



Centre for  
Heart Valve Innovation  
St. Paul's Hospital, Vancouver

# Transcatheter Valve-In-Valve Aortic Bioprostheses

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# **Disclosure Statement of Financial Interest**

**Consultant:**

**Edwards Lifesciences**

**JC Medical Inc.**

# Transcatheter Valve-in-Valve



**Surgical Valve**

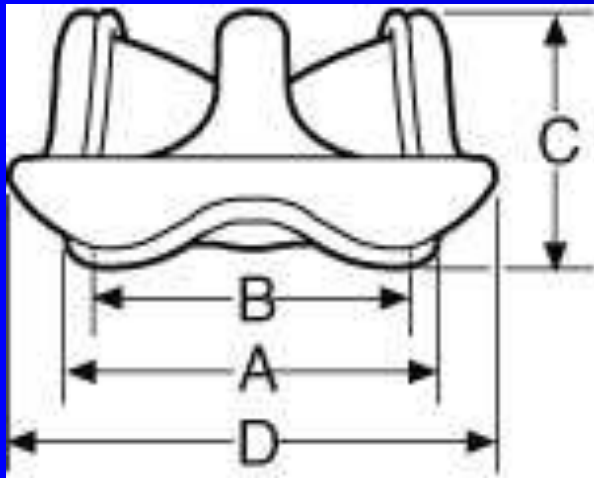


**Edwards Sapien™ Valve**



**Valve-In-Valve**


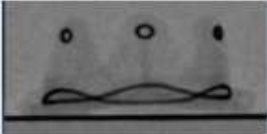
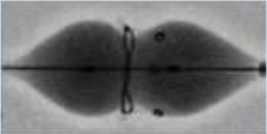


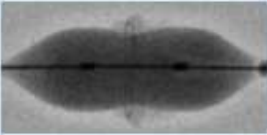


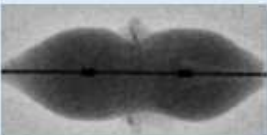

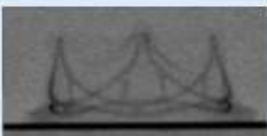
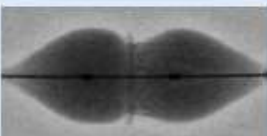


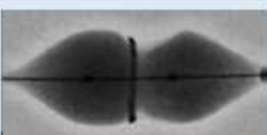


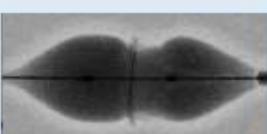


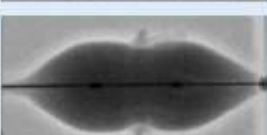
# Aortic Pericardial Tissue Valve (Model 2700TFX)



- A. Mounting Diameter (Annulus)
- B. Internal Diameter (Stent I.D.)
- C. Profile Height
- D. External Sewing Ring Diameter

Size	19mm	21mm	23mm	25mm	27mm	29mm
A	19	21	23	25	27	29
B	18	20	22	24	26	28
C	13	14	15	16	17	18
D	28	31	33	35	38	40


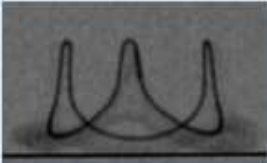
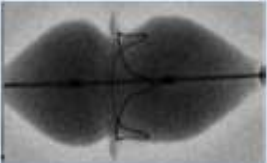

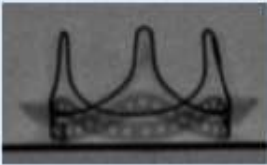
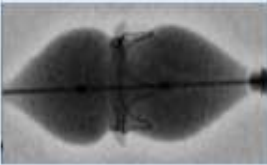

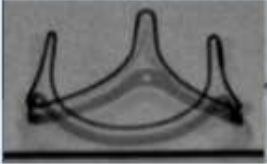
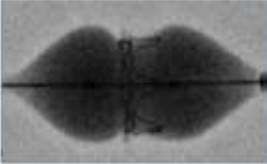

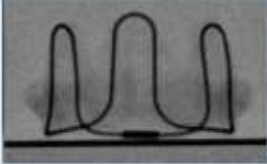
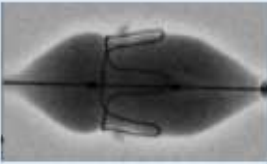


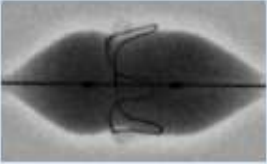

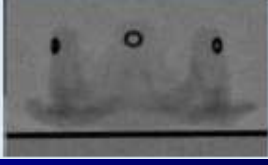
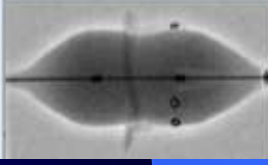
**TABLE 1** Main Characteristics of SHVs

Manufacturer	Valve Model	SHV Image	Leaflet Tissue	Relationship of Leaflets to the Stent Frame	SHV Fluoroscopic Image	Neoannulus Fluoroscopic Image
<b>Stented SHV</b>						
St. Jude Medical (St. Paul, Minnesota)	Hancock II Tissue valve		Porcine	Inside		
	Epic (Biocor) valve		Porcine	Inside		
	Epic Supra (Biocor Supra) valve		Porcine	Inside		
Sorin (Milan, Italy)	Trifecta		Bovine Pericardium	Outside		
	Mitroflow		Bovine Pericardium	Outside		
	Soprano Armonia		Bovine Pericardium	Inside		
Vascutek (Inchinnan, United Kingdom)	Aspire		Porcine	Inside		

*Continued on the next page*

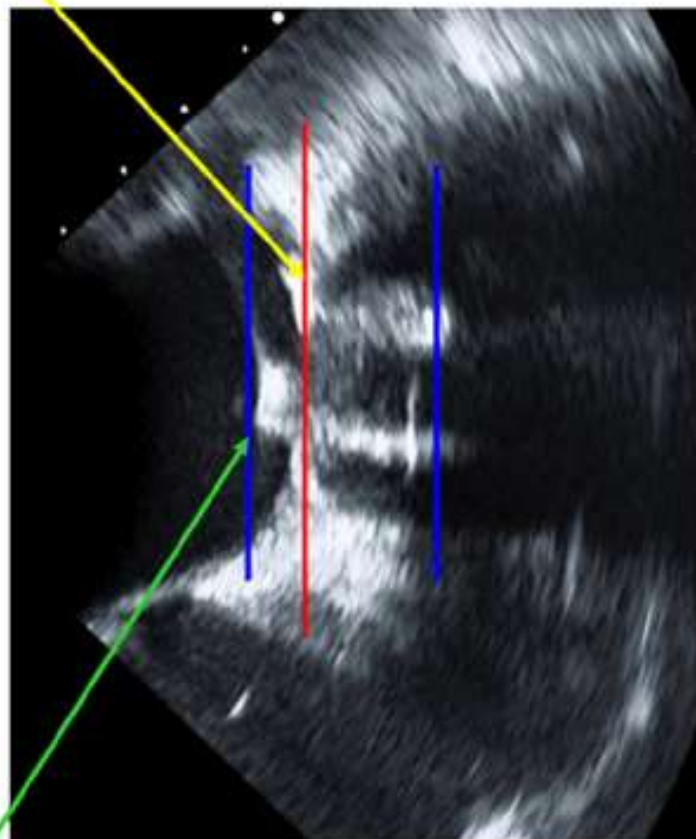
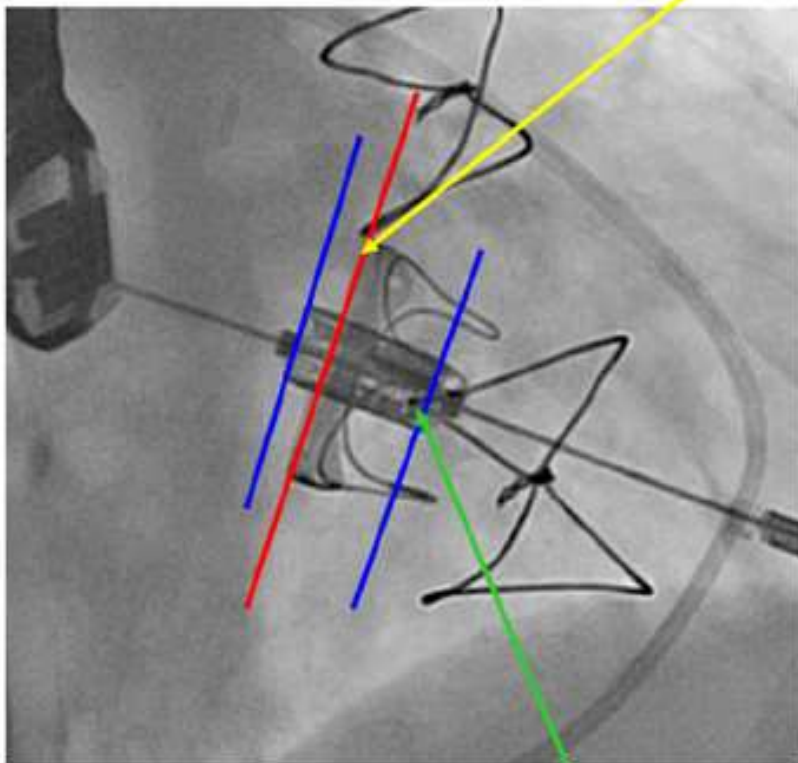


**TABLE 1** Main Characteristics of SHVs

Manufacturer	Valve Model	SHV Image	Leaflet Tissue	Relationship of Leaflets to the Stent Frame	SHV Fluoroscopic Image	Neoannulus Fluoroscopic Image
<b>Stented SHV</b>						
Edwards Lifesciences (Irvine, California)	Carpentier-Edwards Perimount 2700		Bovine Pericardium	Inside		
	Carpentier-Edwards Perimount		Bovine Pericardium	Inside		
	Carpentier-Edwards Perimount Magna and Magna ease		Bovine Pericardium	Inside		
	Carpentier-Edwards aortic porcine bioprosthesis		Porcine	Inside		
	Carpentier-Edwards supra-annular aortic porcine bioprosthesis		Porcine	Inside		
Medtronic (Minneapolis, Minnesota)	Mosaic Tissue valve		Porcine	Inside		

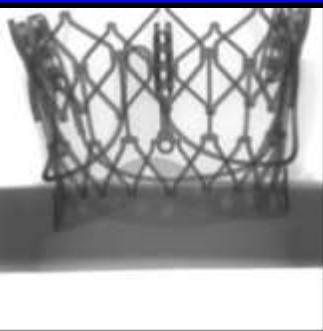
# Positioning of Transcatheter Valve

**Surgical Valve**

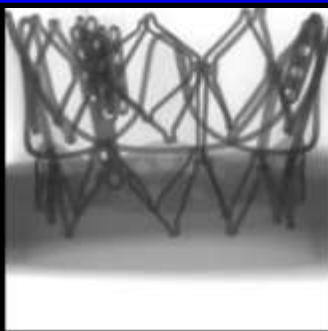


**Transcatheter Valve Stent**

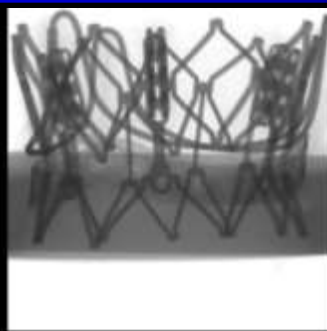
# SAPIEN XT In-Vitro Assessment



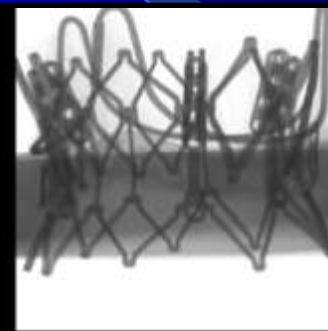
-2.2 mm (-15.6%)



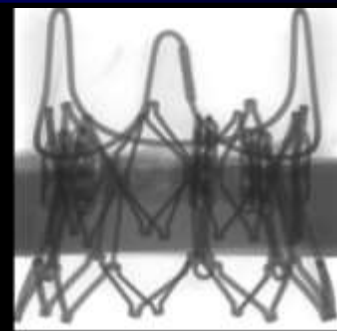
1 mm (7.4%)



2.6 mm (18.6%)



4.1 mm (28.9%)

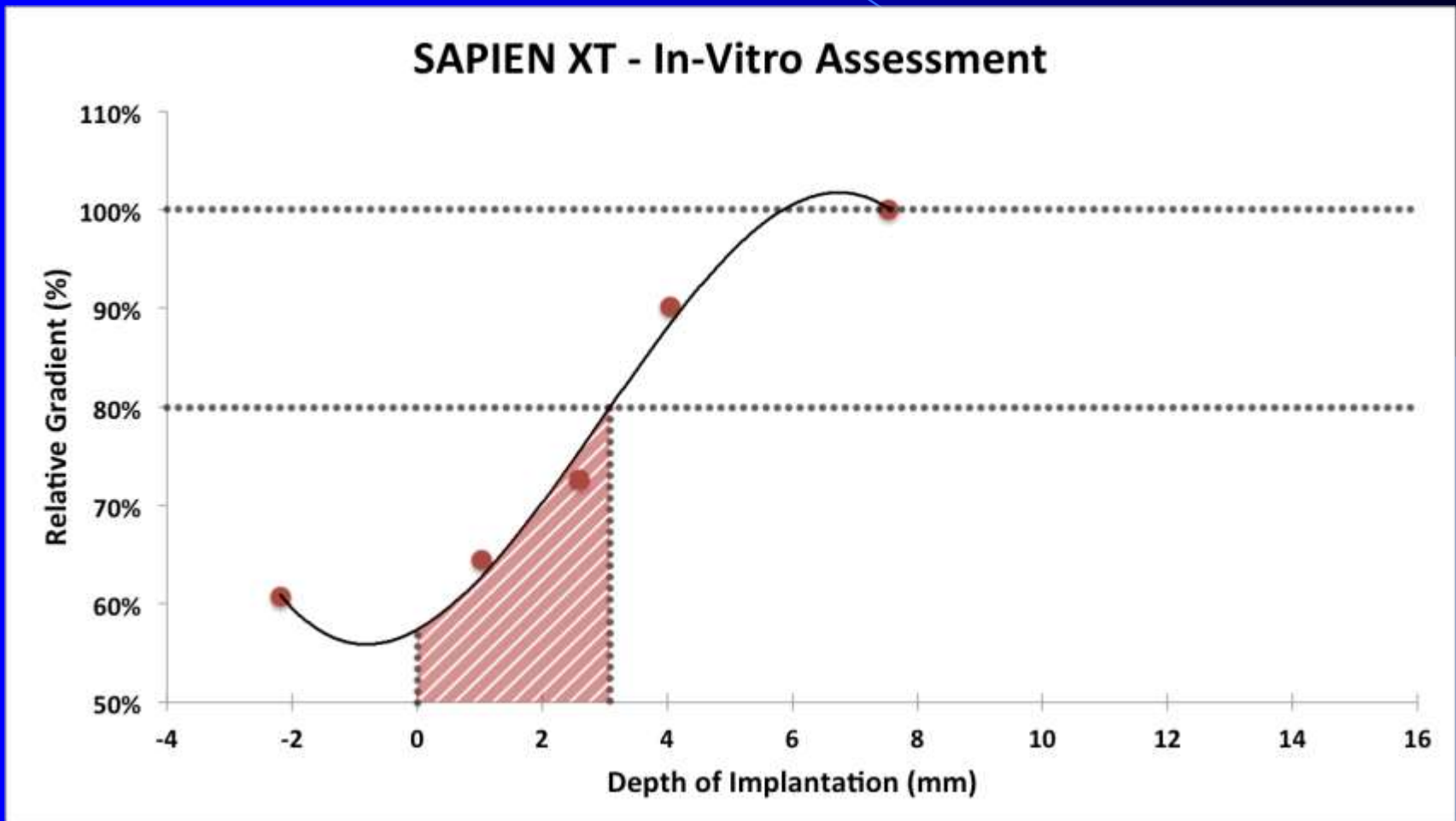


7.5 mm (53.8%)

**SAPIEN XT 23mm in Perimount 19mm**



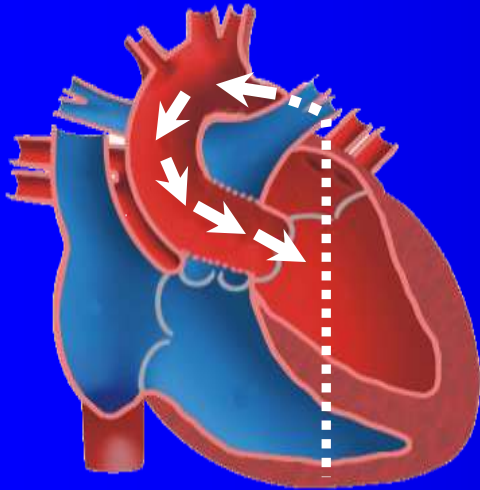
# SAPIEN XT 23mm in Perimount 19mm



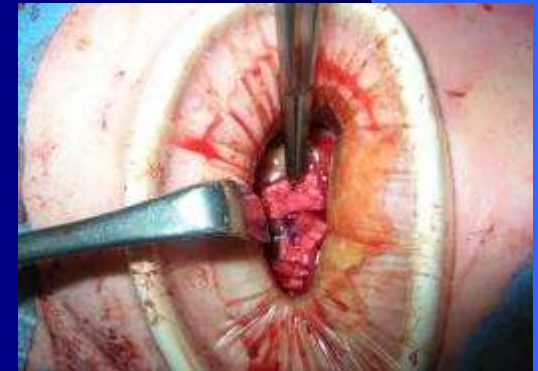
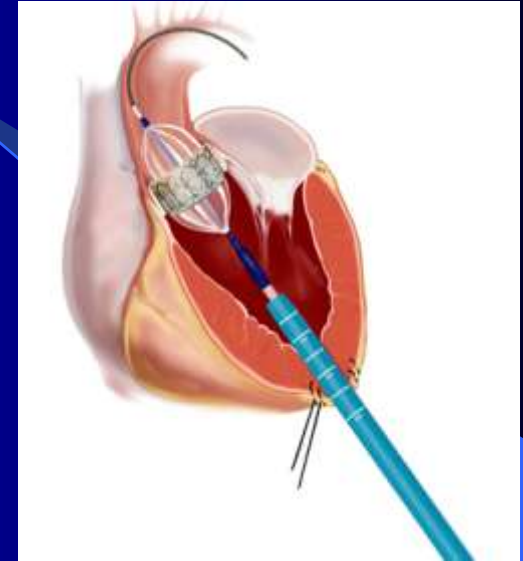
**Danny Dvir, MD**

# Approaches

## Aortic Valve-in-Valve



Edwards Sapien



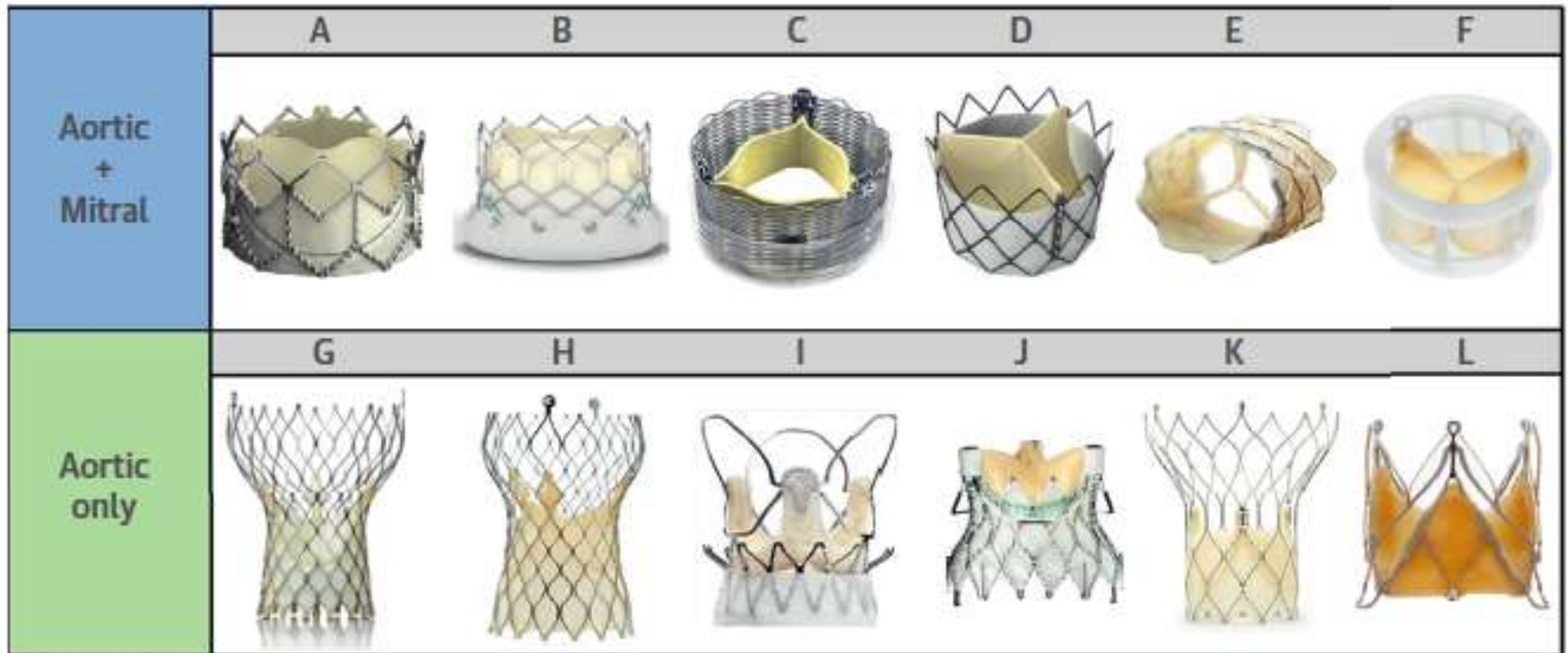
Transapical



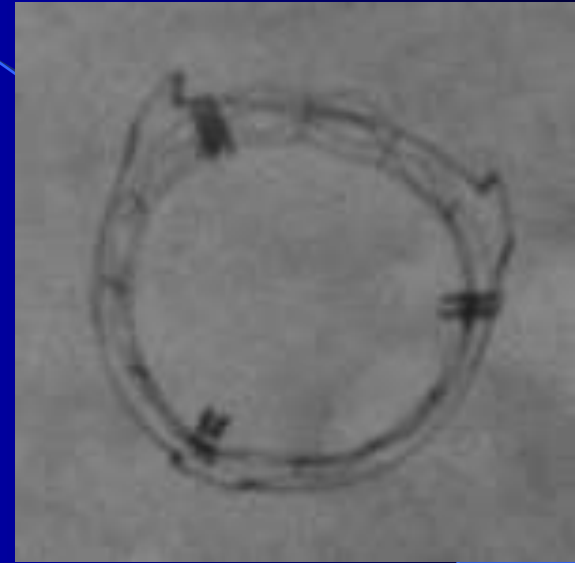
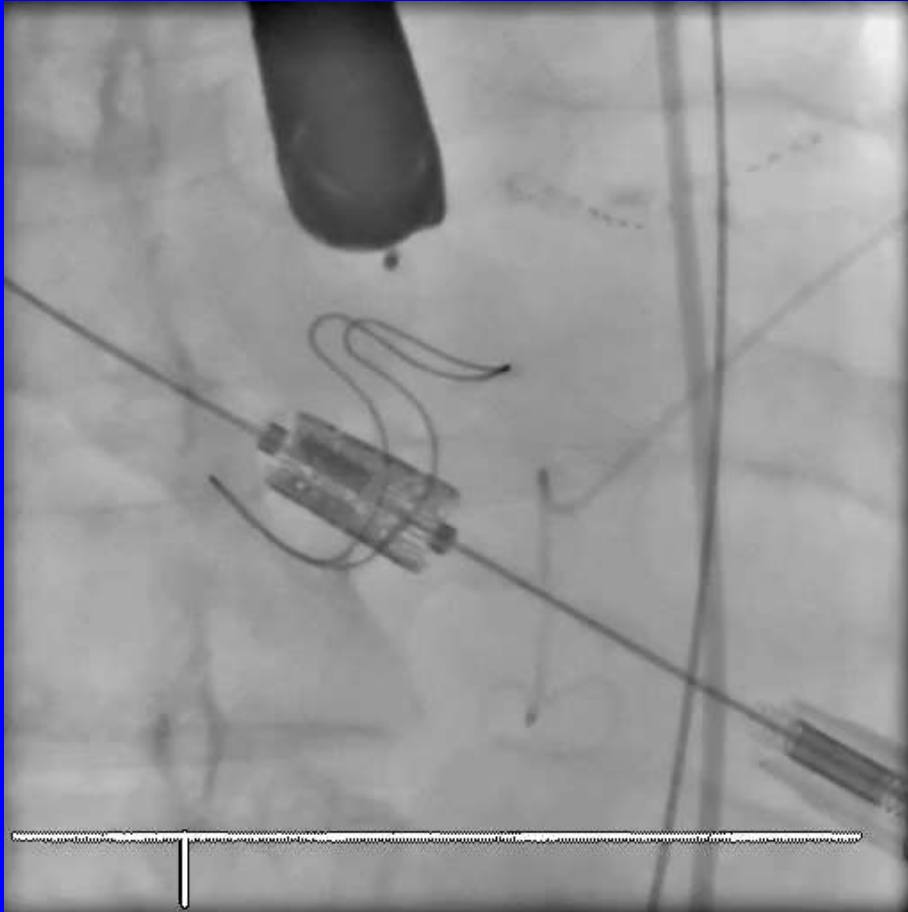
Transarterial

# Transcatheter Valves Used for Valve-in-Valve

Transcatheter Valves Used for Valve-in-Valve Procedures

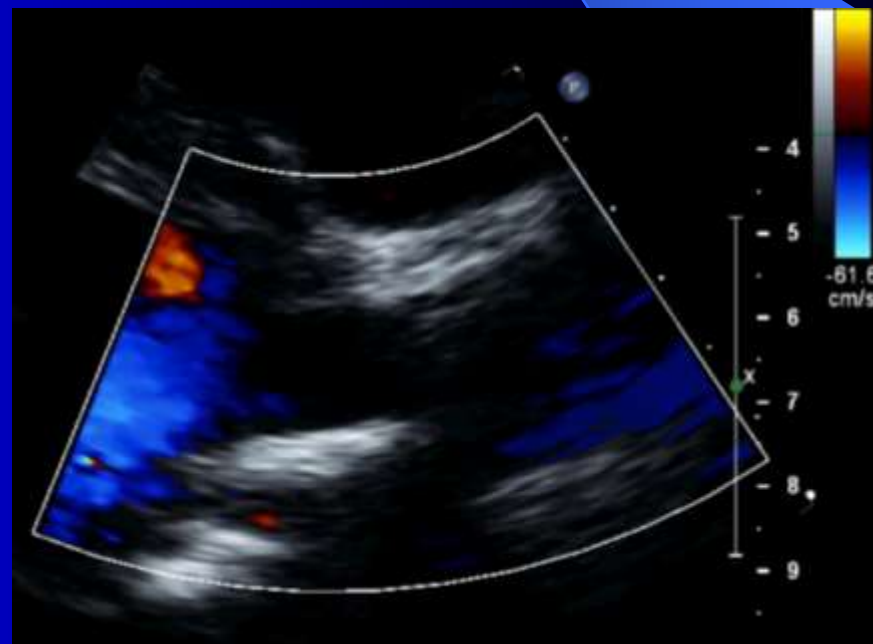
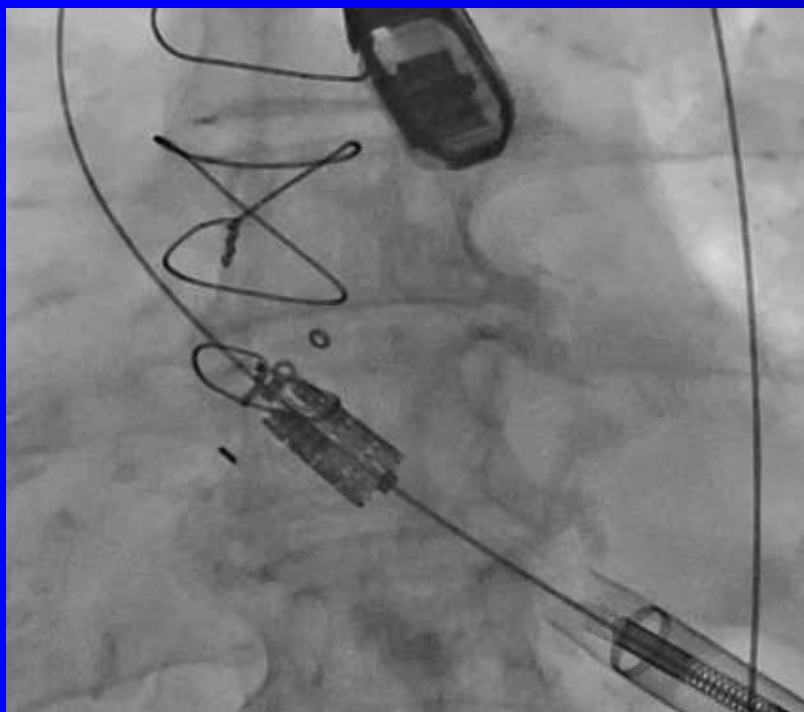
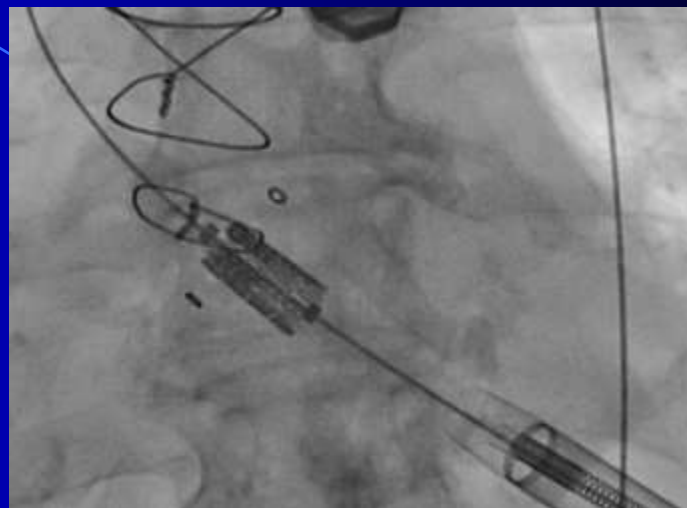


# Aortic Valve-in-Valve



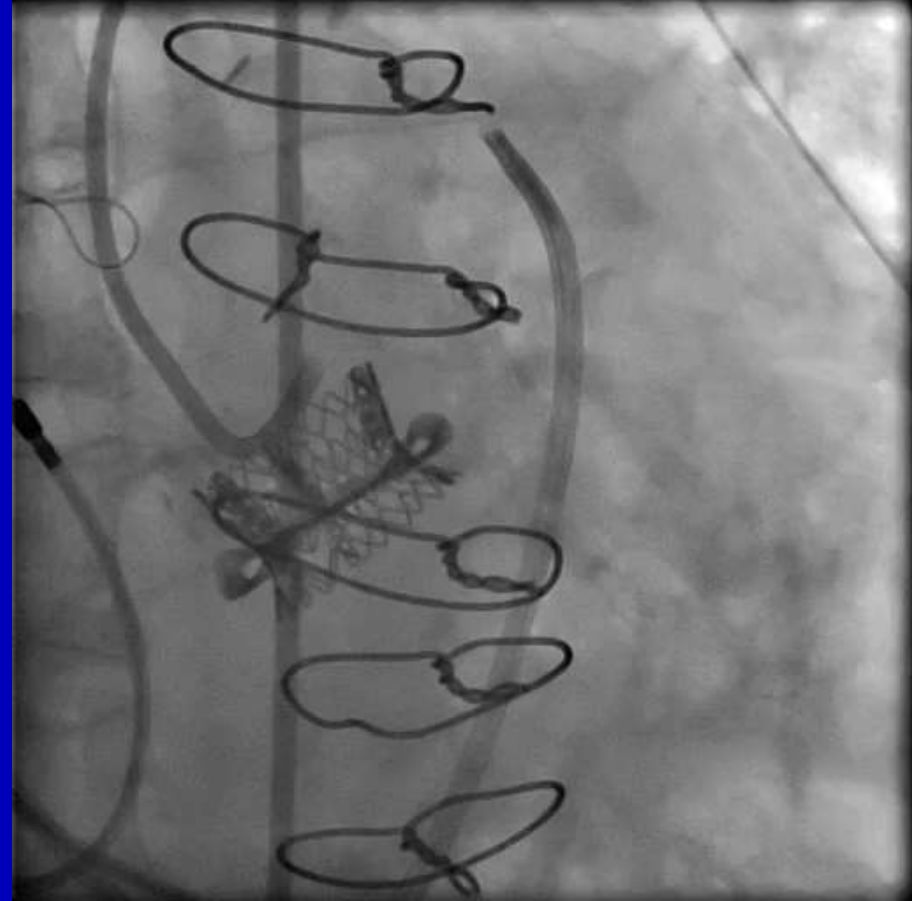
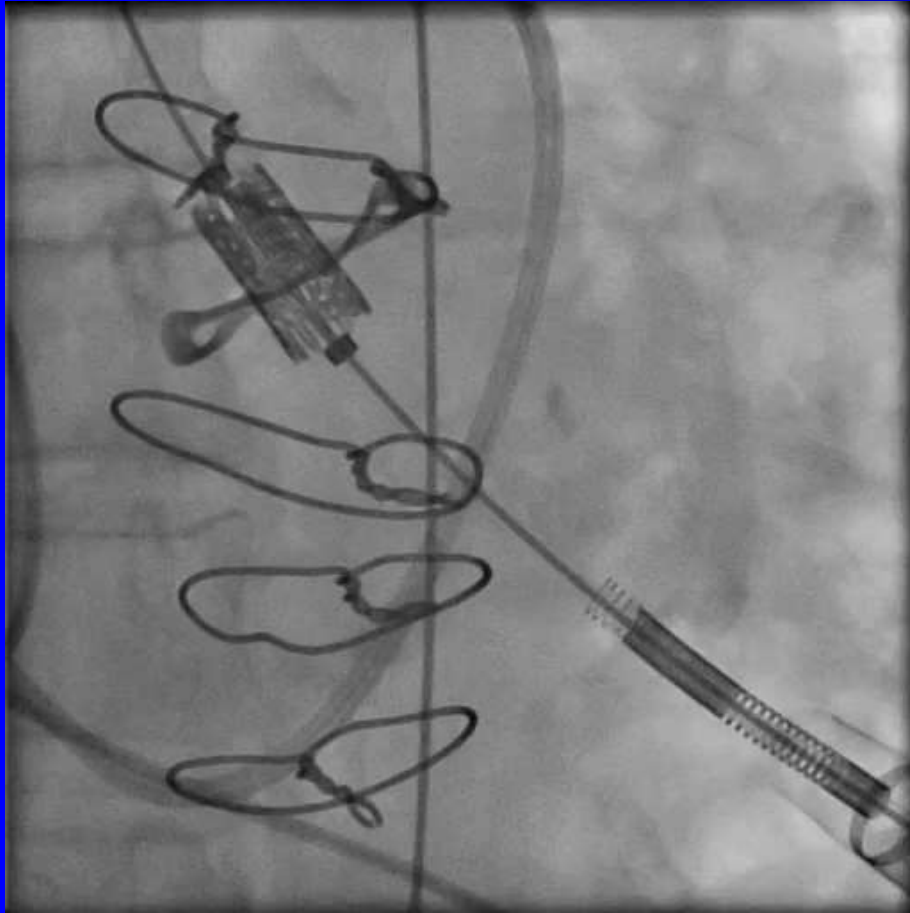


# Aortic Valve-in-Valve – Mosiac valve





# Left Main Obstruction



# Transcatheter Aortic and Mitral Valve-in-Valve Implantation for Failed Surgical Bioprosthetic Valves

## An 8-Year Single-Center Experience

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Min Gao, MD, PhD,‡ Christopher R. Thompson, MD,† Brad Munt, MD,† Robert R. Moss, MD,†  
Philipp Blanke, MD,§ Jonathon Leipsic, MD,§ Danny Dvir, MD,† John G. Webb, MD†

### ABSTRACT

**OBJECTIVES** We report our 8-year experience in transcatheter aortic and mitral valve-in-valve (VinV) implantation.

**BACKGROUND** Feasibility and good early outcomes associated with transcatheter aortic and mitral VinV implantation into failed surgical bioprostheses have been confirmed, but the mid-term and long-term outcomes of transcatheter aortic and mitral VinV is unknown.

**METHODS** A total of 73 patients with aortic ( $n = 42$ ) and mitral ( $n = 31$ ) bioprosthetic valve dysfunction underwent transcatheter VinV implantation between April 2007 and December 2013. Edwards balloon-expandable transcatheter valves (Edwards Lifesciences Inc., Irvine, California) were used. Median follow-up was 2.52 years with a maximum of 8 years.

**TABLE 1** Baseline Characteristics

	All (n = 73)	Aortic (n = 42)	Mitral (n = 31)
Age, yrs	79.7 ± 9.4	80.5 ± 9.8	78.7 ± 8.8
Male	41 (56.2)	28 (67.7)	13 (42.0)
Diabetes mellitus	17 (23.3)	10 (23.8)	7 (22.6)
Coronary artery disease	45 (61.6)	29 (69.0)	16 (51.6)
PASP ≥60 mm Hg	20 (27.4)	7 (16.7)	13 (41.9)
Coronary artery bypass grafting	32 (43.8)	19 (45.2)	13 (41.9)
NYHA functional class III or IV	69 (94.5)	39 (92.9)	30 (96.8)
COPD (moderate + severe)	11 (15.1)	4 (9.5)	7 (22.6)
Cerebrovascular accident	17 (23.3)	7 (16.7)	10 (32.3)
Surgical valve size <23 mm	8 (11.0)	8 (19.0)	0 (0.0)
Peripheral vascular disease	17 (23.3)	13 (31.0)	4 (12.9)
Left ventricular ejection fraction, %	60 (45, 65)	57.5 (47, 65)	60 (40, 65)
Creatinine 100-149 mmol/l	32 (43.8)	20 (47.6)	12 (38.7)
Creatinine ≥150 mmol/l	11 (15.1)	9 (21.4)	2 (6.5)
STS score, %	9.6 (5.9, 13.4)	9.6 (6.2, 11.4)	9.7 (5, 16.6)
Failed surgical valves			
Stenosis	34 (46.6)	22 (52.4)	12 (38.7)
Regurgitation	27 (37.0)	13 (31.0)	14 (54.2)
Mixed	12 (16.4)	7 (16.7)	5 (16.1)

Values are mean ± SD, n (%), or median (quartile 1, quartile 3).

COPD = chronic obstructive pulmonary disease; NYHA = New York Heart Association; PASP = pulmonary artery systolic pressure; STS = Society of Thoracic Surgeons.

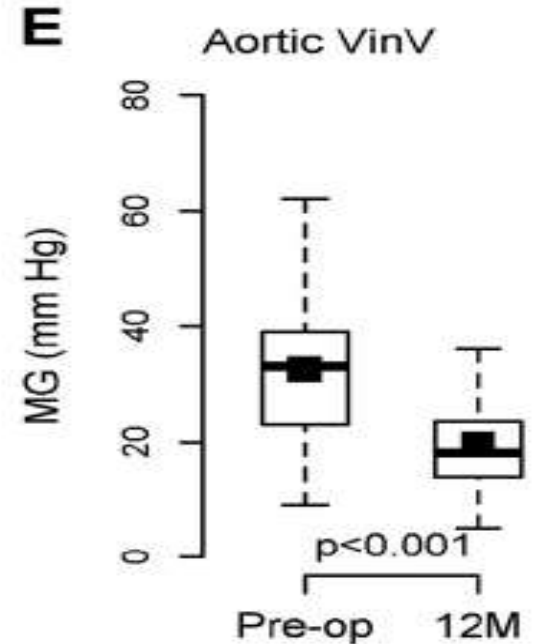
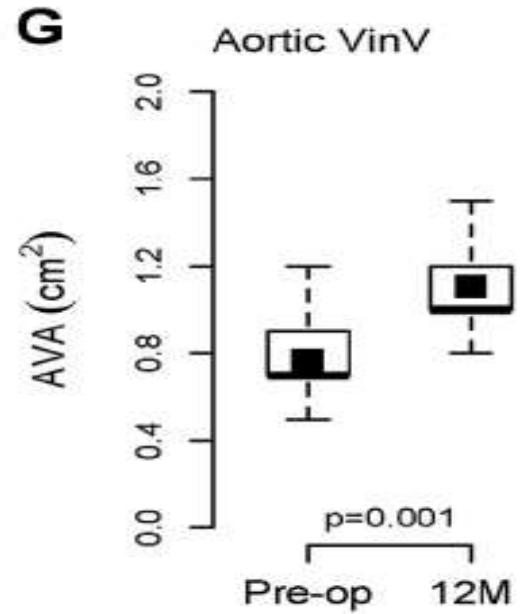
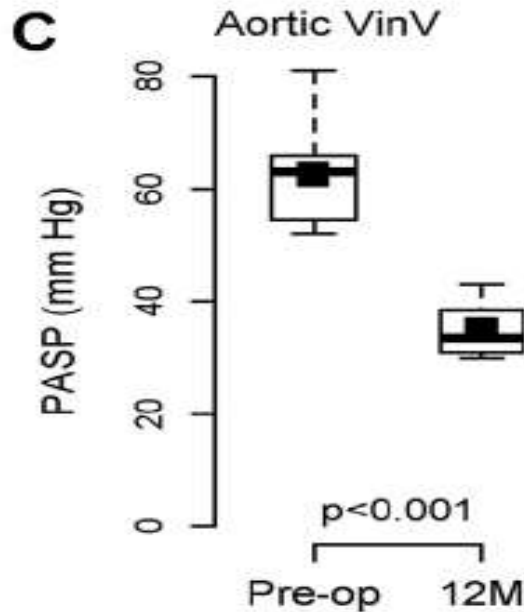
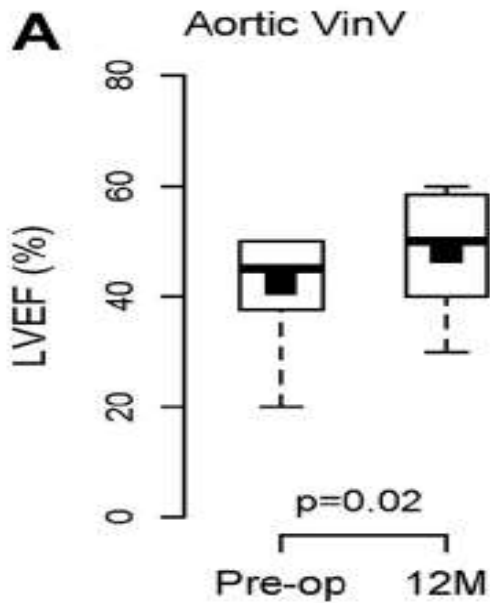


## 30-day all-cause mortality: 1.4%

**TABLE 2** Early and Late Complications

	Aortic Valv (n = 42)	
	30 Days	>30 Days
Major bleeding (2-3 U PRBC)	0	0
Life-threatening bleeding ( $\geq 4$ U PRBC)	2	1
Conversion to open surgery	1	0
Valve migration	0	0
ARF requiring hemodialysis	1	0
Myocardial infarction	0	0
Major vascular complication	0	0
Disabling stroke	0	0
Left main obstruction	1	0
Endocarditis	0	0
Valve thrombosis	0	2
Failed valve (structural)	0	1
THV-in-THV deployment	0	0
Permanent PM implantation	0	0

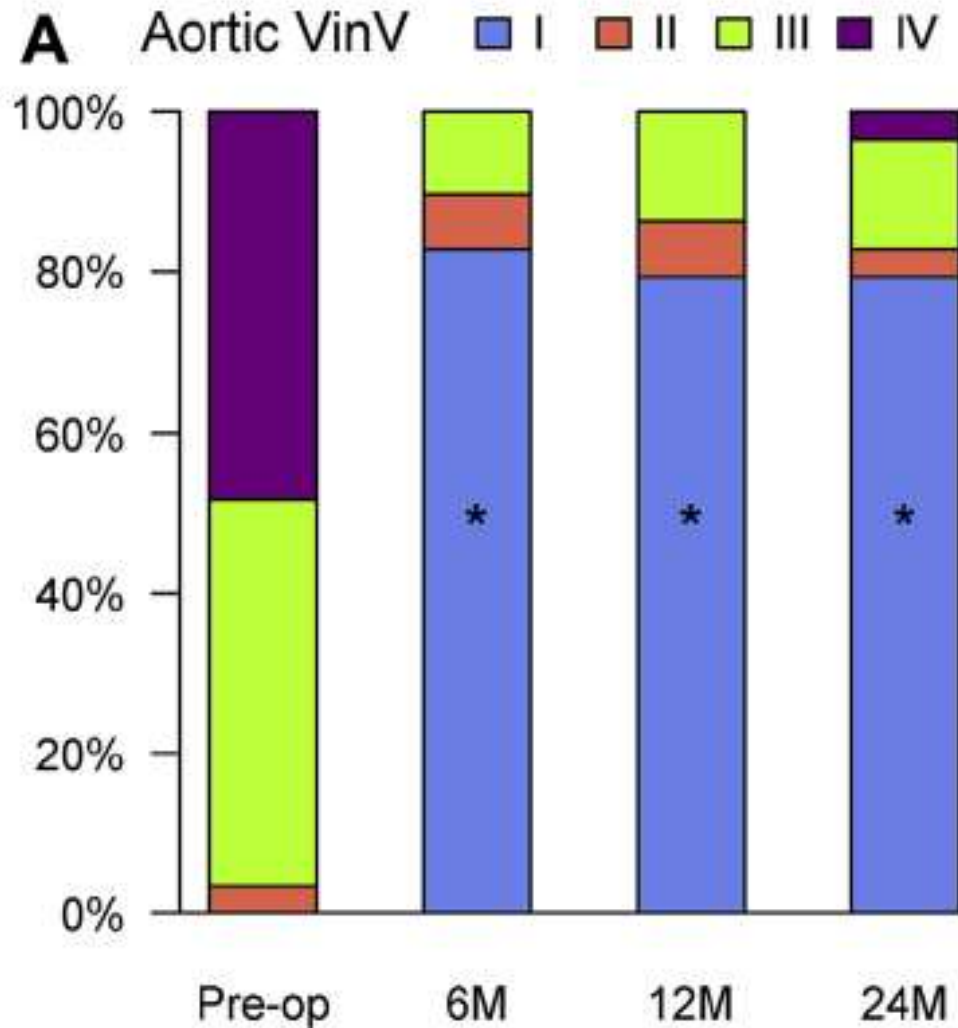
# Echocardiographic Outcomes



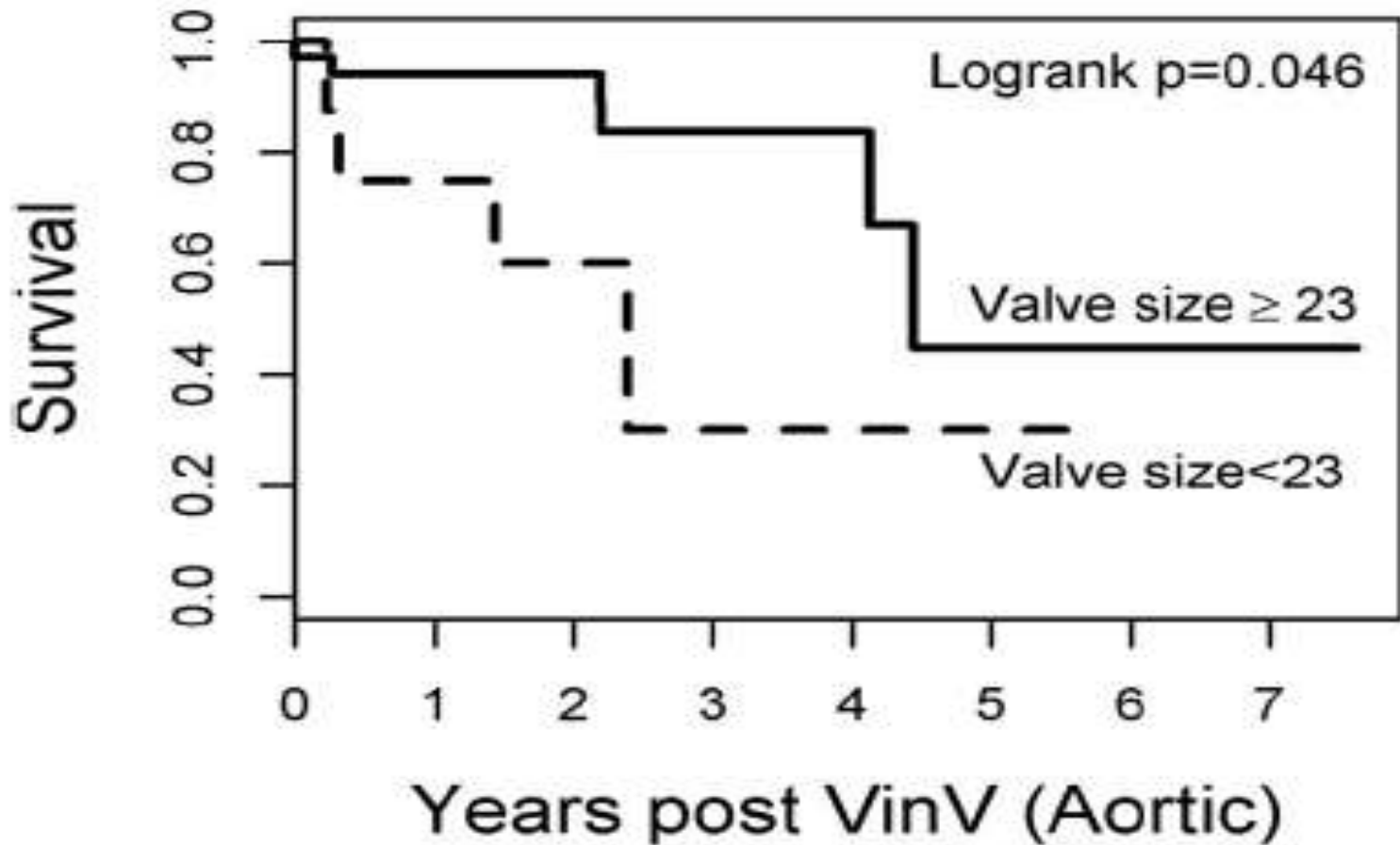


# Clinical Outcome

**FIGURE 2** Pre-Op and Post-Op NYHA Functional Class



# Mid-term Survival



# Factors Influencing Survival of Aortic Valve Patients

**TABLE 4** Factors Influencing the Survival of Aortic Valve Patients (n = 42)

	Univariate Model		Multivariate Model	
	Hazard Ratio (95% CI)	p Value	Hazard Ratio (95% CI)	p Value
Female	2.485 (0.614-10.07)	0.202		
PVD	2.752 (0.747-10.14)	0.128		
PASP $\geq$ 60 mm Hg	2.906 (0.692-12.21)	0.145		
LVEF <50%	1.742 (0.489-6.207)	0.392	2.945 (1.472-25.99)	0.049
CABG $\pm$ CAD	0.784 (0.177-3.475)	0.749		
Creatinine 100-149 mmol/l	0.925 (0.127-6.749)	0.938		
Creatinine $\geq$ 150 mmol/l	2.126 (0.428-10.57)	0.357		
DM	2.601 (0.639-10.59)	0.182	4.779 (0.741-11.71)	0.125
CVA	0.773 (0.995-6.304)	0.810		
Surgical valve size <23 mm	3.420 (0.951-12.30)	0.060	6.186 (1.001-22.82)	0.013

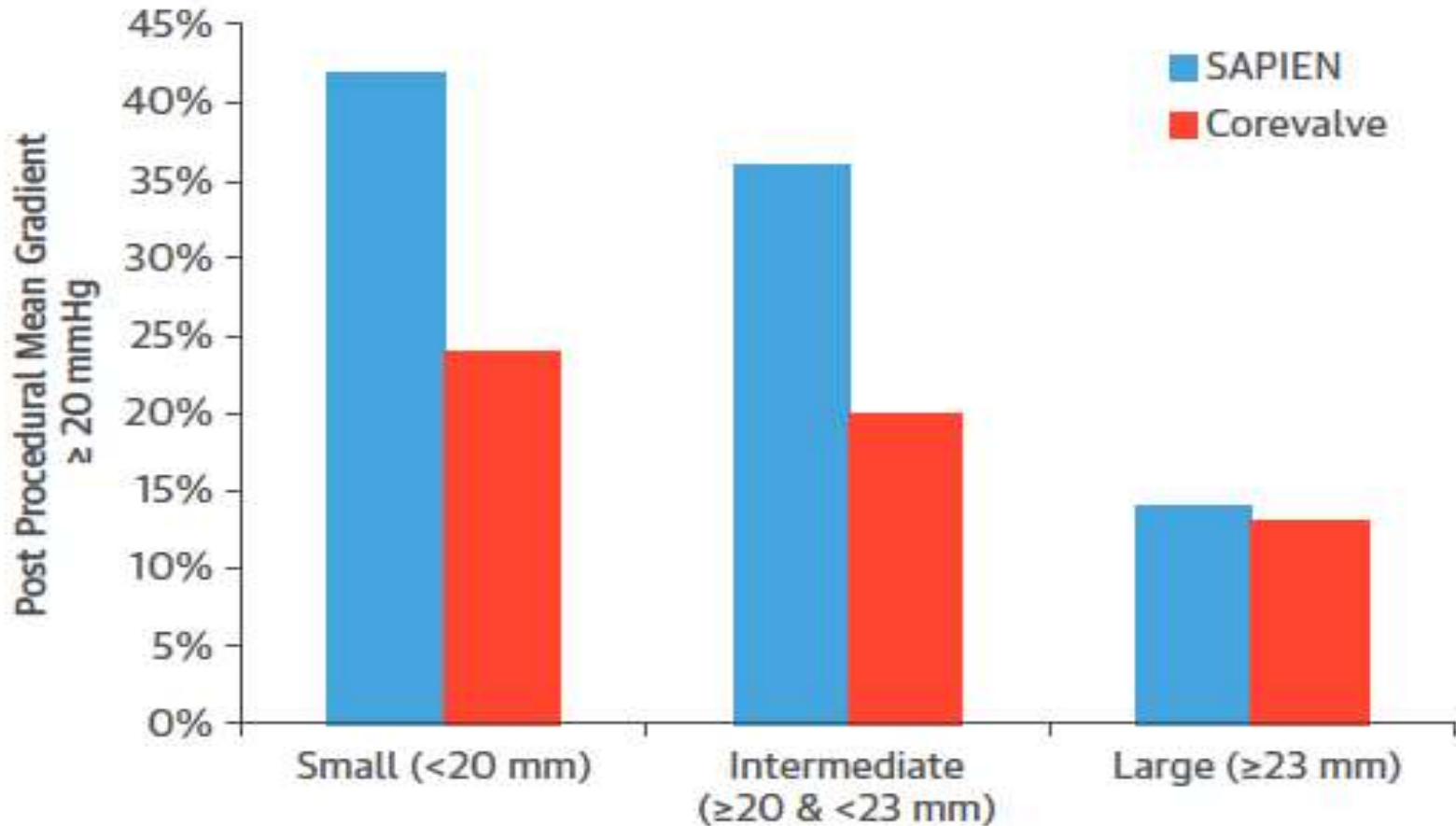
# Influence of Surgical Aortic Valve Sizes on Transcatheter Valve Hemodynamics

**TABLE 5** Influence of Surgical Valve Sizes on Transcatheter Valve Hemodynamics in Aortic Valvular Patients

Group	Surgical Valve Size (mm)	THV Size (mm)	Post-Op AVA (cm <sup>2</sup> )	Post-Op MG (mm Hg)
I (n = 8)	19 or 21	20 or 23	0.88 ± 0.15	25.7 ± 9.5
II (n = 14)	23	23 or 26	1.02 ± 0.17*	22.5 ± 7.9
III (n = 19)	25, 27, or 29	23, 26, or 29	1.35 ± 0.27*†	15.8 ± 6.2*†

# Global VinV Registry

**FIGURE 6** Rate of High Transvalvular Gradients Following Aortic Valve-in-Valve Procedures

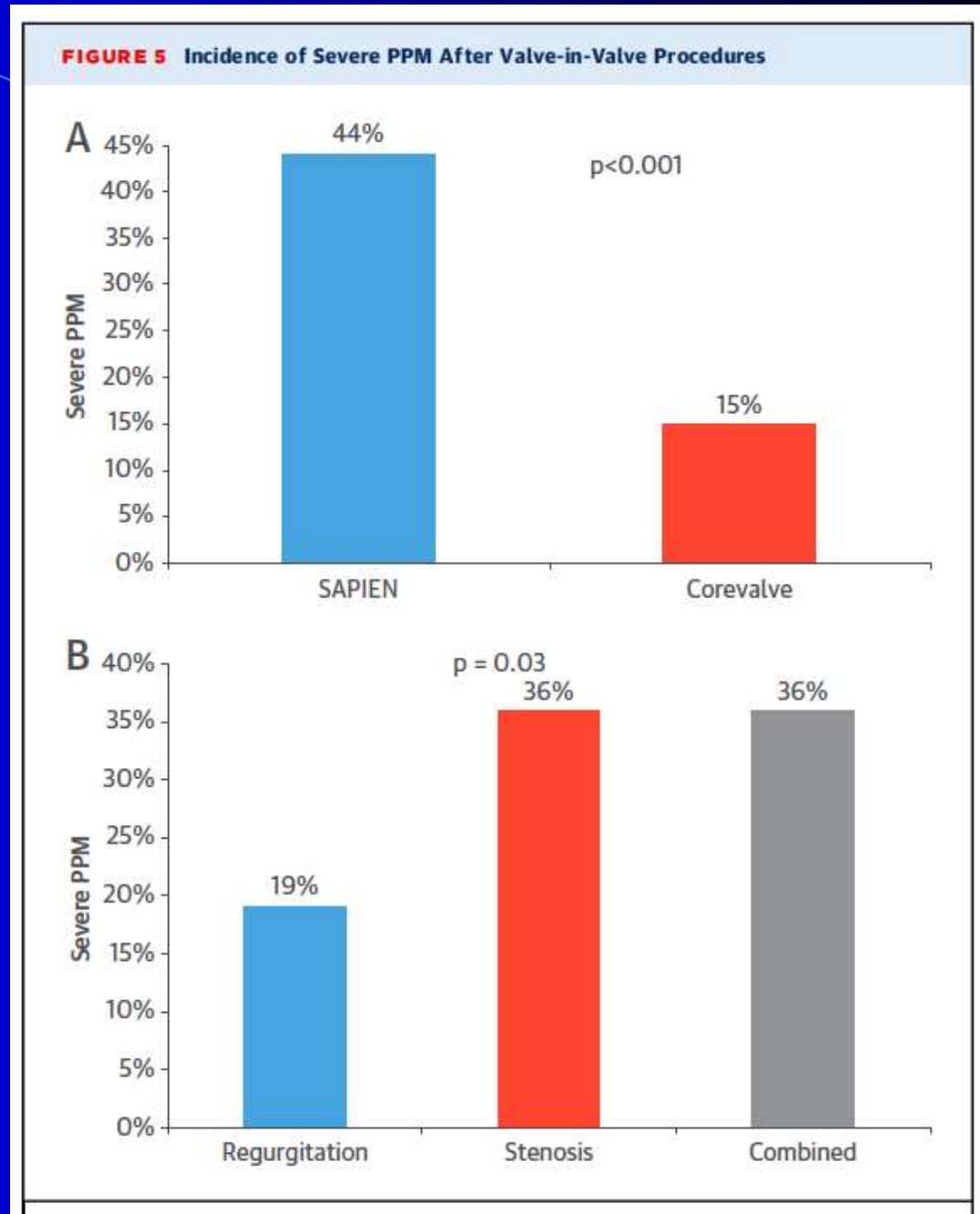




# Global VinV Registry

Severe PPM = Effective  
orifice area  $<0.65 \text{ cm}^2/\text{m}^2$

Dvir D. EuroPCR, May 21, 2015



# Conclusions

- Safe procedure and high success rate
- Very low mortality and morbidity
- Good **mid-term** clinical and hemodynamic outcomes in high risk patients
- Initial implantation of surgical bioprostheses large enough ( $\geq 23\text{mm}$ ) to allow for subsequent VinV implant with optimal hemodynamics and clinical outcome
- Consideration of surgical AVR with mechanical valves or root enlargement with bioprostheses in young patients with small aortic annulus.

# Future Perspectives

- Valve-in-Valve will become a standard treatment for failed mitral and aortic (large sizes) bioprostheses in **all anatomically suitable patients** in the near future.
- Redo AVR with root enlargement should still be considered in intermediate and low-risk young patients with small sizes of failed aortic bioprostheses.

THANKS!