Circulation 2012

Valve in Valve International Registry



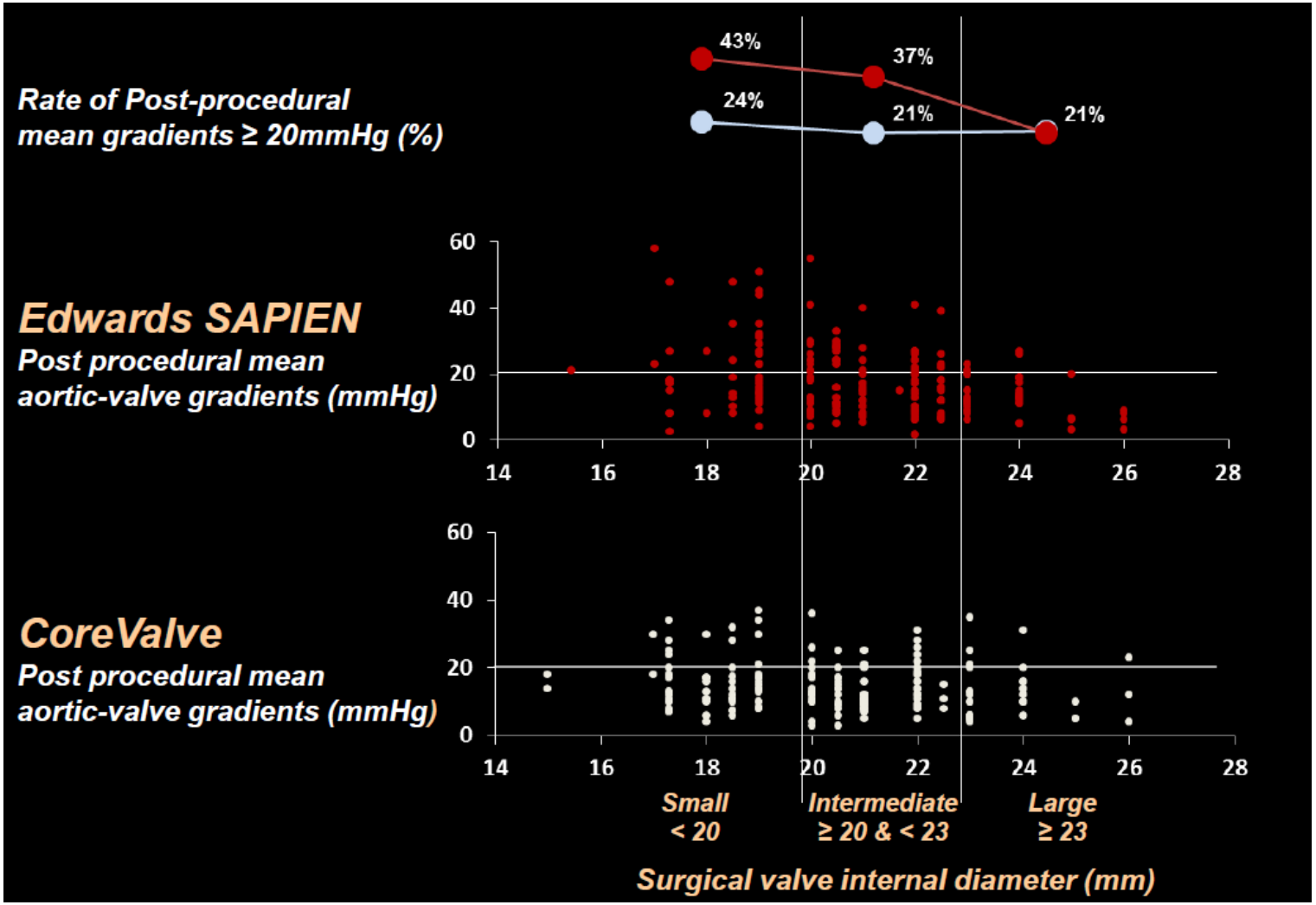
DVIR et al. Circulation 2012

Valve in Valve International Registry



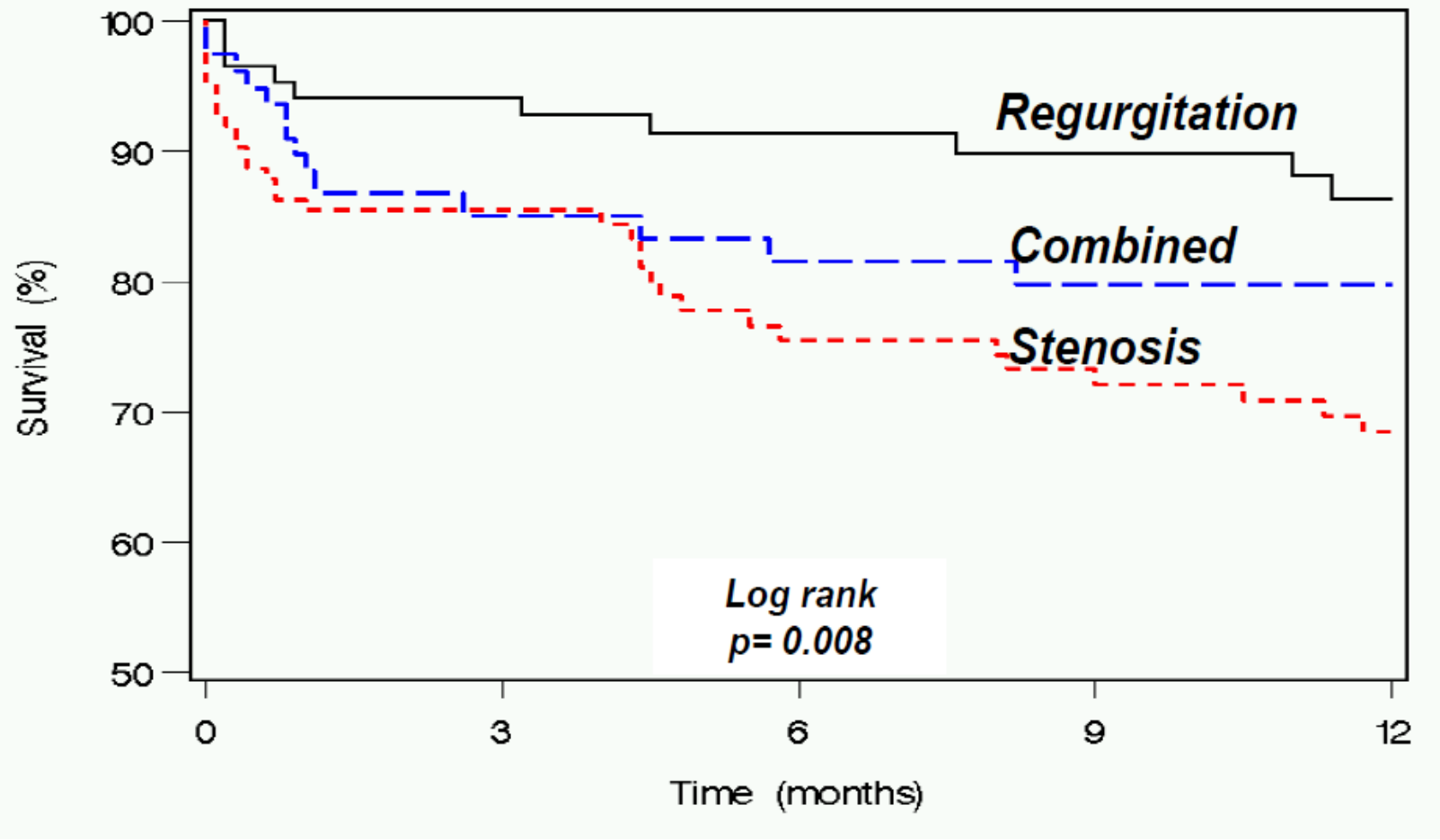
DVIR et al. Circulation 2012

Valve in Valve International Registry



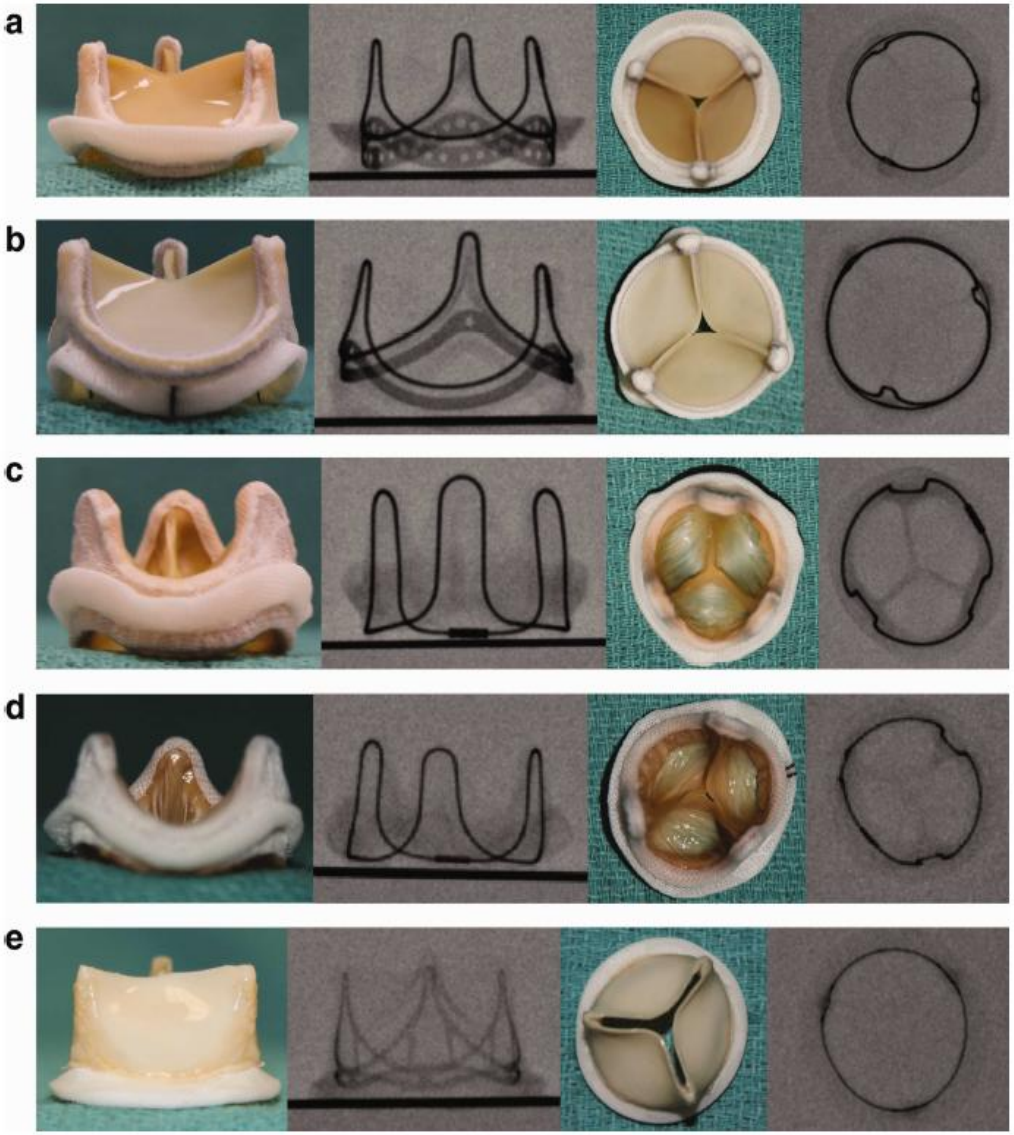
DVIR et al. Euro PCR 2012

Valve in Valve International Registry



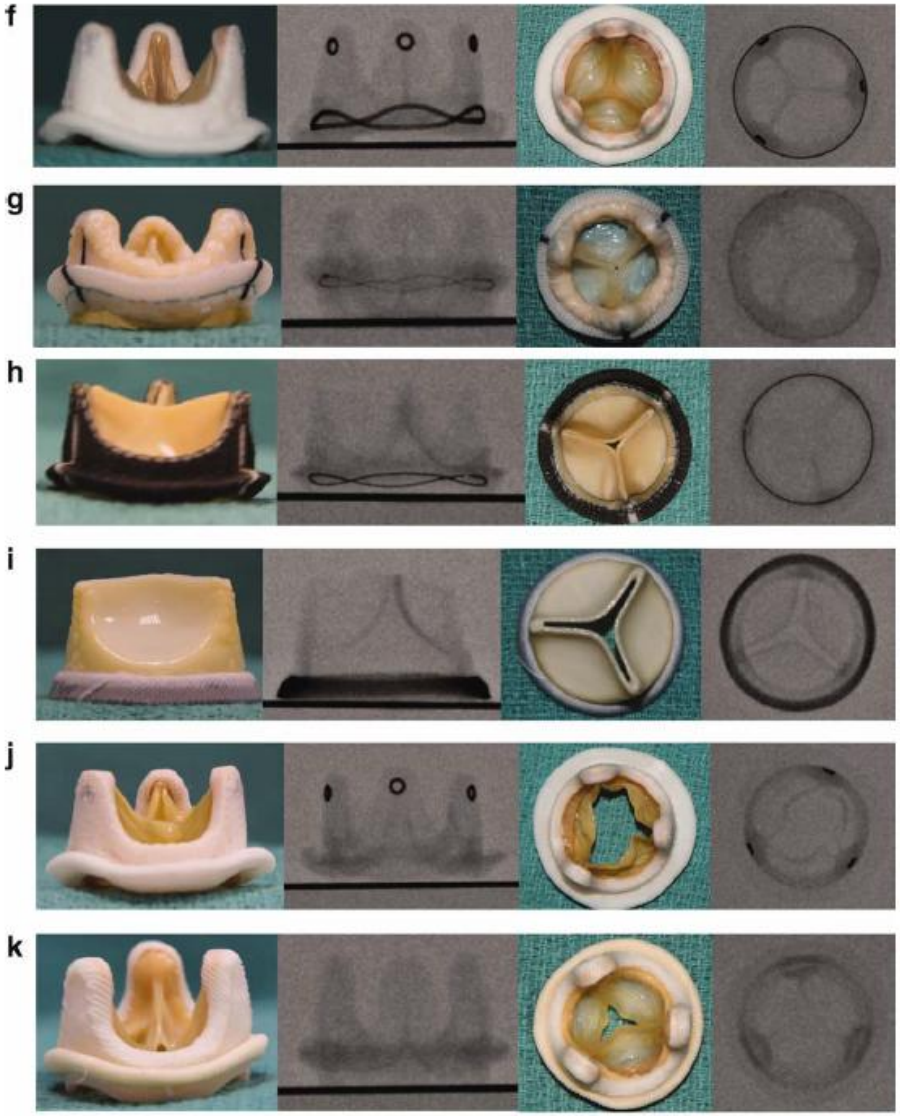
DVIR et al. Euro PCR 2012

Design of Bioprosthetic Valves



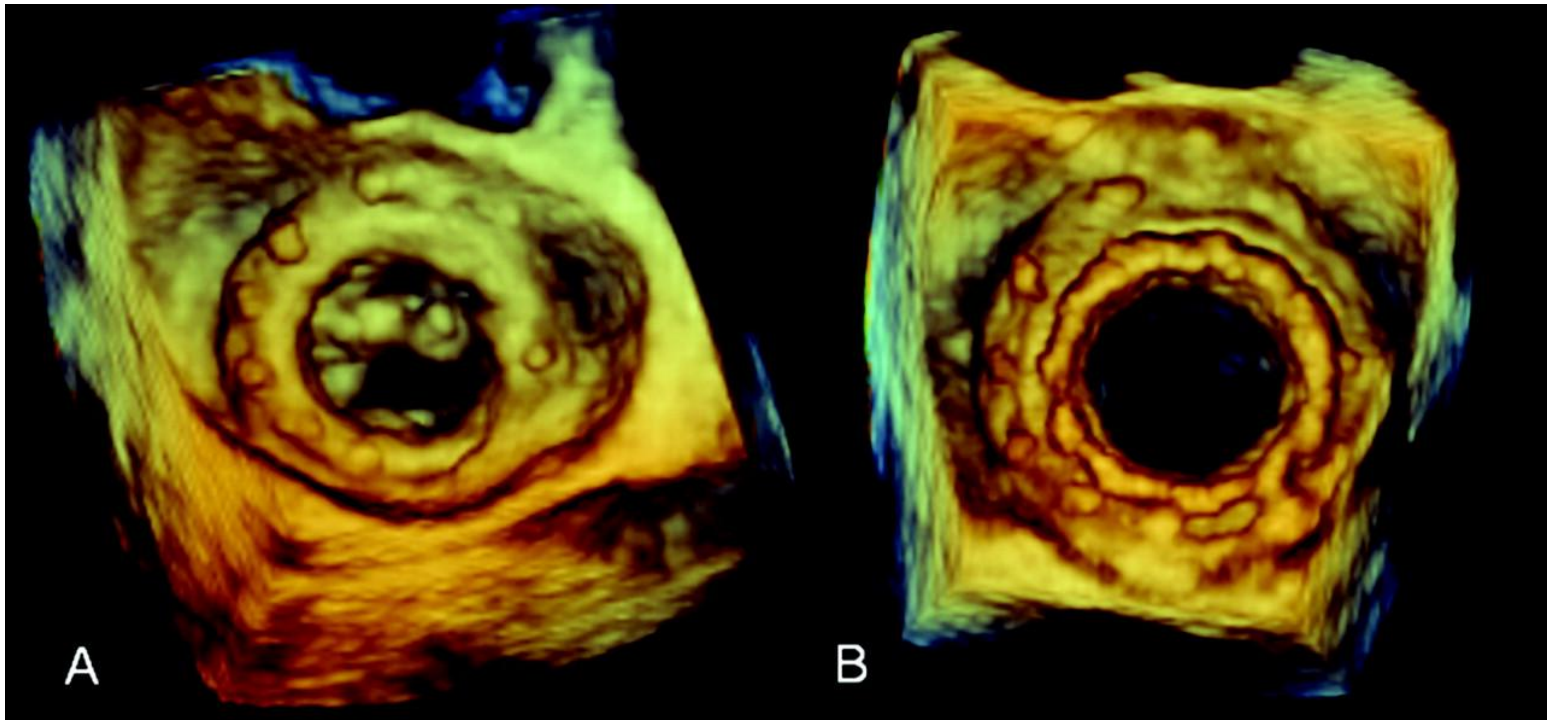
Bapat et al. CCVI 2013;81:853-61

Design of Bioprosthetic Valves



Bapat et al. CCVI 2013;81:853-61

Valve in Valve



Webb et al. Circulation 2010;121:1848-57

Emerging Indications

- ✓ Valve in Valve
- ✓ Pure Aortic Regurgitation
- ✓ Combined CAD
- ✓ Bicuspid Aortic Valves

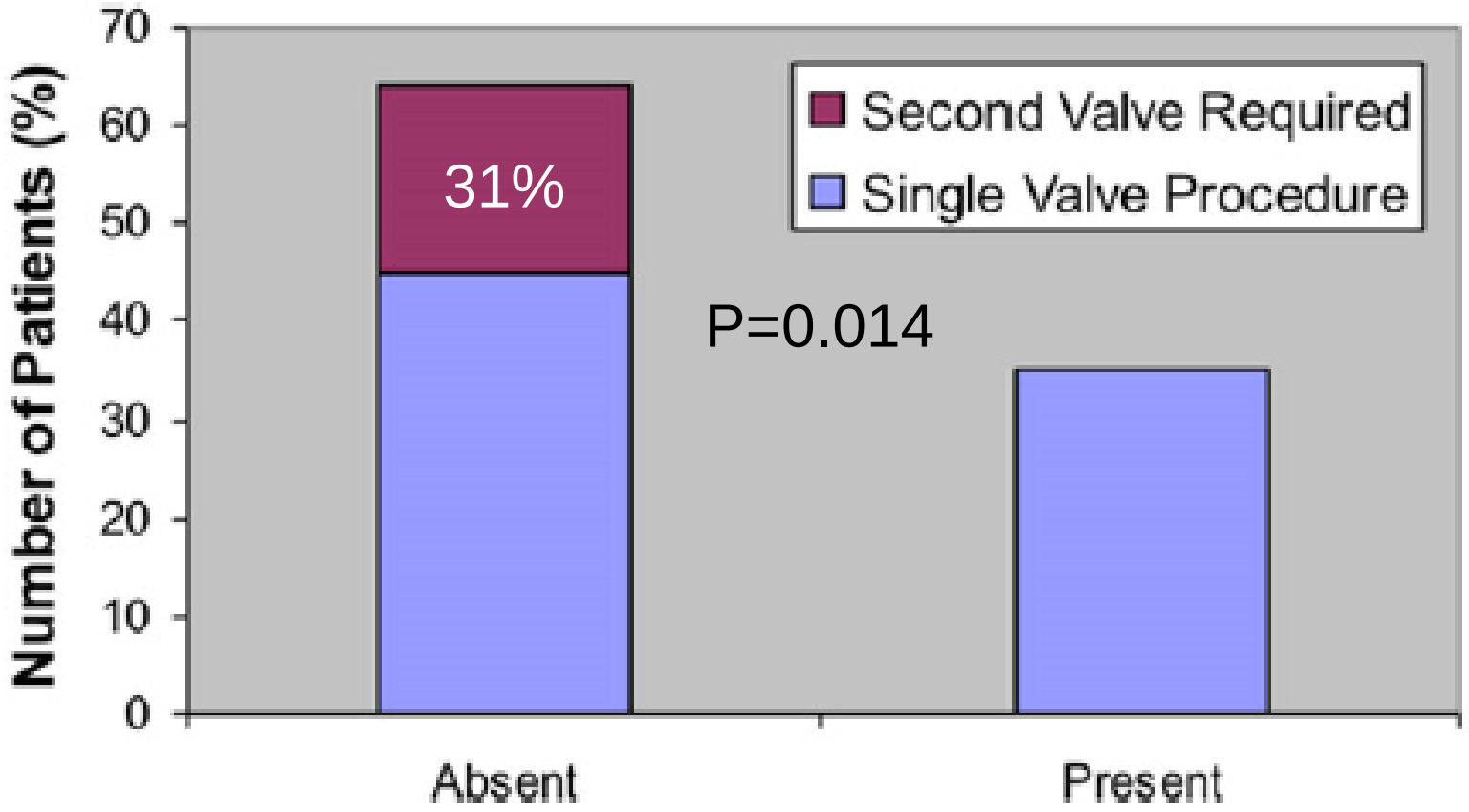
Pure Aortic regurgitation

TAVR for Aortic regurgitation

Patients (n)	43
Non surgical patient (%)	100
Corevalve (%)	100
Implantation success (%)	98
Procedure success (%)	74
Second valve (%)	19
Stroke (%)	5
30-day death (%)	5

Roy et al. JACC 2013 (ahead of print)

TAVR for Aortic regurgitation



Roy et al. JACC 2013 (ahead of print)

Emerging Indications

- ✓ Valve in Valve
- ✓ Pure Aortic Regurgitation
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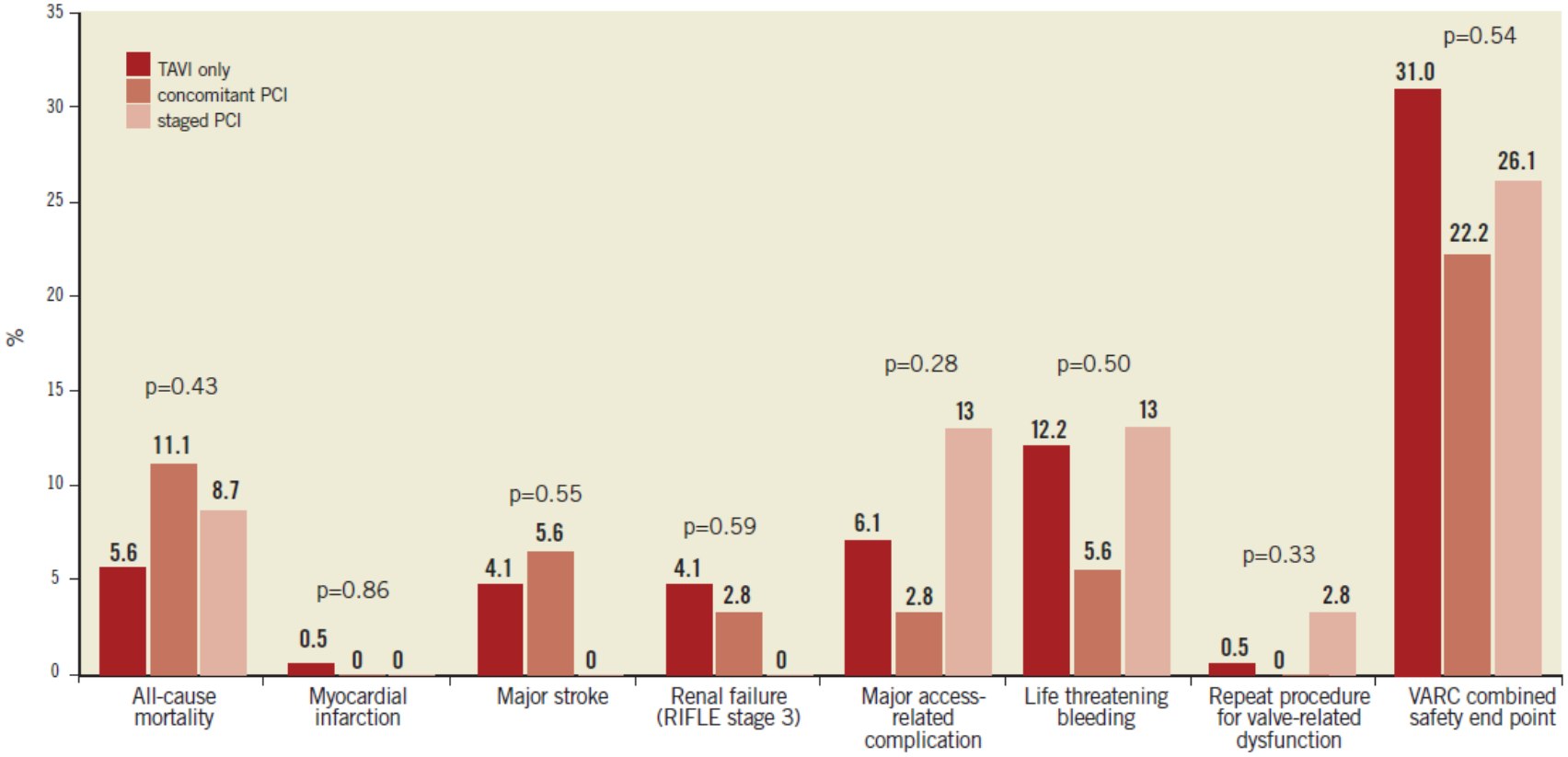
- ✓ Bicuspid Aortic Valves

Combined CAD

TAVI (n)	256
Coronary artery disease (%)	61
TAVI TF (%)	85
Corevalve (%)	73
Stage PCI (%)	9
Concomitant PCI and TAVI (%)	14
PCI success (%)	93

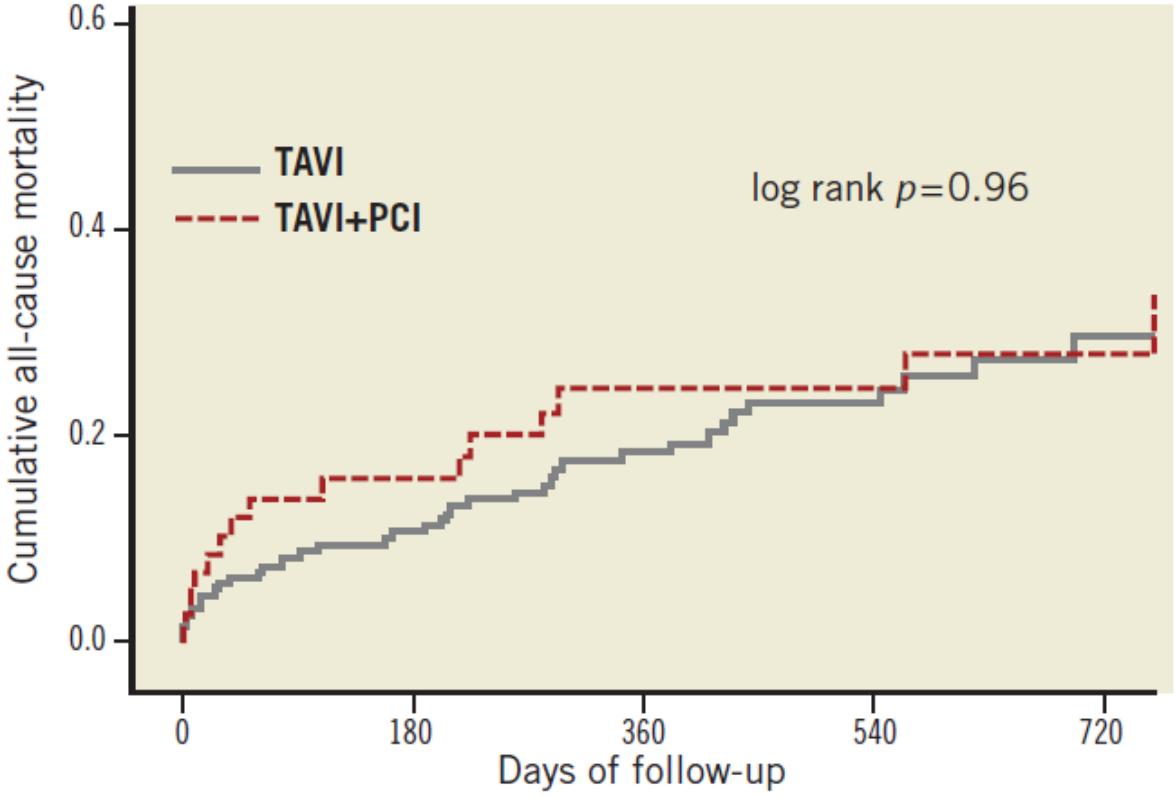
Wenaweser et al. Eurointervention 2011; 7: 541-8

Combined CAD



Wenaweser et al. Eurointervention 2011; 7: 541-8

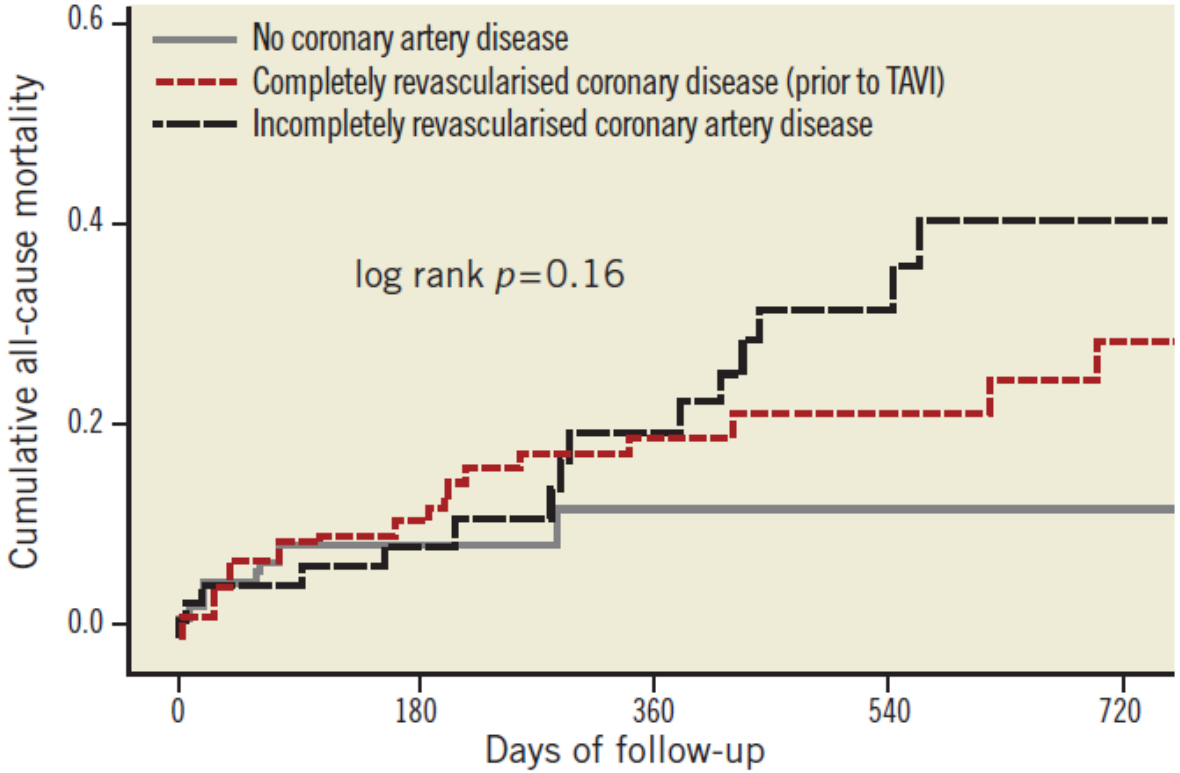
Combined CAD



TAVI	197	145	89	62	30
TAVI+PCI	59	41	31	25	12

Wenaweser et al. Eurointervention 2011; 7: 541-8

Combined CAD



No CAD	89	68	42	30	18
Complete revasc.	53	38	21	16	3
Incomplete revasc.	55	39	26	16	9

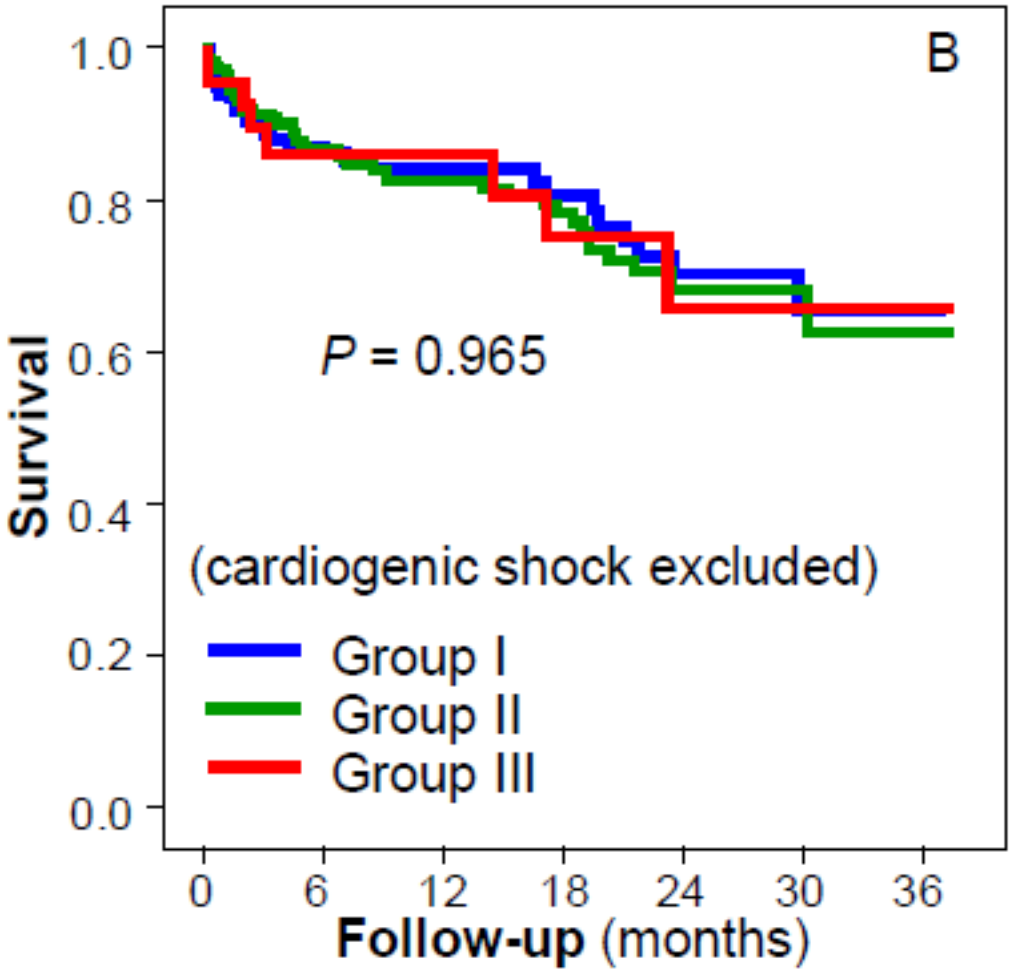
Wenaweser et al. Eurointervention 2011; 7: 541-8

Combined CAD

Transapical TAVI (n)	419
Edwards (%)	100
Coronary artery disease (%)	63
Combined PCI and TAVI (%)	11
PCI after TAVI (%)	98
PCI success (%)	100

Pasic et al. Intreract Cardiovasc Thorac Surg 2012;14(4):463-8

Combined CAD



Pasic et al. Intreract Cardiovasc Thorac Surg 2012;14(4):463-8

Combined CAD

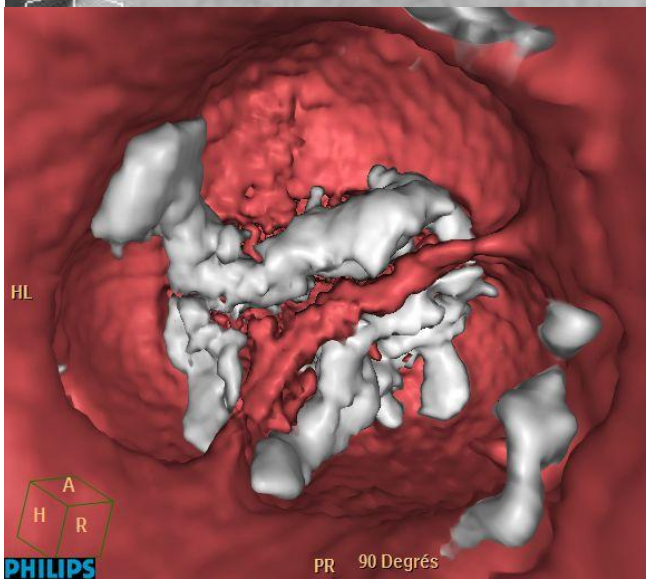
- ✓ Which lesion should be treated ?
- ✓ When should we do it: Before, during or after TAVI ?
- ✓ Which valve ?

Emerging Indications

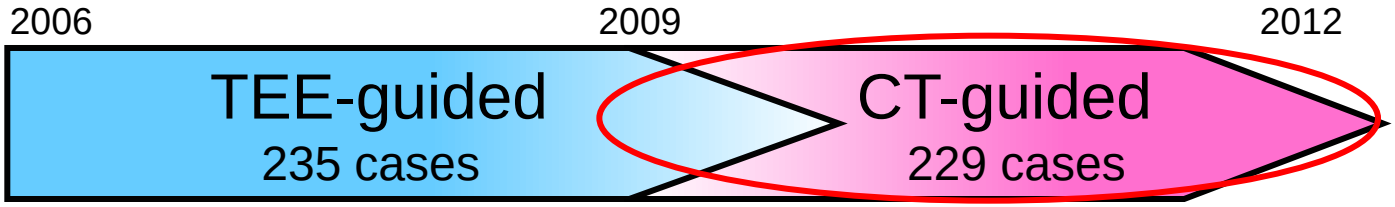
- ✓ Valve in Valve
- ✓ Pure Aortic Regurgitation
- ✓ Combined CAD
- ✓ Bicuspid Aortic Valves

Bicuspid aortic Valve

- Bicuspidy is regarded as a relative contraindication to TAVI due to the risk of uneven expansion of the bioprosthesis.
- Thus, the safety and efficacy of TAVI for this anatomic variation still remains unclear.



Bicuspid aortic Valve



Of 21 cases, 15 (71.4%) were not diagnosed as bicuspid valve by echocardiography

Watanabe, Lefèvre et al. ACC 2012

Bicuspid aortic Valve

	Bicuspid	Non-bicuspid	P
Patient number	21	208	
Age, years	82.0 ± 7.0	83.2 ± 6.5	0.43
Male gender	12 (57.1%)	111 (53.4%)	0.74
NYHA class III / IV	19 (90.5%)	183 (88.0%)	0.74
Coronary artery disease	10 (47.6%)	121 (58.2%)	0.35
Previous CABG	2 (9.5%)	28 (13.5%)	0.61
Peripheral artery disease	5 (23.8%)	68 (32.7%)	0.41
Cerebrovascular disease	1 (4.8%)	13 (6.2%)	0.79
COPD	5 (23.8%)	50 (24.0%)	0.98
eGFR <60 ml/min.	12 (57.1%)	124 (59.6%)	0.83
Logistic EuroSCORE, %	19.9 ± 11.9	20.1 ± 11.4	0.95

Watanabe, Lefèvre et al. ACC 2012

Bicuspid aortic Valve

	Bicuspid	Non-bicuspid	P
Patient number	21	208	
Aortic valve area, cm^2	0.67 ± 0.11	0.65 ± 0.14	0.56
Mean pressure gradient, mmHg	47.8 ± 18.6	48.1 ± 17.0	0.94
LVEF <40%	6 (28.6%)	54 (26.0%)	0.80
Aortic annulus size (TEE), mm	23.4 ± 2.7	22.5 ± 1.9	0.15
Aortic regurgitation (0-4)	0.95 ± 0.74	0.83 ± 0.70	0.47
Mitral regurgitation (0-4)	0.74 ± 0.87	0.82 ± 0.67	0.62

Watanabe, Lefèvre et al. ACC 2012

Bicuspid aortic Valve

	Bicuspid	Non-bicuspid	P
Patient number	21	208	
Mean annulus size (CT), mm	**24.7 ± 3.0**	**23.7 ± 1.9**	**0.14**
Short-axis annulus size (CT), mm	22.7 ± 2.8	21.9 ± 1.9	0.21
Long-axis annulus size (CT), mm	**27.4 ± 3.1**	**26.4 ± 2.5**	**0.08**
Long/short Diam-CT ratio	1.21 ± 0.07	1.21 ± 0.08	0.89

Watanabe, Lefèvre et al. ACC 2012

Bicuspid aortic Valve

	Bicuspid	Non-bicuspid	P
Patient number	21	208	
Edwards	11 (52.4%)	174 (83.7%)	<0.01
Transfemoral	5 (23.8%)	79 (38.0%)	0.93
Transapical	3 (14.3%)	37 (17.8%)	
Transaortic	3 (14.3%)	58 (27.9%)	
CoreValve	10 (47.6%)	34 (16.3%)	<0.01
Transfemoral	8 (38.1%)	26 (12.5%)	0.71
Transsubclavian	0	3 (1.4%)	
Transaortic	2 (9.5%)	5 (2.4%)	
Valve size, mm	27.8 ± 3.0	26.4 ± 2.1	0.07

Watanabe, Lefèvre et al. ACC 2012

Bicuspid aortic Valve

	Bicuspid	Non-bicuspid	P
Patient number	21	208	
Mean pressure gradient, mmHg	**10.0 ± 3.4**	**9.7 ± 4.1**	**0.78**
LVEF, %	53.2 ± 15.1	54.4 ± 12.2	0.67
Aortic regurgitation ≥2	**4 (19.0%)**	**31 (14.9%)**	**0.54**
Aortic regurgitation ≥3	0	2 (1.0%)	0.83
Annulus rupture	0	3 (1.4%)	0.75
Valve migration	0	3 (1.4%)	0.75
Coronary occlusion	1 (4.8%)	4 (1.9%)	0.39
Major vascular complication	1 (4.8%)	9 (4.3%)	0.63
Acute kidney injury	1 (4.8%)	23 (11.1%)	0.33
New pacemaker	3 (14.3%)	15 (7.2%)	0.22

Watanabe, Lefèvre et al. ACC 2012

Bicuspid aortic Valve

	Bicuspid	Non-bicuspid	P
Patient number	21	208	
Device success	21 (100%)	193 (92.8%)	0.23
30-day mortality	1 (4.8%)	17 (8.2%)	0.49
30-day combined safety point	3 (14.3%)	28 (13.5%)	0.56
ICU stay, days	4.5 ± 3.6	4.1 ± 4.2	0.70
Hospital stay, days	8.5 ± 3.6	11.0 ± 6.2	0.08

Watanabe, Lefèvre et al. ACC 2012

Conclusions (Bicuspid valves)

- ✓ The best cases were probably selected.
- ✓ Bicuspidy is underestimated by 2D echo as compared to MSCT.
- ✓ There is a trend toward larger aortic annulus requiring larger bioprosthesis.
- ✓ Device success and clinical outcome after TAVI is similar.
- ✓ Long term durability remains to be assessed