Transcatheter Mitral Valve-in-Valve and Valve-in-Ring

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On behalf of the TMVR Registry Investigators

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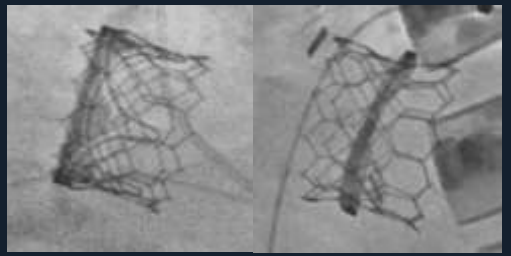
Disclosure Statement of Financial Interest

Sung-Han Yoon, MD

Within the past 12 months, I or my spouse/partner have had no financial interest/arrangement or affiliation with any organization(s).

Background

- Valvular heart disease will increase with aging population
- High risk for repeat cardiac surgery for degenerated mitral bioprostheses and failed annuloplasty rings
- Transcatheter treatment has become standard for AS
- Transcatheter mitral valve replacement (TMVR) as less invasive alternative



Methods

- The TMVR multicenter registry was used to evaluate the outcomes of mitral valve-in-valve (ViV) and valve-in-ring (ViR)
- Procedural and clinical outcomes were assessed according to MVARC criteria
- Outcomes of mitral ViV and ViR were compared

Participating Institutions (N = 25)

Country	Institution (cases)	Investigator
U.S.	Cedars-Sinai Heart Institute (33)	Raj Makkar
Germany	German Heart Center (33)	Sabine Bleiziffer
U.S.	Intermountain Heart Institute (30)	Brian Whisenant
Germany	Hamburg University Heart Center (22)	Niklas Schofer, Ulrich Schaefer
Italy	San Raffaele Scientific Institute (21)	Azeem Latib, Antonio Columbo
Germany	Hamburg University Cardiovascular Center (15)	Joachim Schofer
Netherland	Leiden University Medical Center (14)	Victoria Delgado, Jeroen J. Bax
U.K.	St. Thomas Hospital (11)	Bernard Prendergast, Simon Redwood
Germany	Rahr-University Bochum (10)	Buntaro Fujita, Stephan M. Ensminger
Switzerland	University Hospital Zurich (8)	Francesco Maisano, Fabian Nietlispach
Switzerland	Bern University Hospital (8)	Thomas Pilgrim, Stephan Windecker
U.S.	New York-Presbyterian Hospital (8)	S. Chiu Wong
U.S.	Houston Methodist DeBakey Heart and Vascular Center (7)	Colin Barker, Michael Reardon
U.S.	University of Alabama-Birmingham (7)	James Davies
Germany	German Heart Center (6)	Markus Kasel
Spain	Hospital Clinicio San Carlos (6)	Luis Nombela-Franco
U.S.	University of Texas Health Science Center (6)	Abhijeet Dhoble
U.K.	Sussex Cardiac Center (4)	David Hildick-Smith
Canada	Center Hospitalier de l'universite de Montreal (4)	Jean-Bernard Masson
Germany	Cardiovascular Center (3)	Horst Sievert
U.K.	Leed Teaching Hospital (2)	Daniel J. Blackman
Spain	Hospital General Universitario Gregorio Maranon (2)	Enrique Gutierrez-Ibanes

Baseline Characteristics

Demographics

	Overall (n = 248)	ViV (n = 176)	ViR (n = 72)	P value
Age, years	73 ± 12	73 ± 13	71 ± 10	0.36
Female	57%	63%	42%	0.002
NYHA class III / IV	89%	88%	92%	0.41
STS score, %	8.9 ± 6.8	9.3 ± 7.0	8.1 ±6.2	0.24
Logistic EuroSCORE, %	26.9 ± 15.8	26.2 ±15.6	28.2 ±16.2	0.44

Baseline Characteristics

Comorbidities

	Overall (n = 248)	ViV (n = 176)	ViR (n = 72)	P value
Diabetes mellitus	23%	26%	17%	0.11
Creatinine, mg/dl	1.5 ± 1.2	1.4 ± 1.1	1.7 ± 1.4	0.08
Peripheral vascular disease	7%	6%	10%	0.34
Prior CVA	17%	21%	6%	0.003
Chronic lung disease	25%	24%	28%	0.58
Prior CABG	27%	22%	38%	0.01

Baseline Characteristics

Ecocardiogram

	Overall (n = 248)	ViV (n = 176)	ViR (n = 72)	P value
LVEF, %	53 ± 14	55 ± 11	46 ± 17	< 0.001
Mean gradient, mm Hg	11 ± 6	12 ± 6	7 ± 5	< 0.001
MR ≥ moderate at baseline	77%	71%	90%	0.001
Mechanism of failure				
MR	48%	36%	78%	< 0.001
MS	27%	36%	4%	< 0.001
Combined	25%	28%	18%	0.11

Baseline Characteristics

Procedure

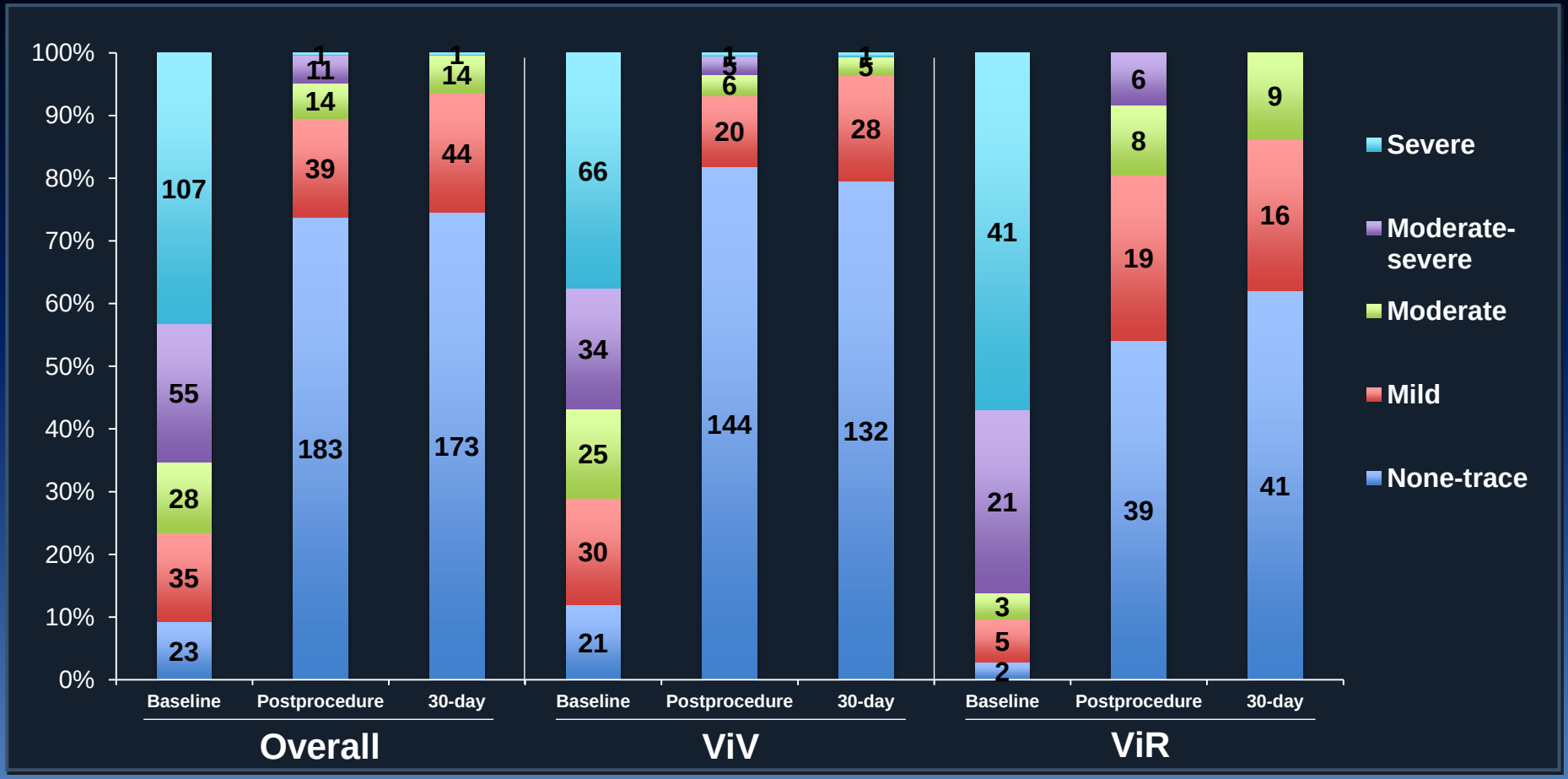
	Overall (n = 248)	ViV (n = 176)	ViR (n = 72)	P value
Transseptal access	33%	65%	28%	0.26
Transapical access	67%	64%	72%	0.23
Device type				
Balloon-expandable valves	90%	94%	79%	< 0.001
Sapien XT	38%	39%	35%	0.56
Sapien 3	41%	43%	38%	0.46
Lotus	6%	5%	8%	0.24
Direct Flow	9%	10%	13%	< 0.001

Procedural Outcomes

	Overall (n = 248)	ViV (n = 176)	ViR (n = 72)	P value
Procedure-related death	1.2%	1.1%	1%	> 0.99
Conversion to surgery	2.0%	1.1%	4.2%	0.15
LVOT obstruction	3.2%	2.3%	2.3%	0.18
Valve embolization	1.6%	1.1%	2.8%	0.58
Need for second valve	5.1%	2.8%	11.1%	0.008
LV perforation	0.4%	0.6%	0.0%	> 0.99
Technical success *	92.3%	96%	83%	0.001

* Absence of procedural mortality; successful access, delivery; and retrieval of the device delivery system; successful deployment and correct positioning of the first intended device; freedom from emergent surgery or reintervention

Mitral Valve Regurgitation



Procedural Outcomes

	Overall (n = 248)	ViV (n = 176)	ViR (n = 72)	P value
Re-intervention	10.1%	7.4%	16.7%	0.03
PVL closure	3.6%	2.3%	6.9%	0.07
ASD closure	4.0%	4.0%	4.2%	0.95
Surgical MVR	1.6%	1.1%	2.8%	0.58
Echocardiographic findings				
LVEF, %	50 ± 14	53 ± 12	44 ± 15	< 0.001
MR ≥ moderate	10.3%	6.8%	19.4%	0.003
Device success *	85.5%	89.2%	76.4%	0.001

* Absence of procedural mortality and stroke; proper placement and positioning of device; freedom from unplanned surgical or interventional procedures; no significant MS or MR (> moderate)

Clinical Outcomes

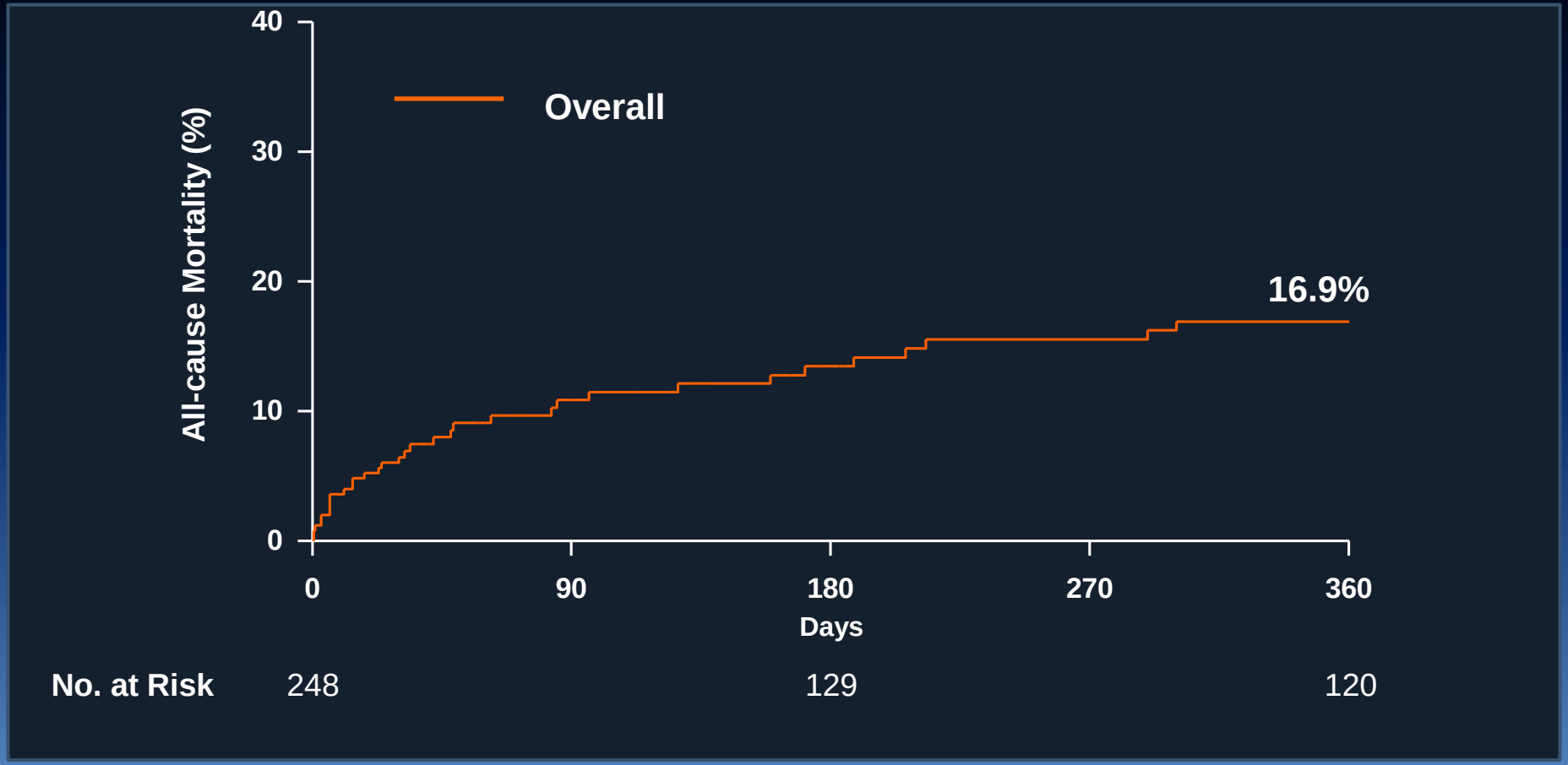
	Overall (n = 248)	ViV (n = 176)	ViR (n = 72)	P value
All-cause mortality at 30 days	6.5%	5.7%	8.3%	0.44
Stroke	1.6%	2.3%	0.0%	0.33
Life-threatening bleeding	4.0%	2.3%	8.3%	0.03
Major vascular complication	1.6%	1.7%	1.4%	> 0.99
AKI (stage 2 or 3)	6.0%	4.0%	11.1%	0.03
Procedural success*	73.4%	79.5%	58.3%	0.001

* Device success without death, stroke, life-threatening bleeding, major vascular complications, stage 2 or 3 AKI, congestive heart failure, valve-related dysfunction, or other complications requiring surgery or repeat intervention.

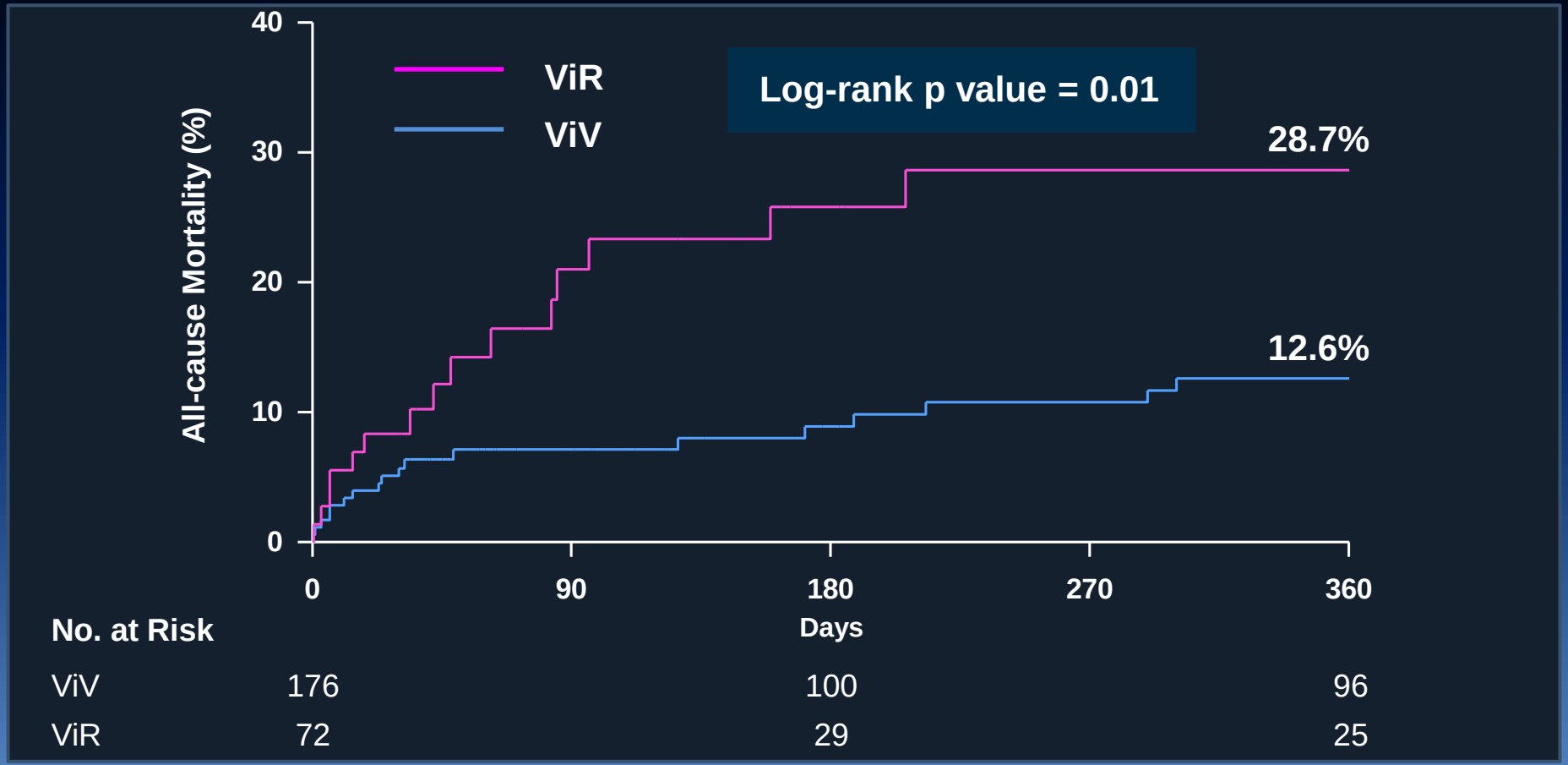
Mid-term Mortality

1-year All-cause Mortality

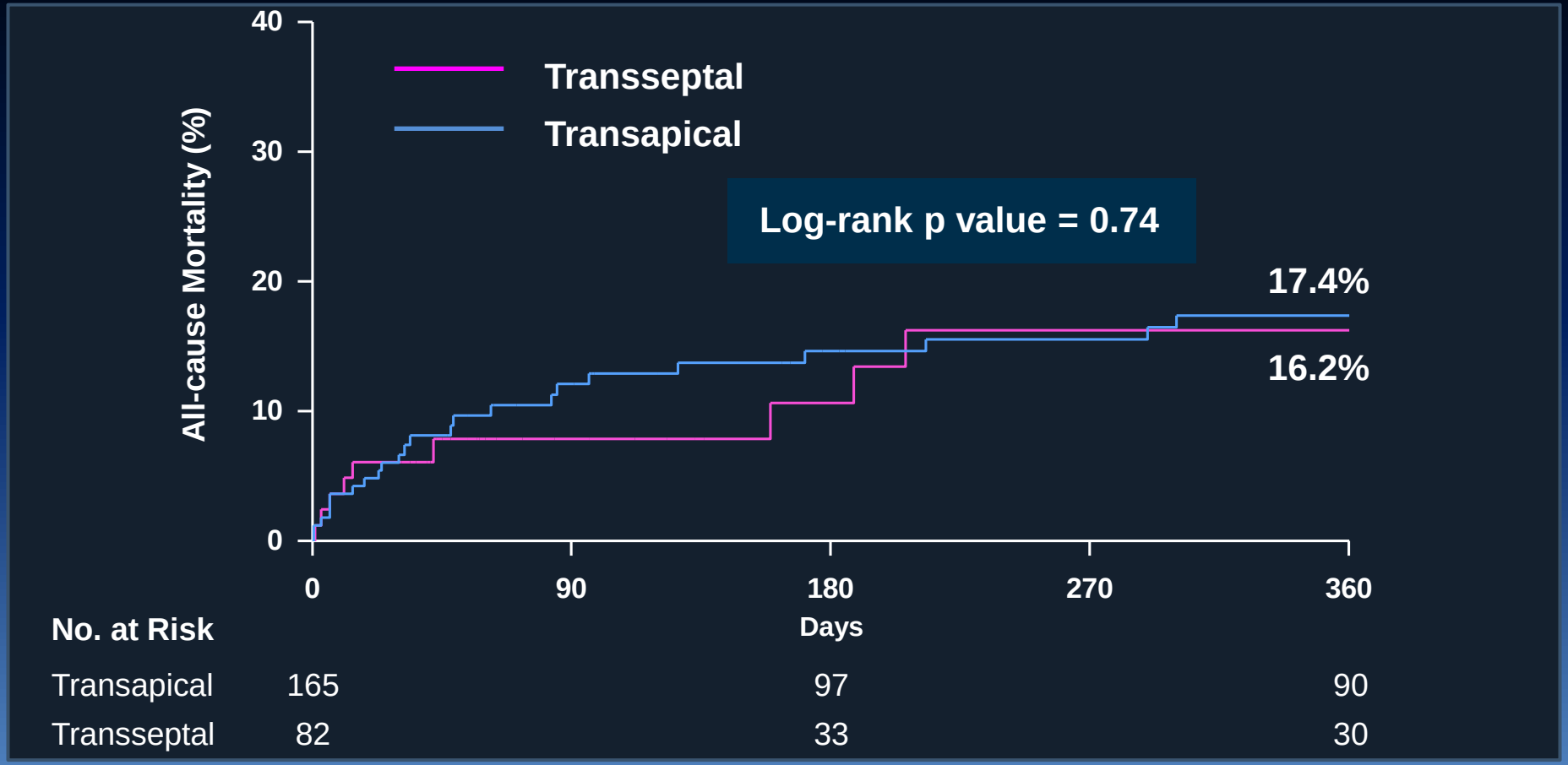
Overall



1-year All-cause Mortality
ViV vs ViR



1-year All-cause Mortality
Transseptal vs Transapical

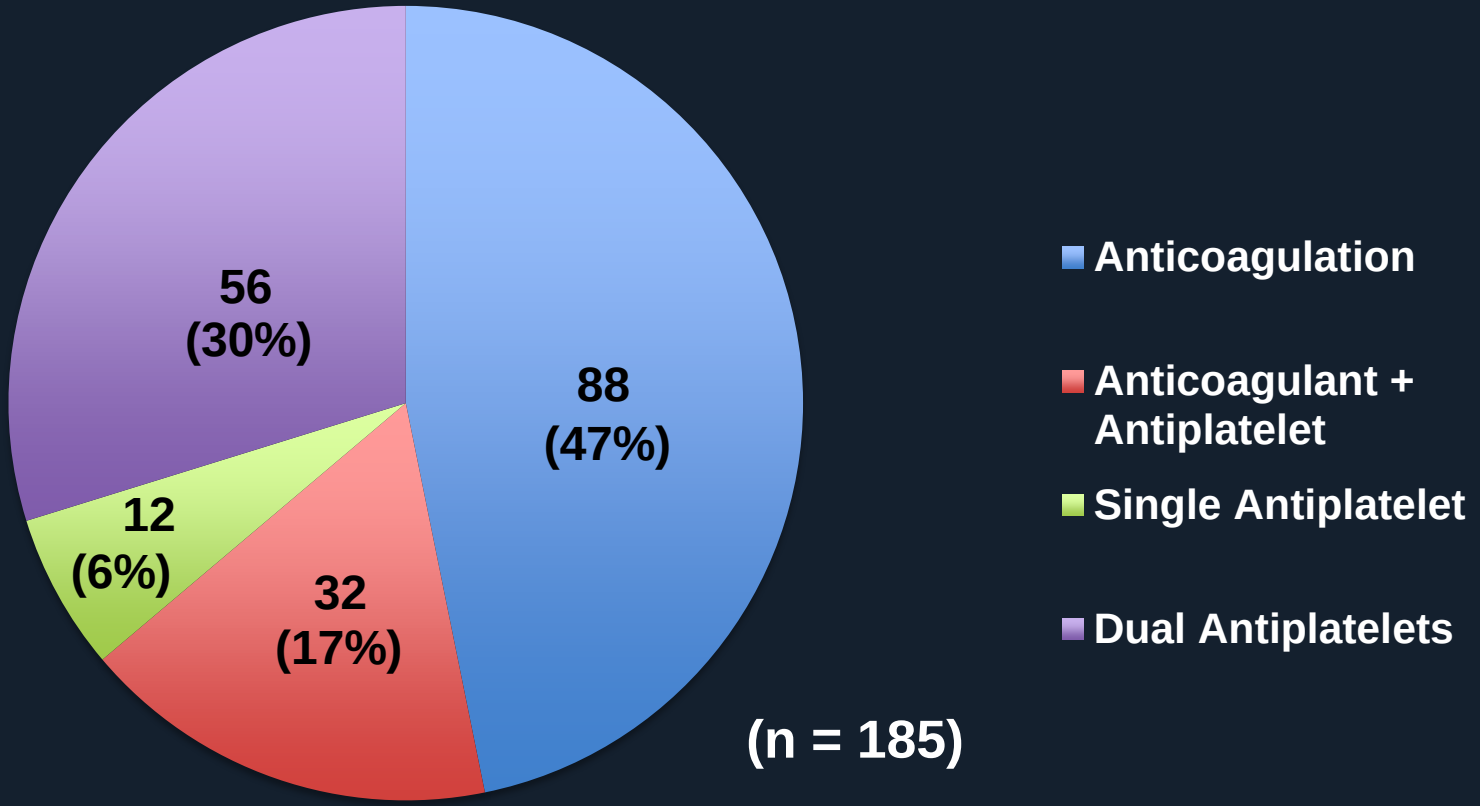


No. at Risk			
Transapical	165	97	90
Transseptal	82	33	30

Anticoagulation and Thrombosis

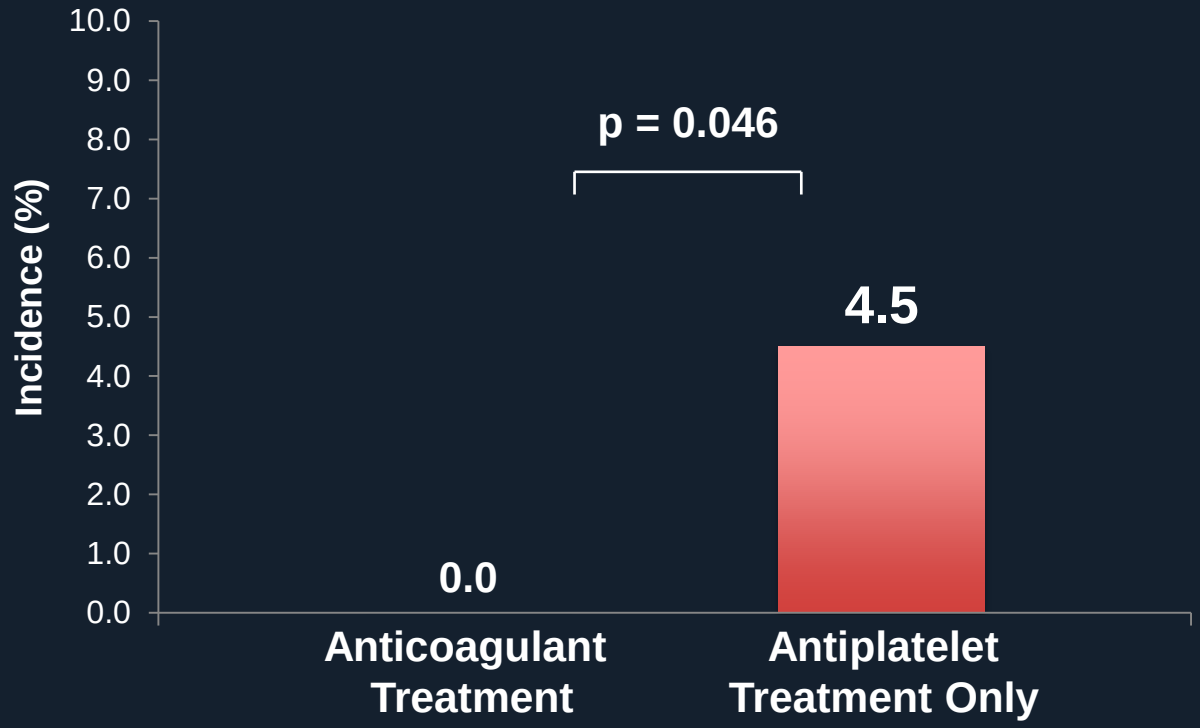
Antithrombotic Treatment

The first 3 months



Clinical Thrombosis

Anticoagulant vs Antiplatelet only

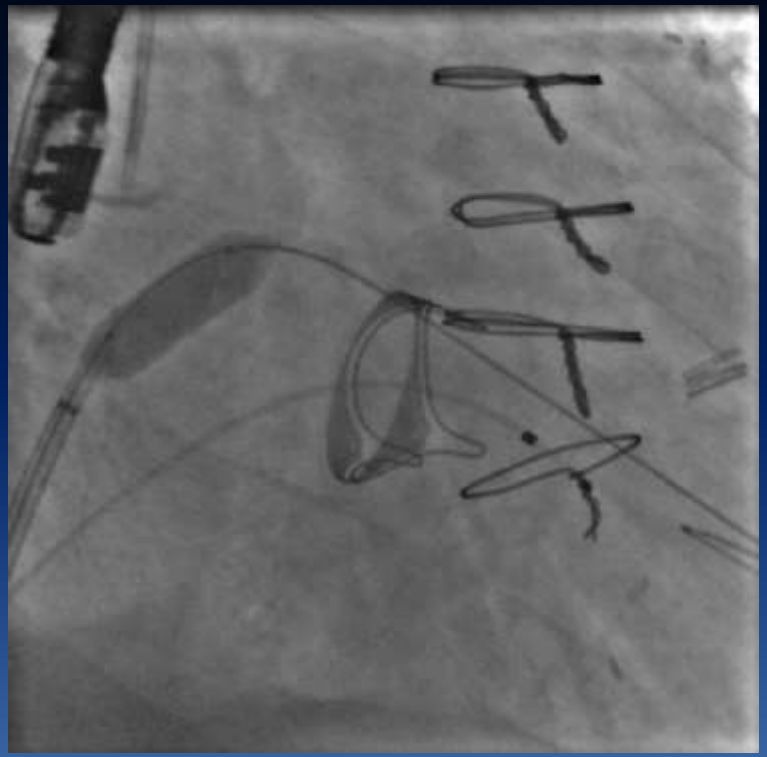


Conclusions

- TMVR for degenerated mitral bioprostheses or failed annuloplasty rings showed acceptable outcomes
- Compared to mitral ViV, mitral ViR was associated with lower technical, device and procedural success
- The 1-year all-cause mortality was higher in mitral ViR compared with mitral ViV
- Absence of anticoagulant for the first 3 months after TMVR was associated with increased rate of clinical thrombosis

Mitral Valve-in-Valve Case 1

Mitral ViV for Failed Magna Valve

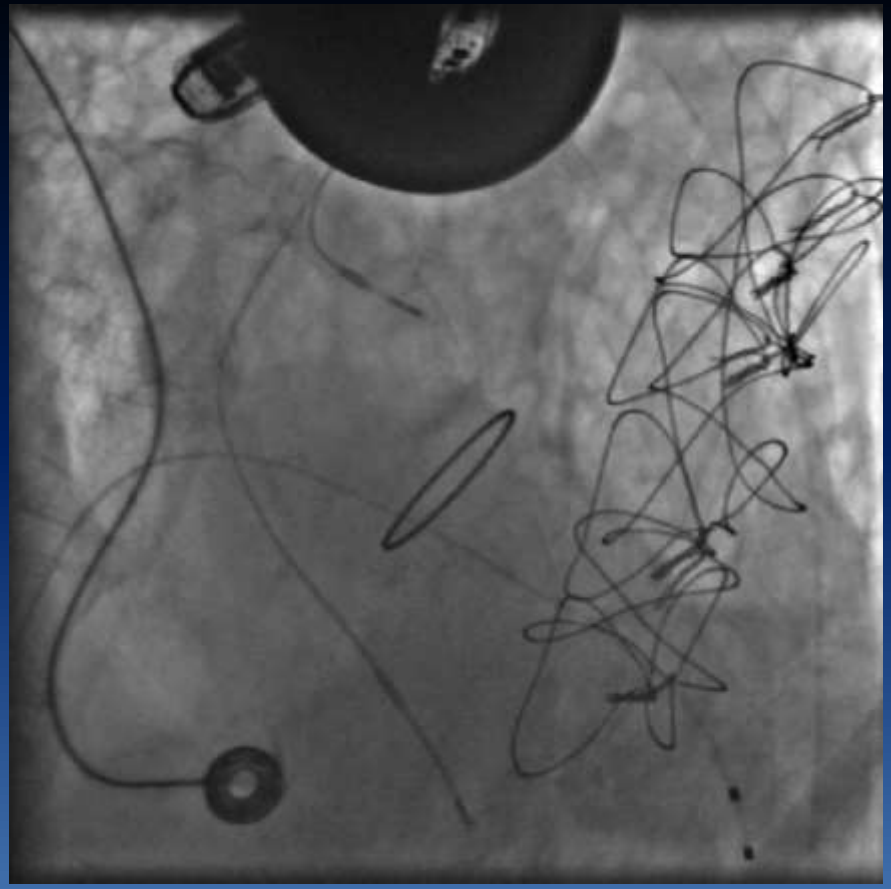


Mitral ViV for Failed Magna Valve

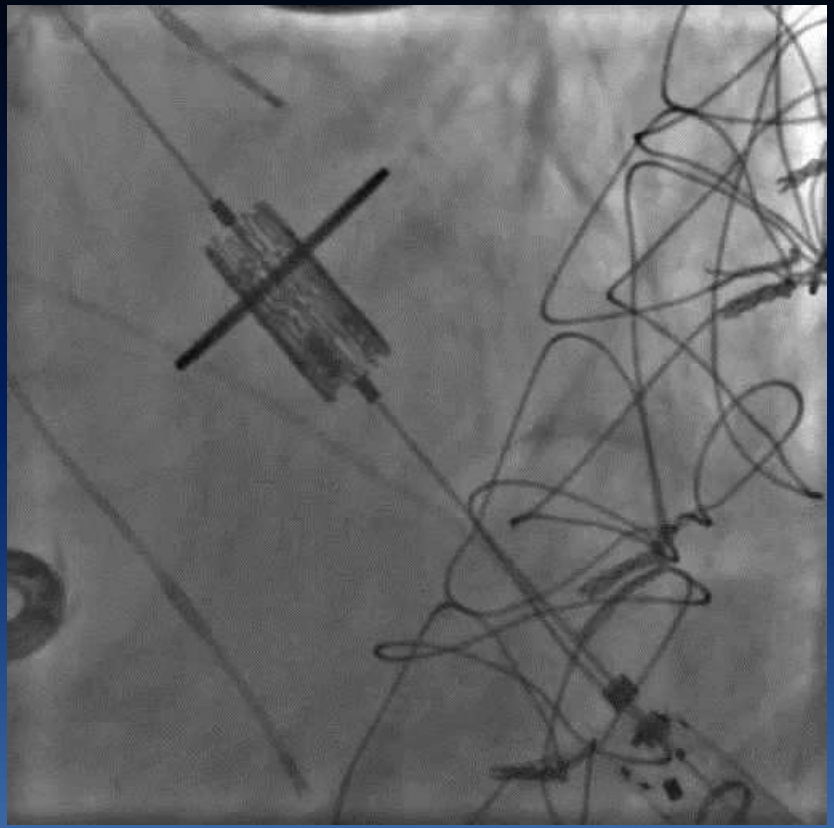
No MR

Mitral Valve-in-Valve Case 2

Mitral ViV for Failed Hancock Valve

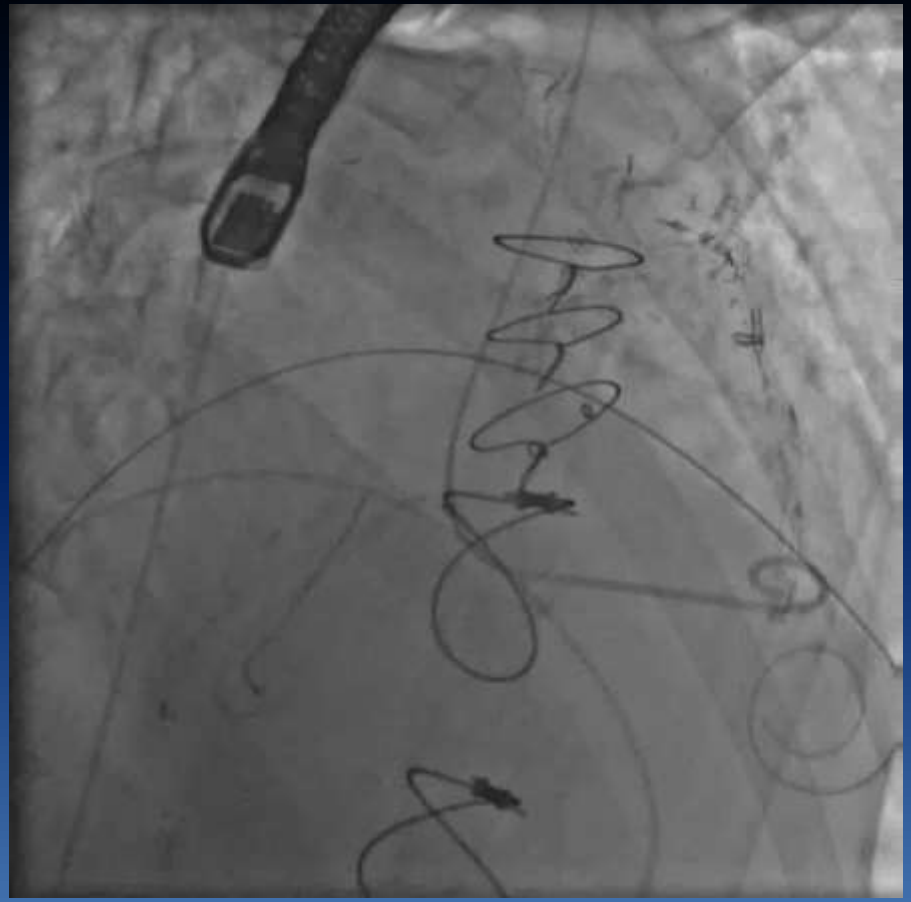


Mitral ViV for Failed Hancock Valve

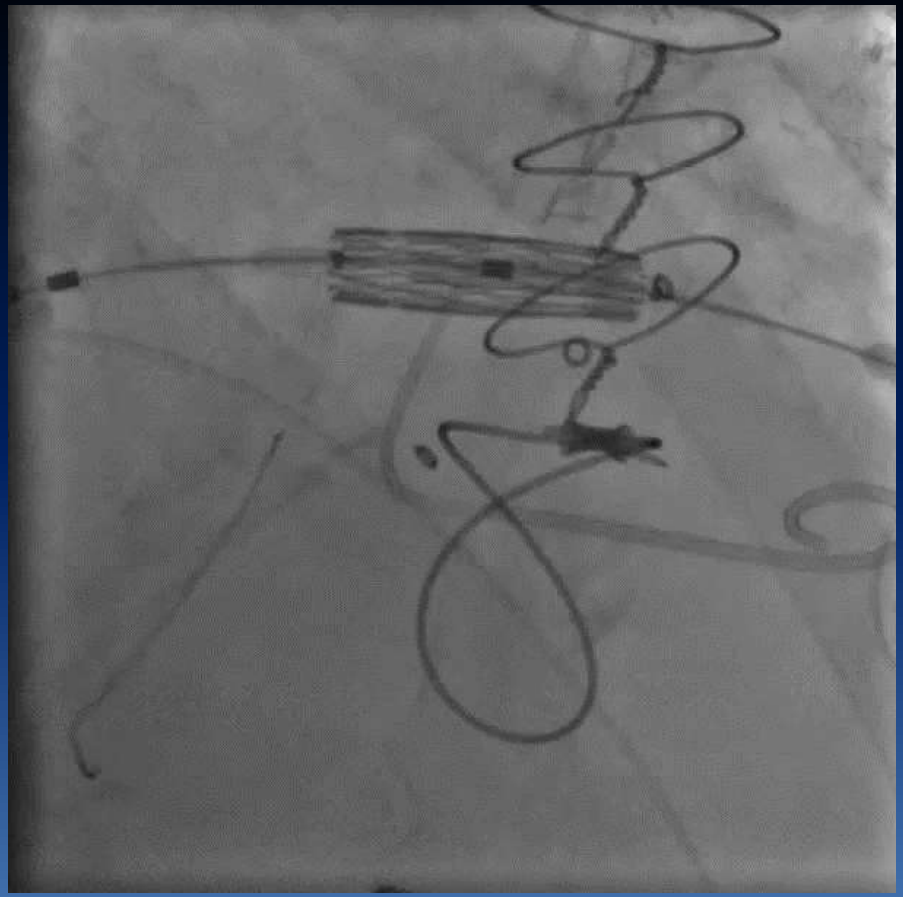


Mitral Valve-in-Valve Case 3

Mitral ViV for Failed Mosaic Valve



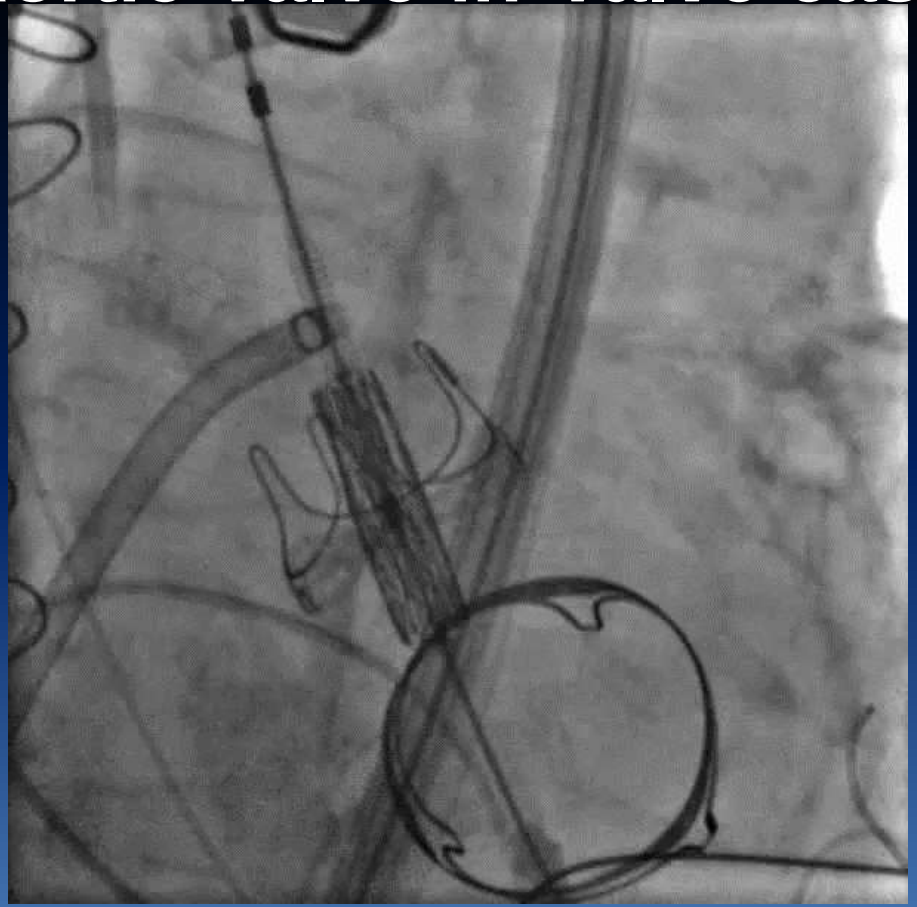
Mitral ViV for Failed Mosaic Valve



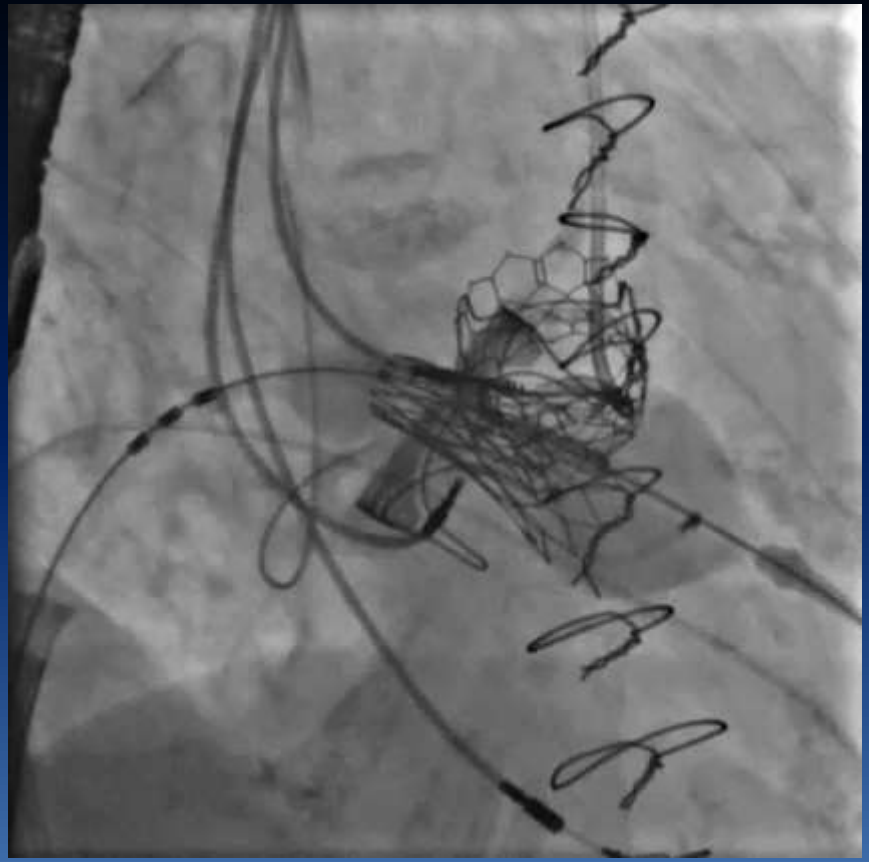
Trivial MR

Aortic and Mitral Valve-in-Valve Case

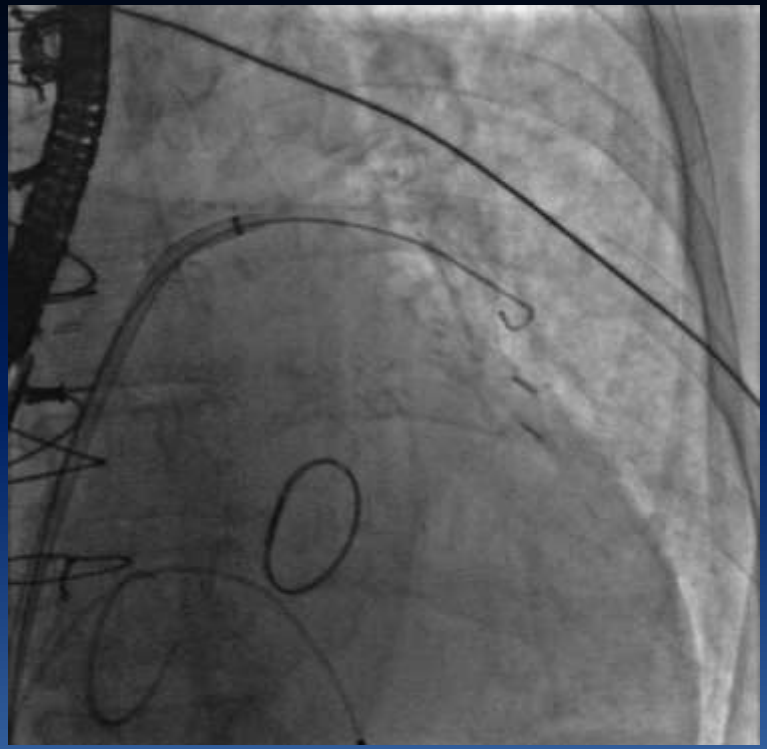
Aortic Valve-in-Valve case



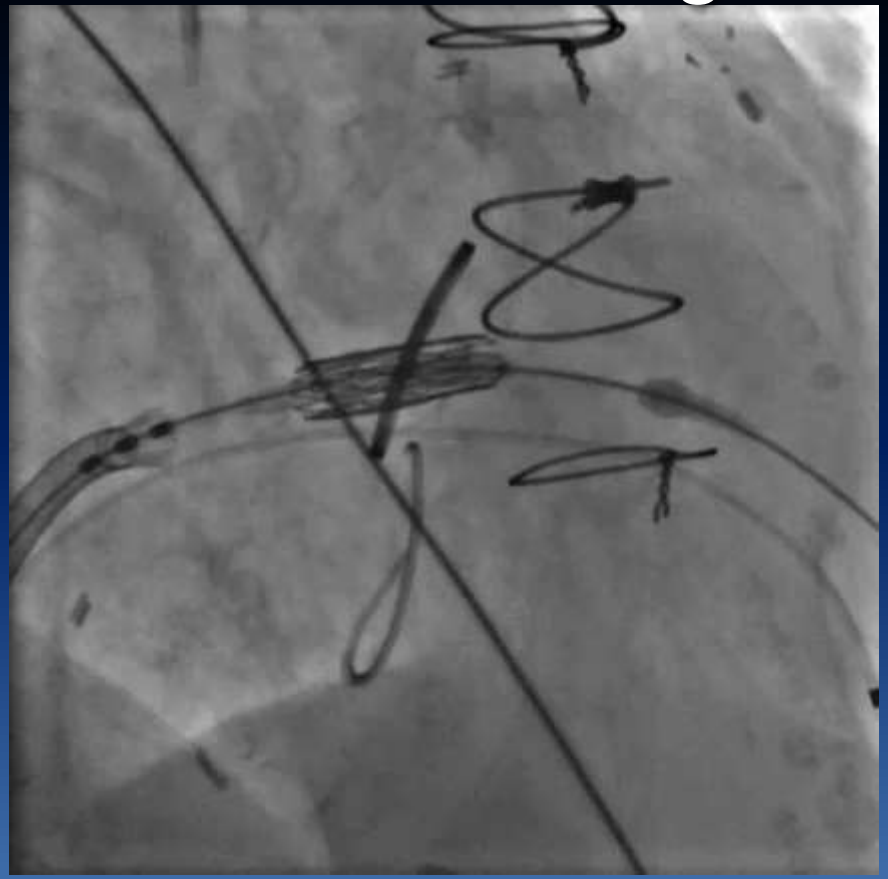
Mitral ViV for Failed Carpenter Edwards valve



Mitral Valve-in-Ring Case



Mitral Valve-in-Ring case



Mild MR

Mitral Valve-in-Ring case

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Transcatheter Mitral Valve Replacement for Degenerated Bioprosthetic Valves and Failed Annuloplasty Rings

Sung-Han Yoon, Raj Makkar et al