



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

Transcatheter Valve-In-Valve Implantation for Failed Aortic and Mitral Bioprostheses

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Disclosure Statement of Financial Interest

Consultant:

Edwards Lifesciences

JC Medical Inc.

Transcatheter Valve-in-Valve



Surgical Valve

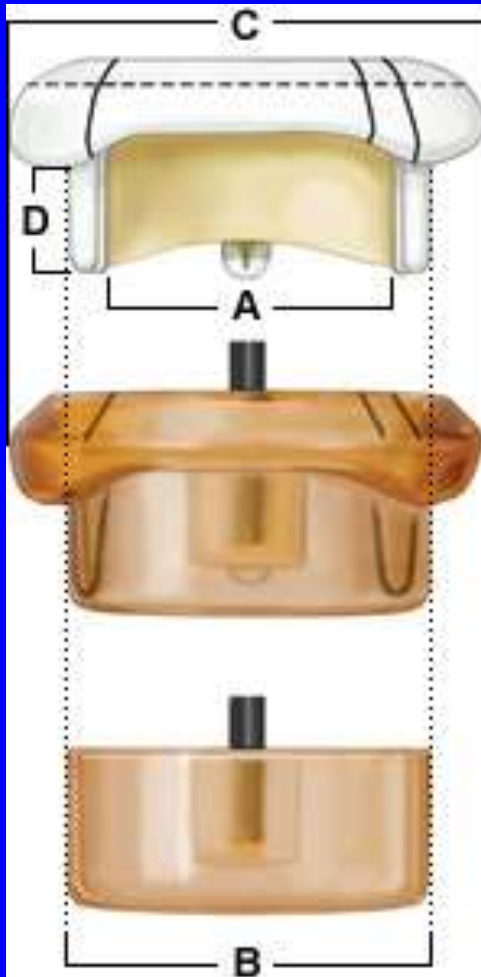


Edwards Sapien™ Valve



Valve-In-Valve

Mitral Pericardial Tissue Valve (Model 7300TFX)

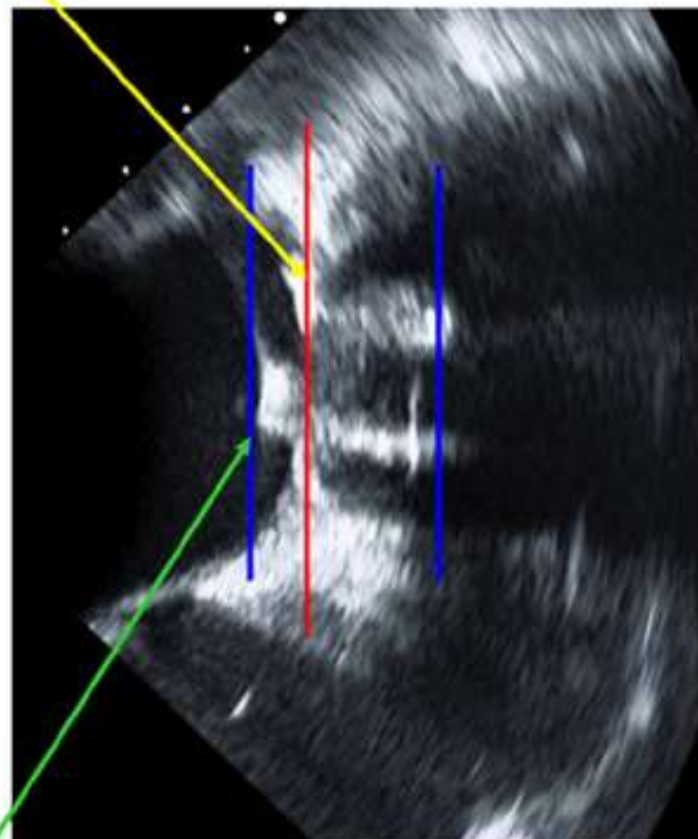
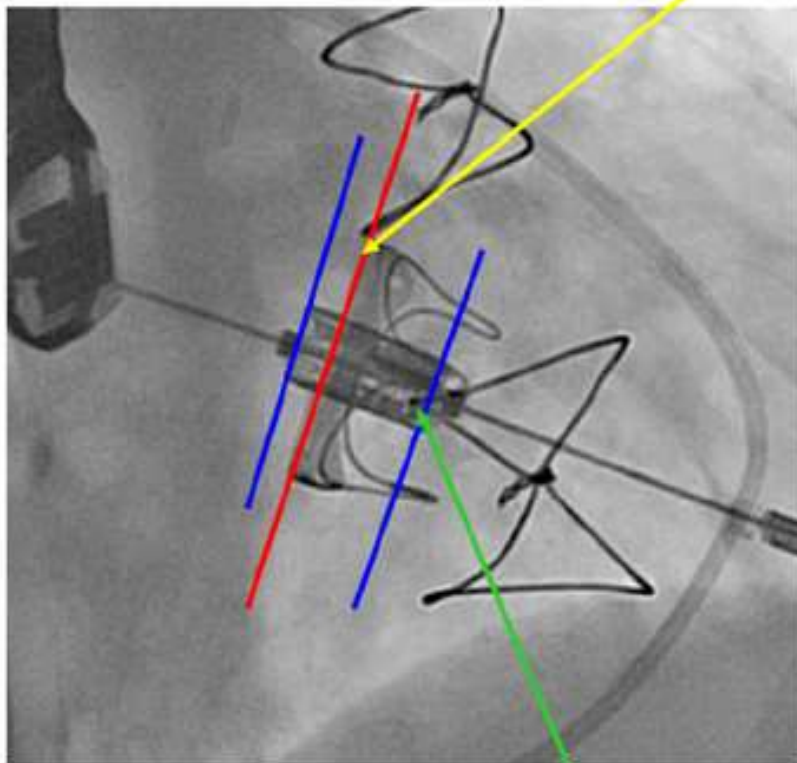


- A** Stent diameter (wireform)
- B** Tissue annulus diameter
- C** External sewing ring diameter
- D** Anterior effective profile

Size	25 mm	27 mm	29 mm	31 mm	33 mm
A	25	27	29	31	31
B	28	29.5	31.5	33.5	33.5
C	36	38	40	42	44
D	7	7.5	8	8.5	8.5

Positioning of Transcatheter Valve

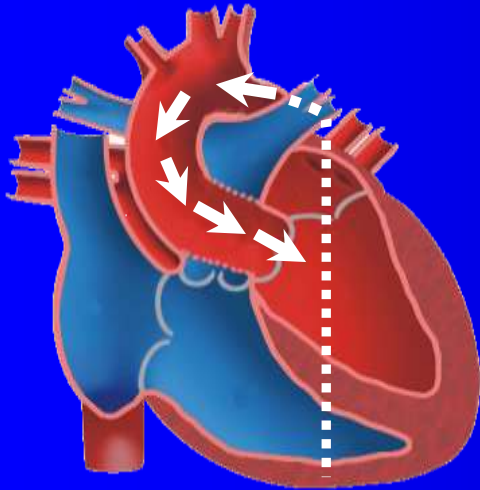
Surgical Valve



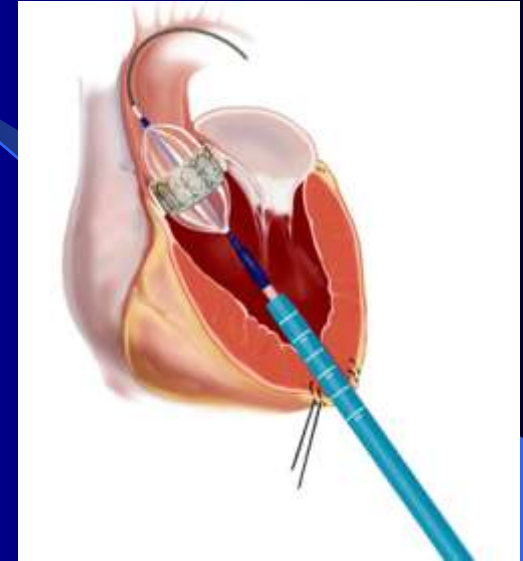
Transcatheter Valve Stent

Approaches

Aortic Valve-in-Valve



Edwards Sapien















Transapical



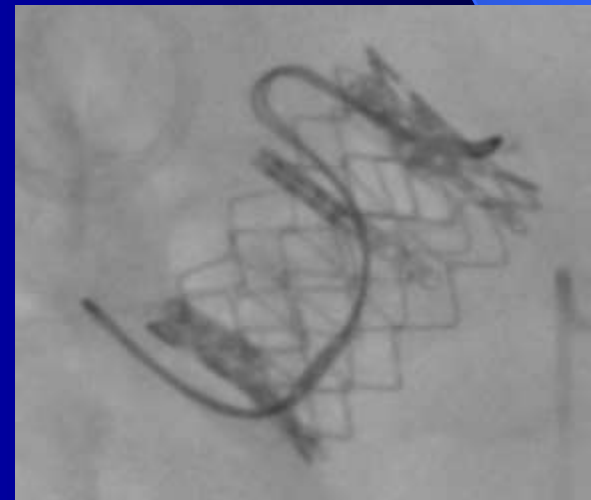
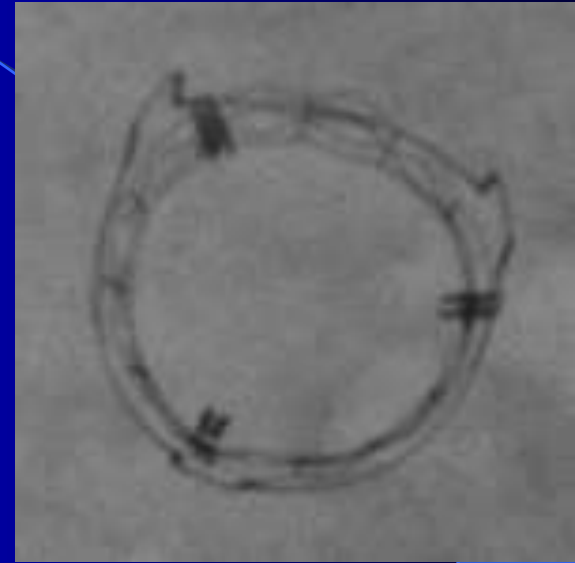
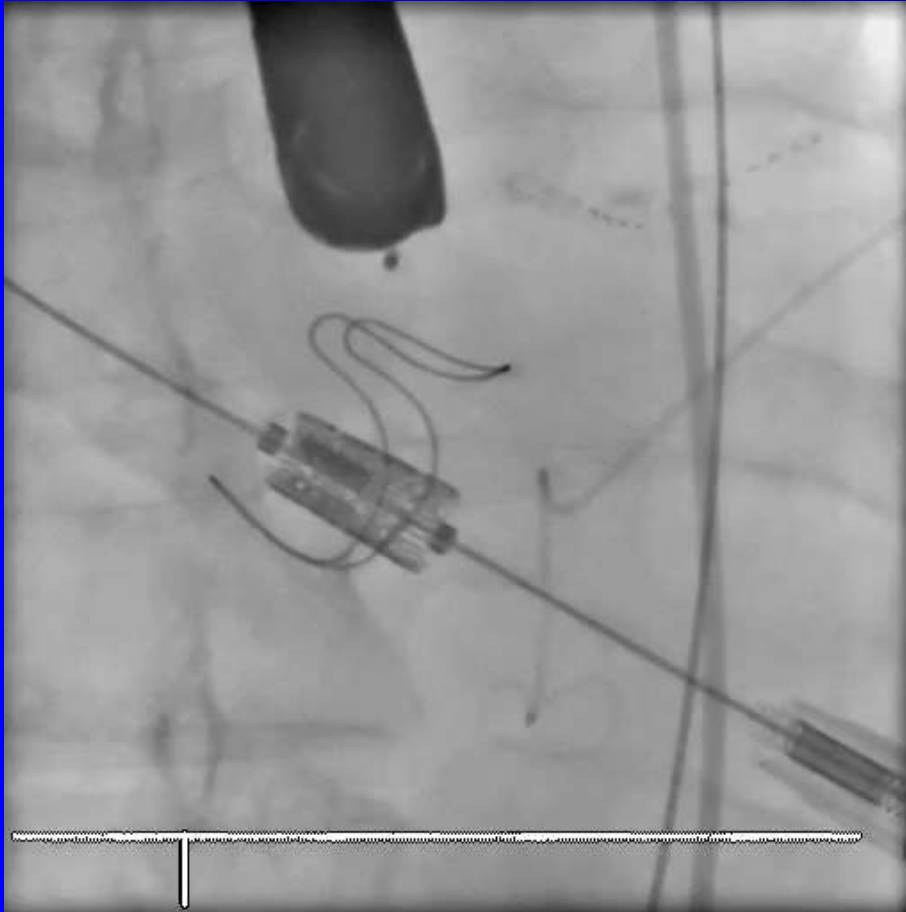
Transarterial

Transcatheter Valves Used for Valve-in-Value

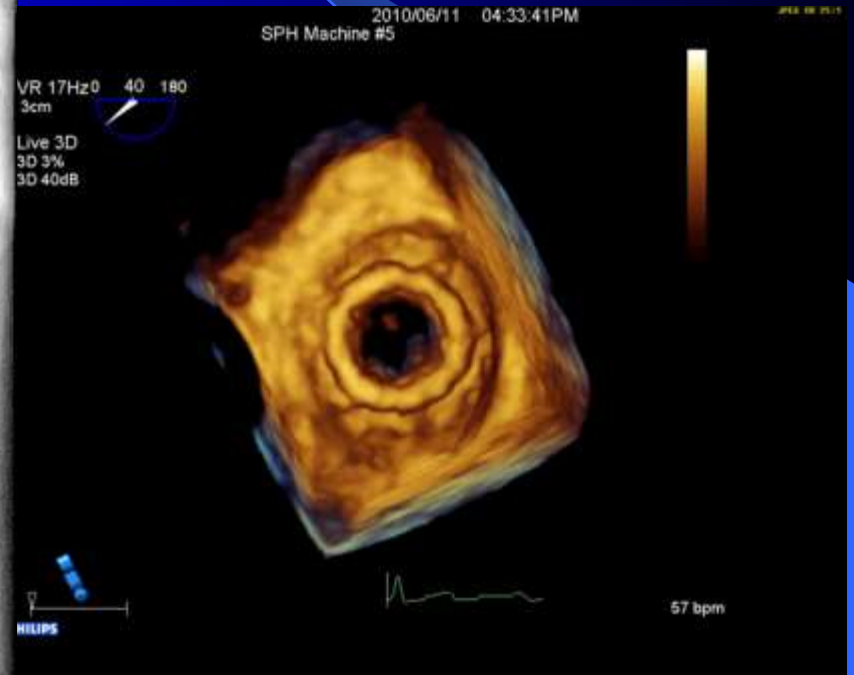
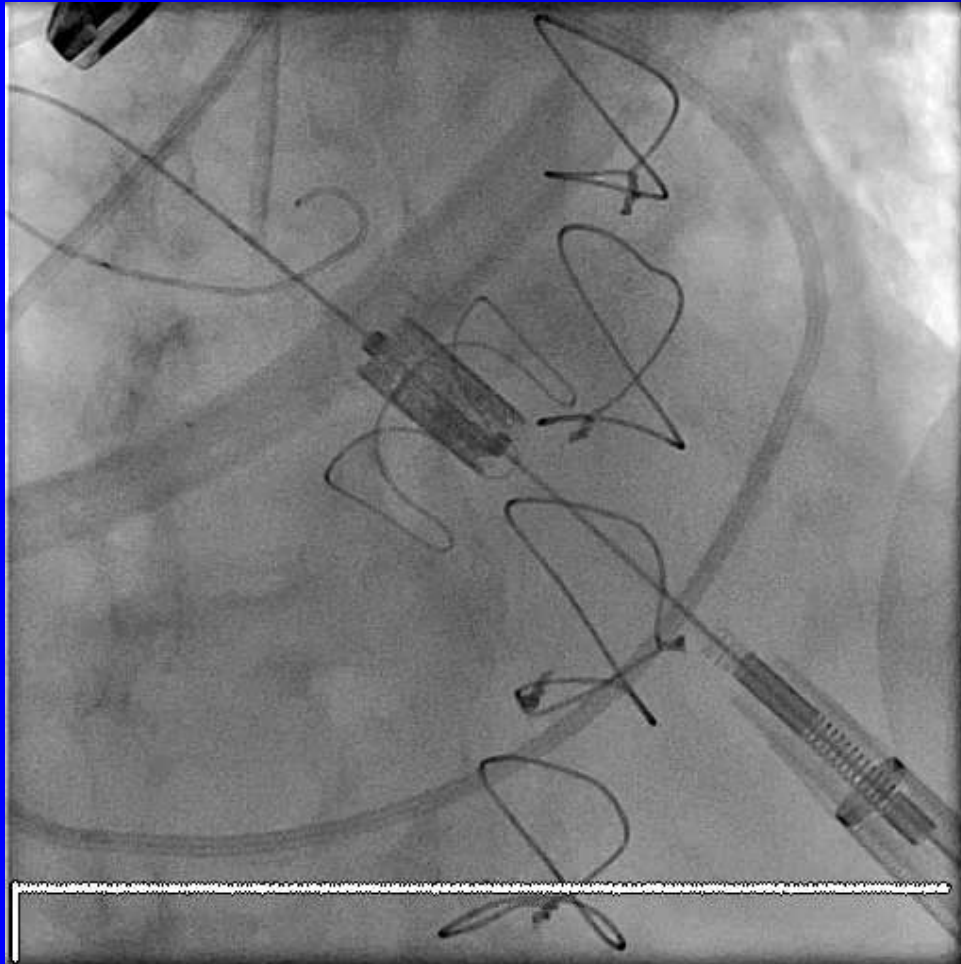
Transcatheter Valves Used for Valve-in-Valve Procedures

	A	B	C	D	E	F
Aortic + Mitral						
Aortic only						

Aortic Valve-in-Valve



Mitral Valve-In-Valve



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

An 8-Year Single-Center Experience

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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.

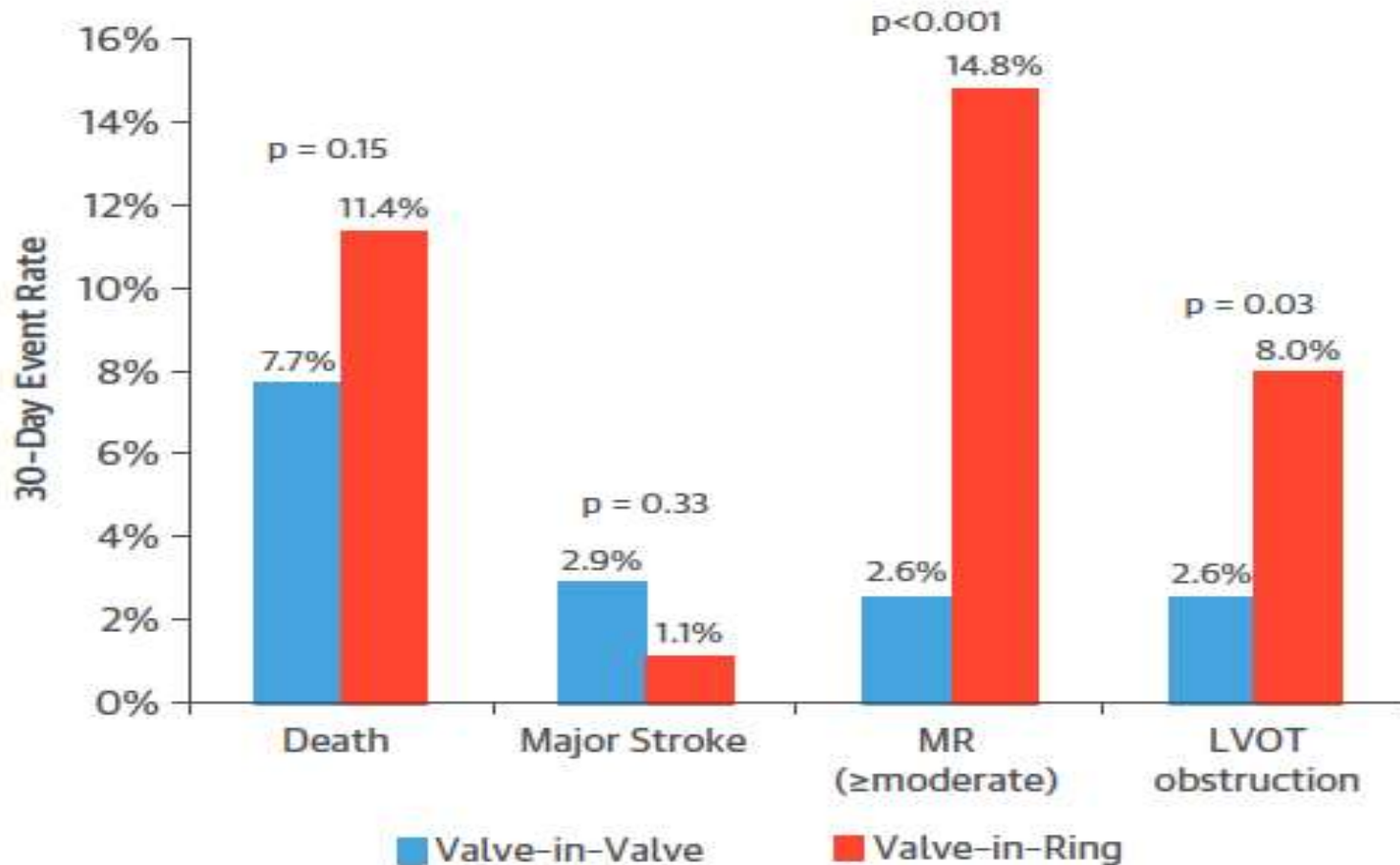
TABLE 2 Early and Late Complications

	<u>Aortic VinV (n = 42)</u>		<u>Mitral VinV (n = 31)</u>	
	30 Days	>30 Days	30 Days	>30 Days
Major bleeding (2-3 U PRBC)	0	0	6	0
Life-threatening bleeding (≥ 4 U PRBC)	2	1	1	0
Conversion to open surgery	1	0	0	0
Valve migration	0	0	0	1
ARF requiring hemodialysis	1	0	1	0
Myocardial infarction	0	0	0	0
Major vascular complication	0	0	0	0
Disabling stroke	0	0	1	1
Left main obstruction	1	0	0	0
Endocarditis	0	0	0	0
Valve thrombosis	0	2	0	2
Failed valve (structural)	0	1	0	0
THV-in-THV deployment	0	0	1	0
Permanent PM implantation	0	0	1	0

30-day all-cause mortality: 1.4%

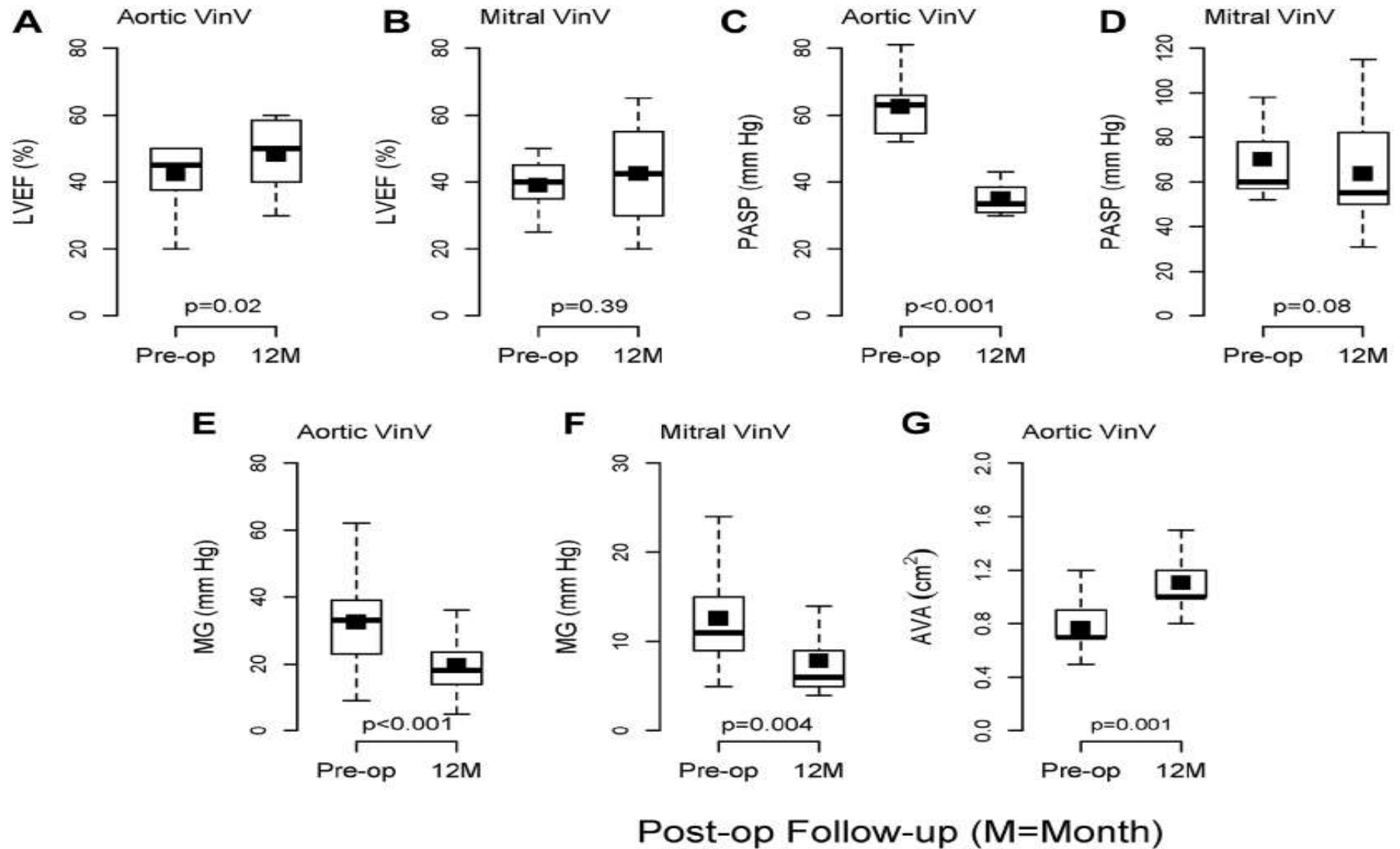
Global VinV Registry

FIGURE 9 30-Day Outcomes After Mitral Valve-in-Valve and Mitral Valve-in-Ring Procedures



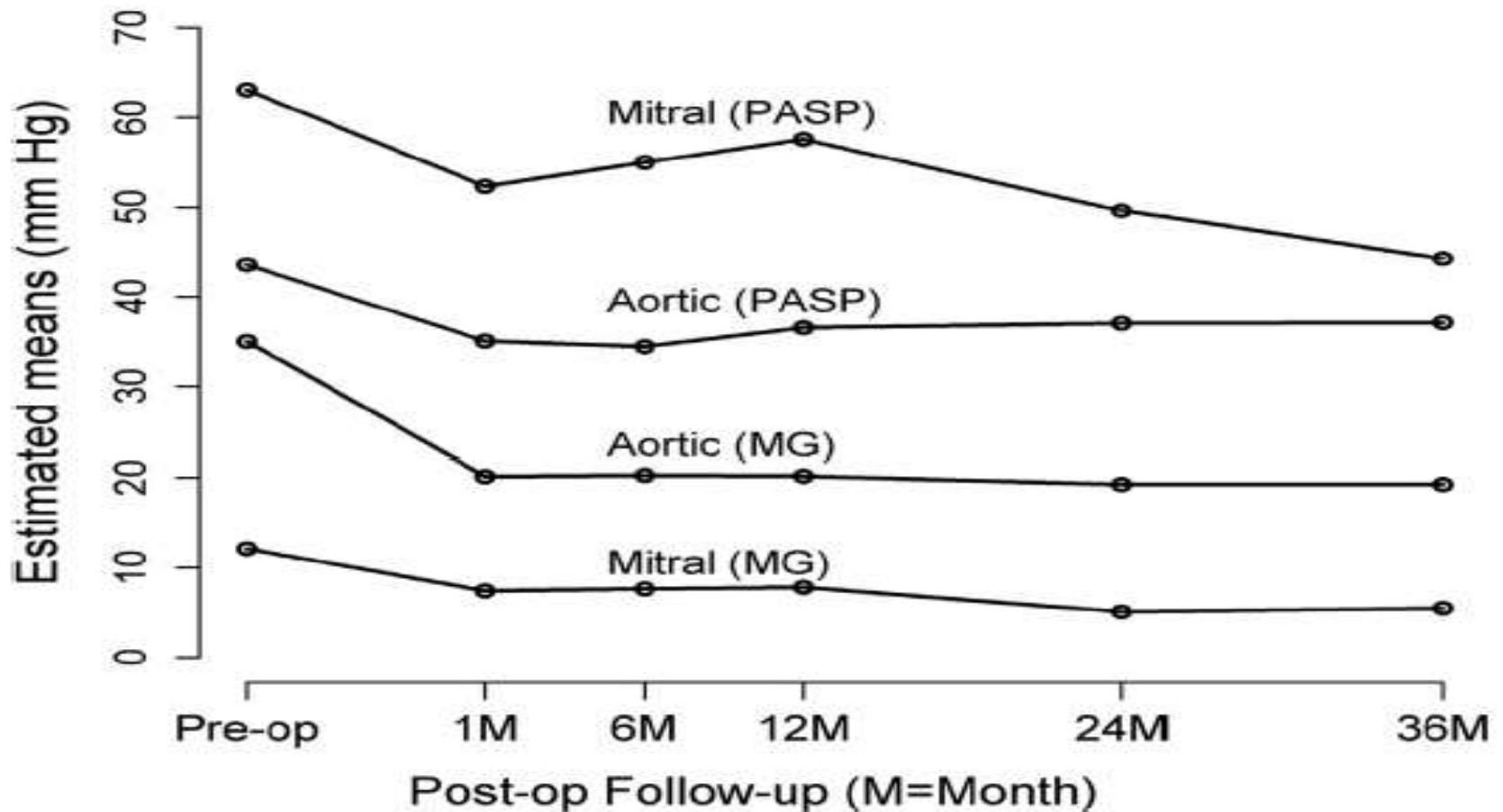
Echocardiographic Outcomes

FIGURE 3 Echocardiographic Outcomes Following Either Aortic or Mitral VinV Implantation In Patients Who Had 12-Month Follow-Up Data



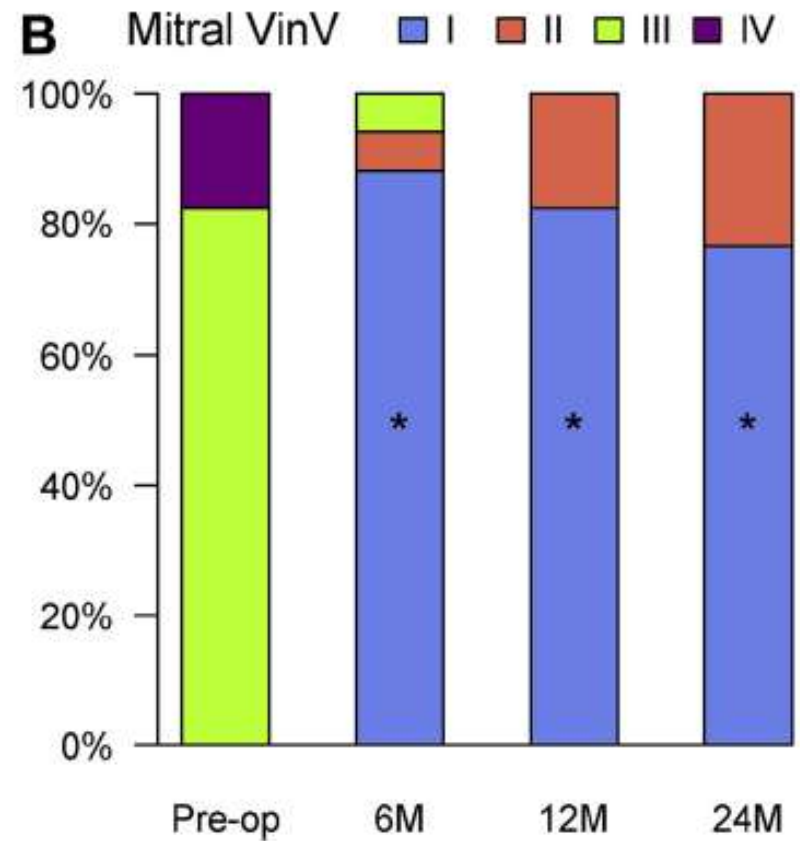
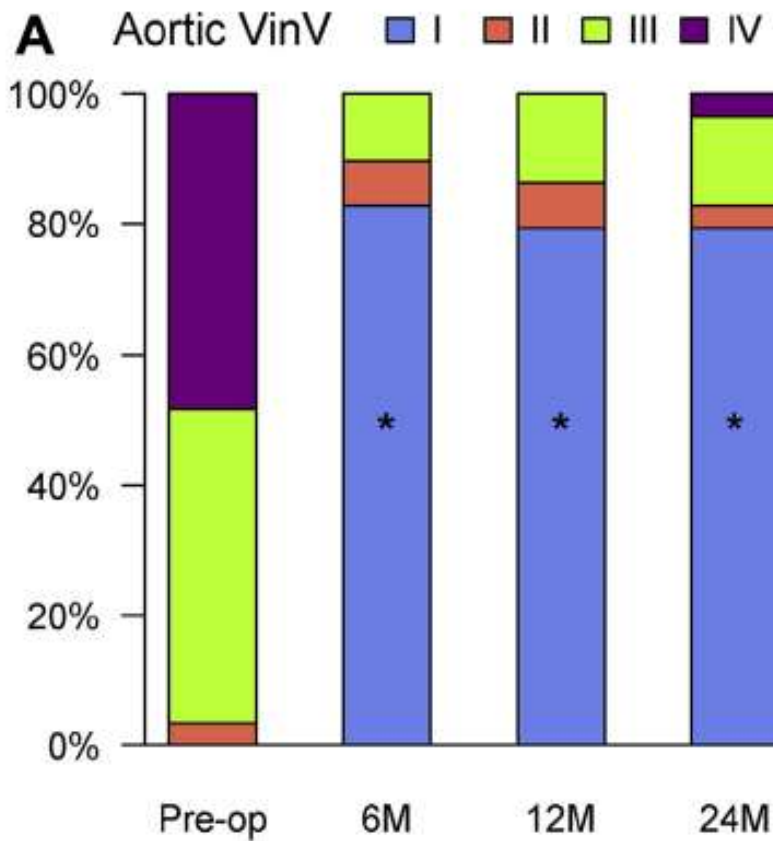
Changes in Estimated Means of Pulmonary Artery Systolic Pressure

FIGURE 4 Changes in Estimated Means of PASP and MG With Time Following VinV Implantation

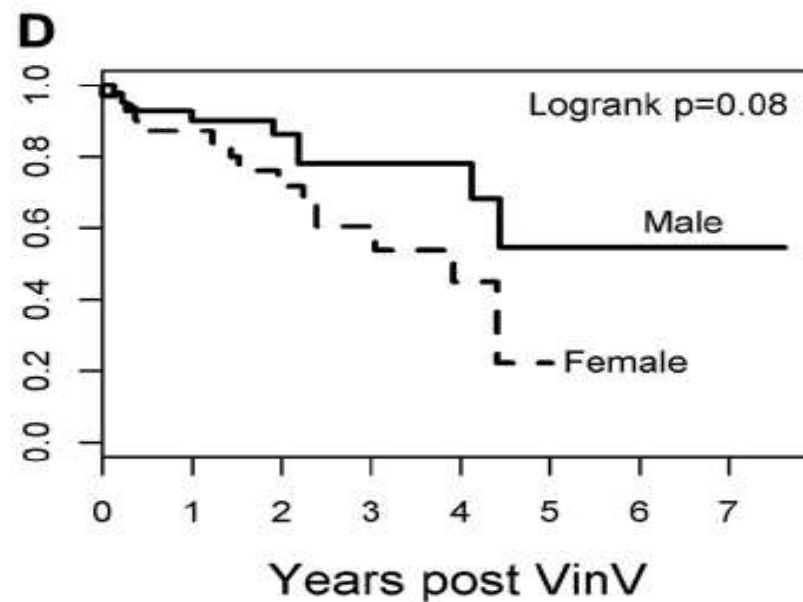
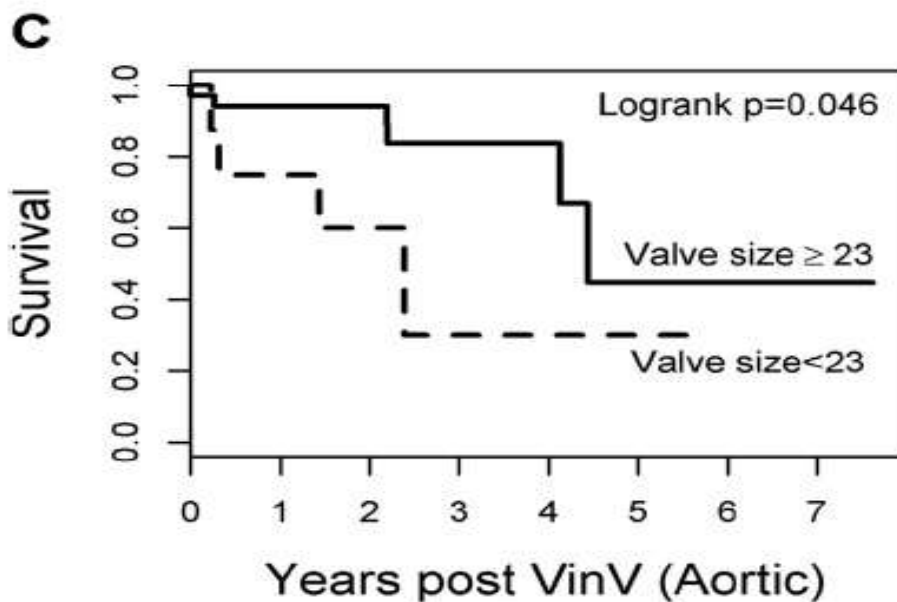
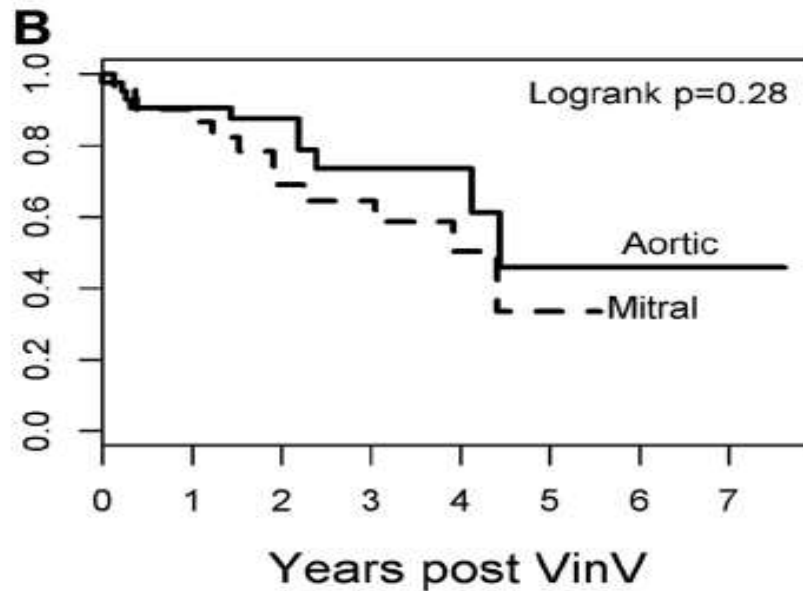
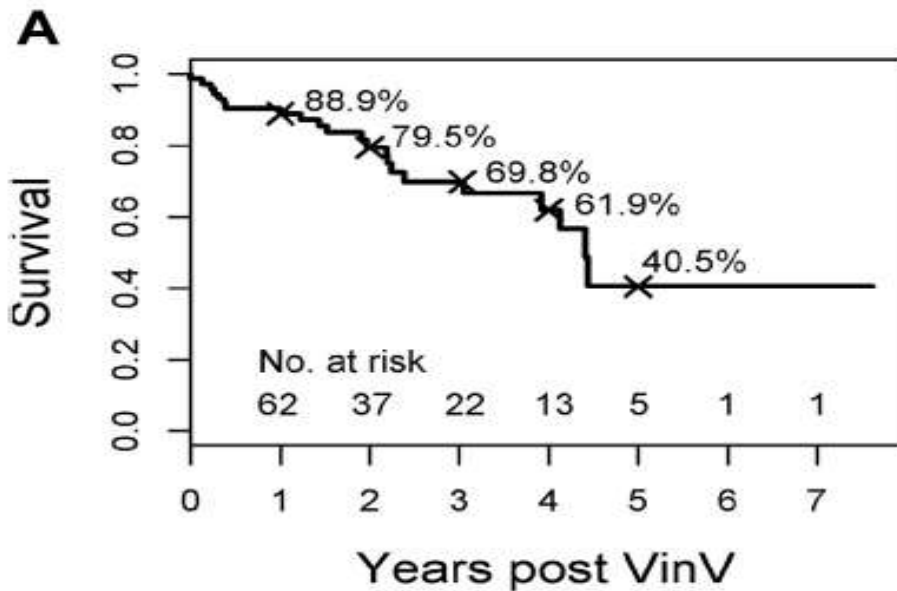


Clinical Outcome

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



Mid-term Survival



Factors Influencing Survival

TABLE 3 Factors Influencing Survival (n = 73)

	Univariate Model		Multivariate Model	
	Hazard Ratio (95% CI)	p Value	Hazard Ratio (95% CI)	p Value
Female	2.136 (0.904-5.049)	0.084	2.570 (0.983-6.719)	0.054
PVD	1.466 (0.590-3.644)	0.411	3.153 (1.070-9.288)	0.037
PASP \geq 60 mm Hg	1.880 (0.775-4.556)	0.162	2.941 (0.963-8.982)	0.058
LVEF <50%	1.459 (0.611-3.482)	0.395	2.658 (0.891-7.931)	0.080
COPD (moderate + severe)	0.645 (0.151-2.763)	0.555		
CABG \pm CAD	1.231 (0.479-3.160)	0.666		
Creatinine 100-149 mmol/l	1.116 (0.325-3.835)	0.862		
Creatinine \geq 150 mmol/l	1.532 (0.593-3.958)	0.379		
DM	1.447 (0.530-3.948)	0.471		
CVA	2.001 (0.794-5.046)	0.142	2.956 (1.033-8.461)	0.043

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

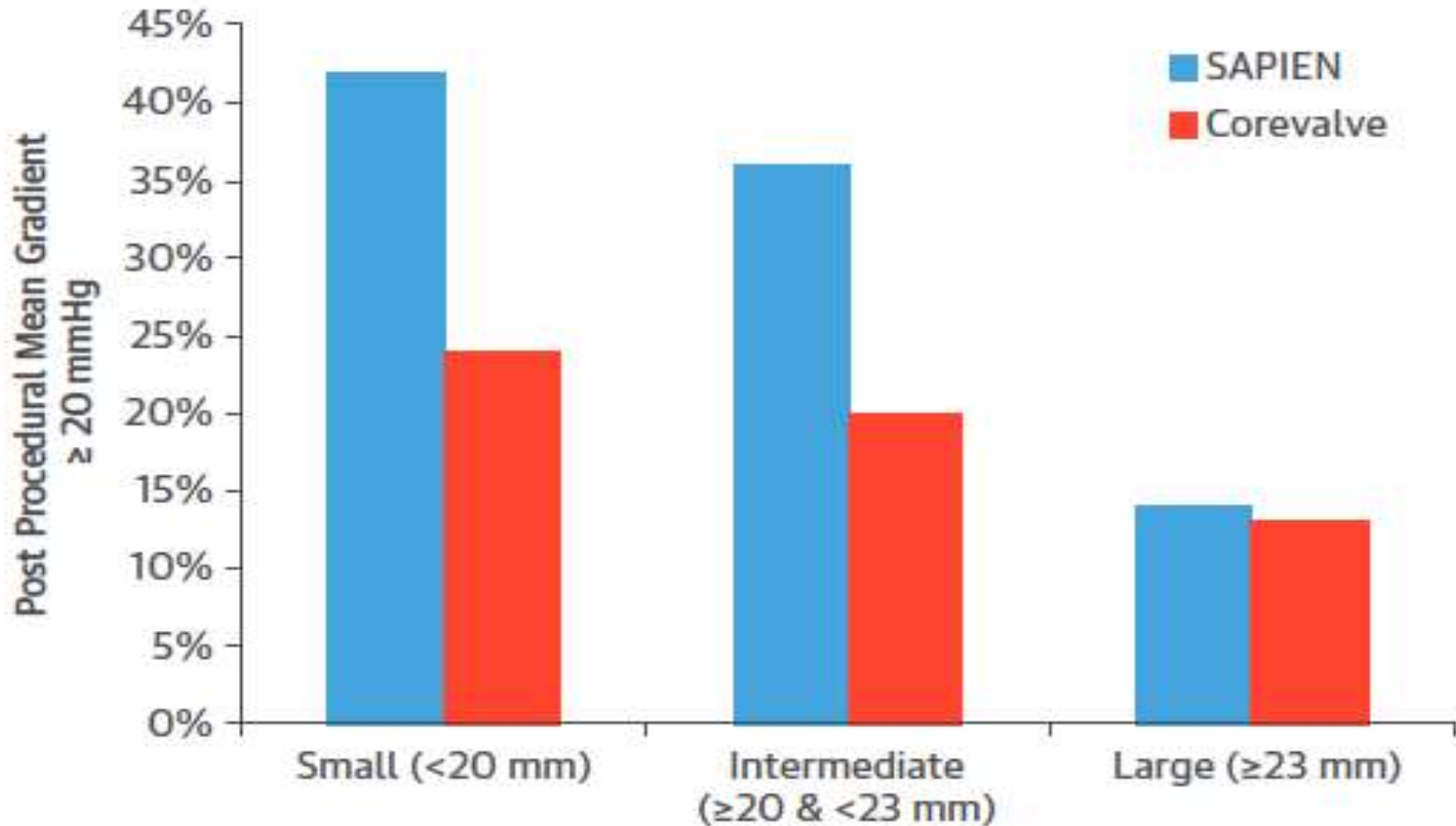
Influence of Surgical Aortic Valve Sizes on Transcatheter Valve Hemodynamics

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 ²)	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

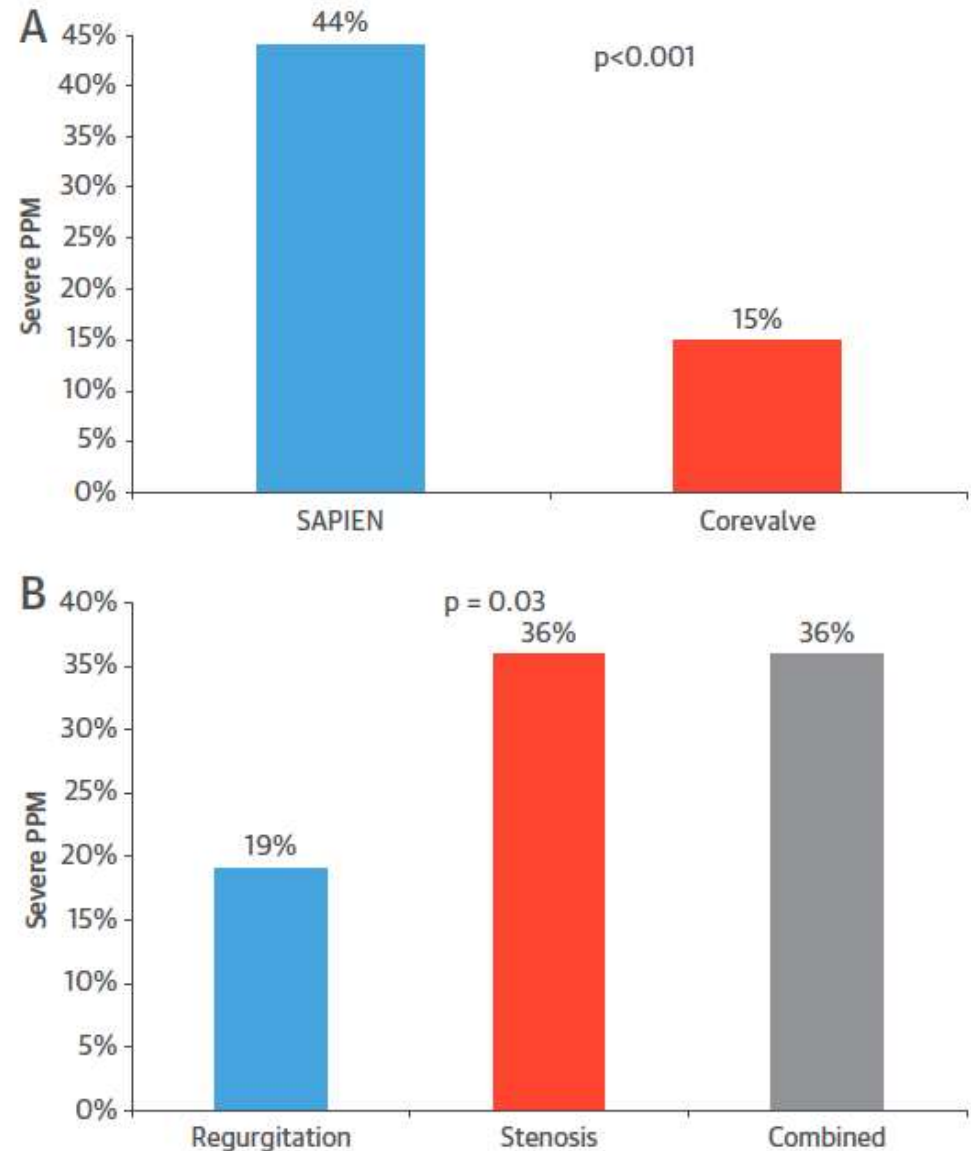


Global VinV Registry

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

Dvir D. EuroPCR, May 21, 2015

FIGURE 5 Incidence of Severe PPM After Valve-in-Valve Procedures



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 intermediate and high risk 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!