AP Valve
Seoul, August 9th, 2019

Outcomes of TMVR for Degenerated Bioprostheses, Failed Annuloplasty Rings and Mitral Annular Calcification

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On Behalf of TMVR Registry Investigators

Sung-Han Yoon et al. European Heart Journal 2018

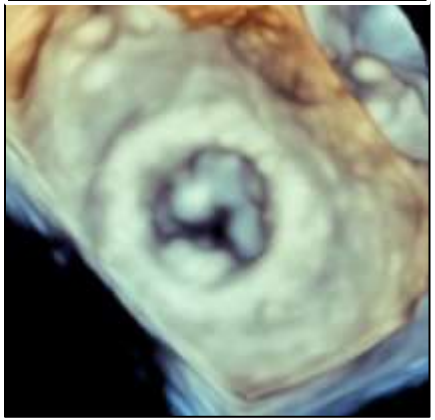
Disclosures

- Grant/Research support from Edwards LifeSciences, Medtronic, Abbott and Boston Scientific

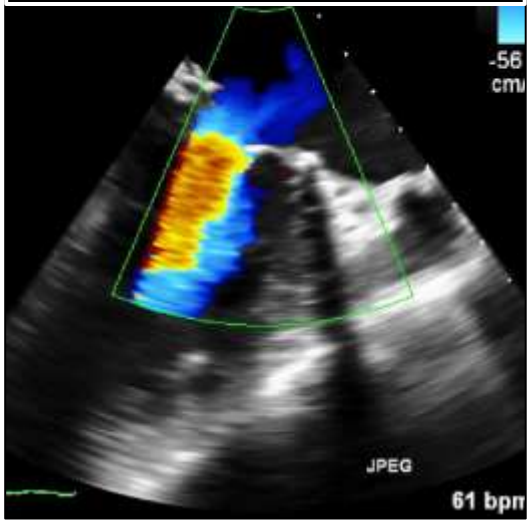
84 y/o male with # 27 Perimount mitral valve

Severe MR and severe MS

Severely restricted leaflets

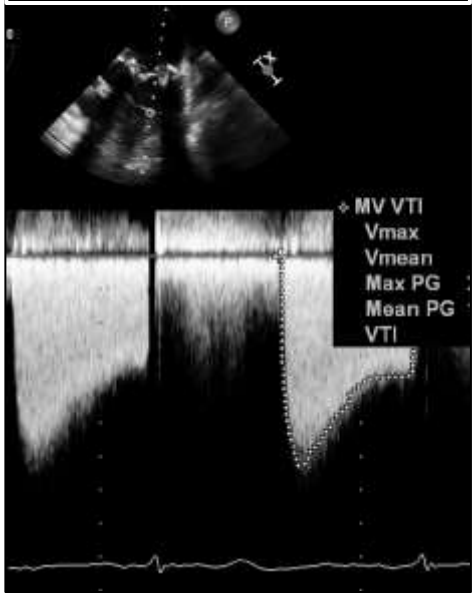


Severe MR

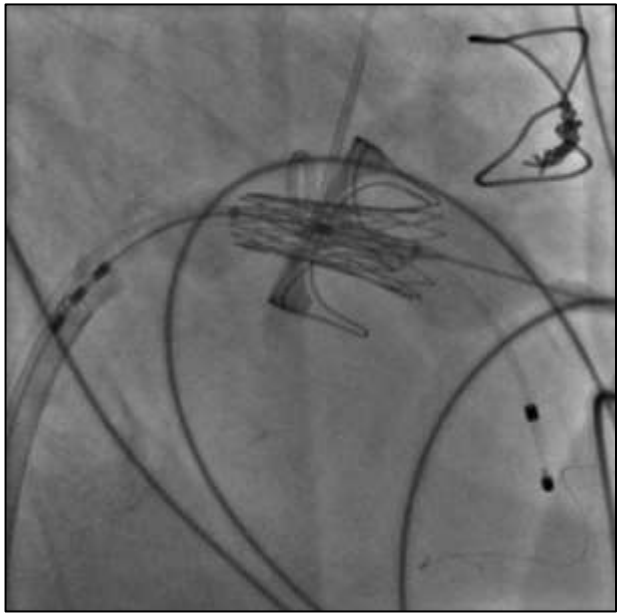


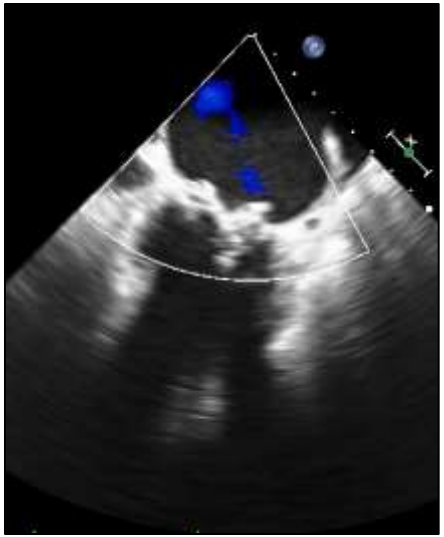
Mitral gradient

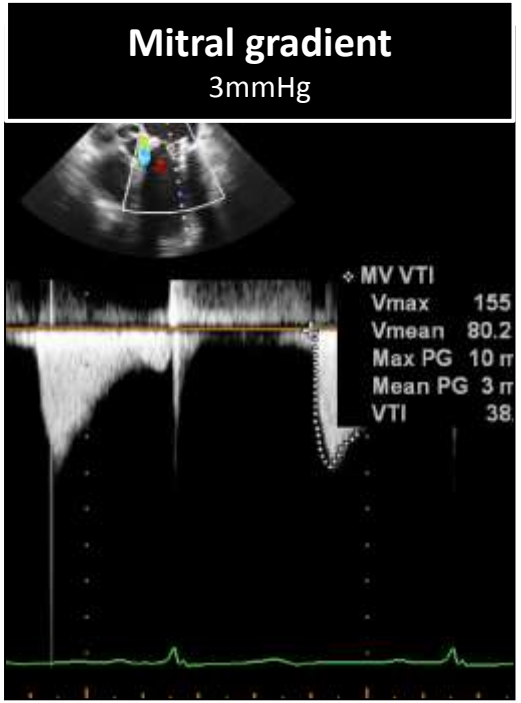
13mmHg



Transcatheter mitral valve in valve performed with a 29mm Sapien 3



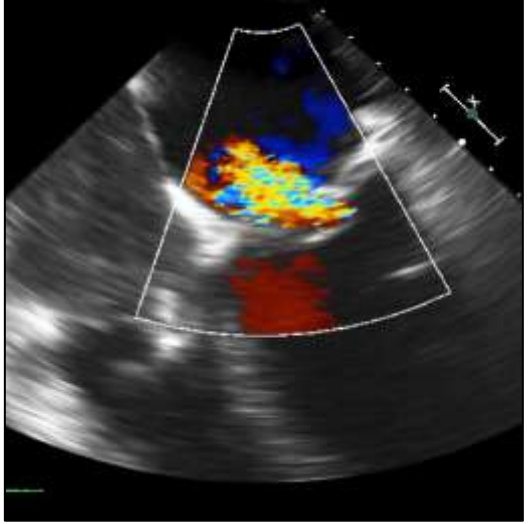




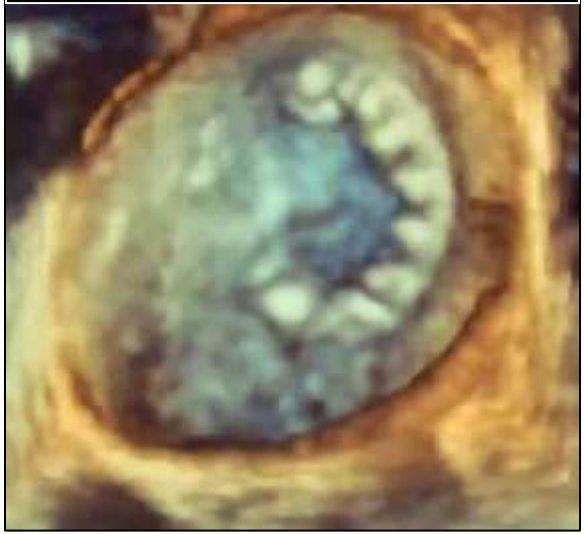
76 y/o male presenting with acute systolic heart failure

Ischemic cardiomyopathy, EF 10%

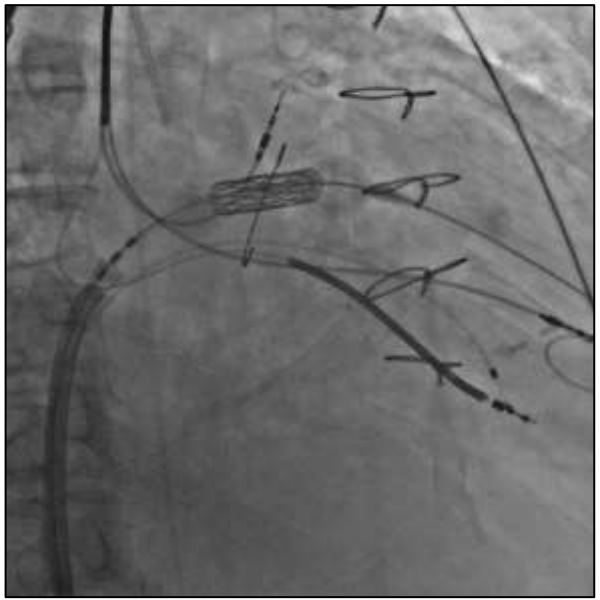
Severe central MR

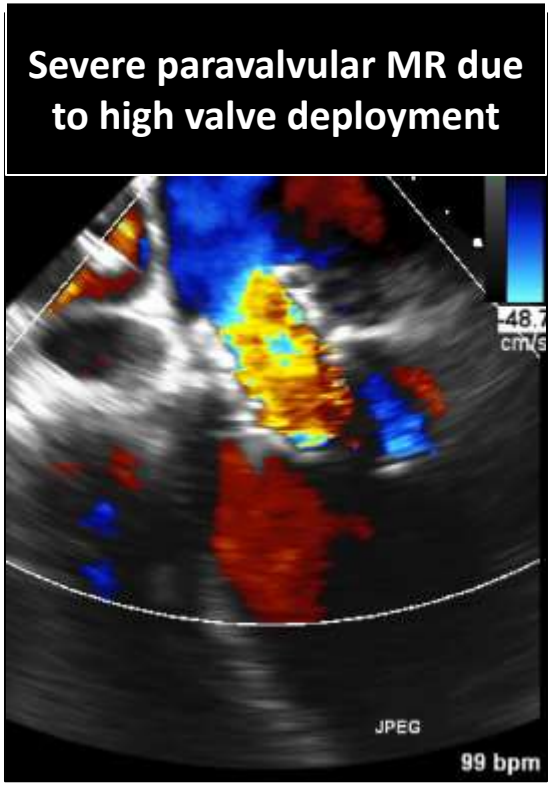


28mm Colvin-Galloway band

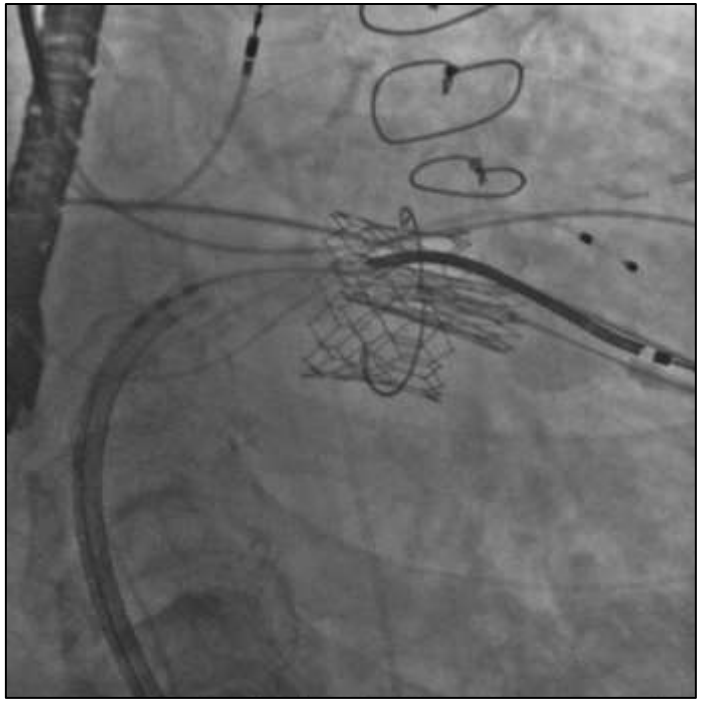


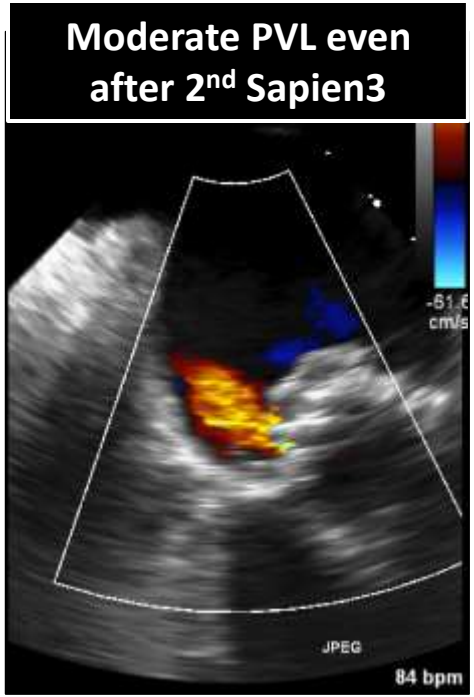
Transcatheter valve in ring performed with 29mm Sapien 3





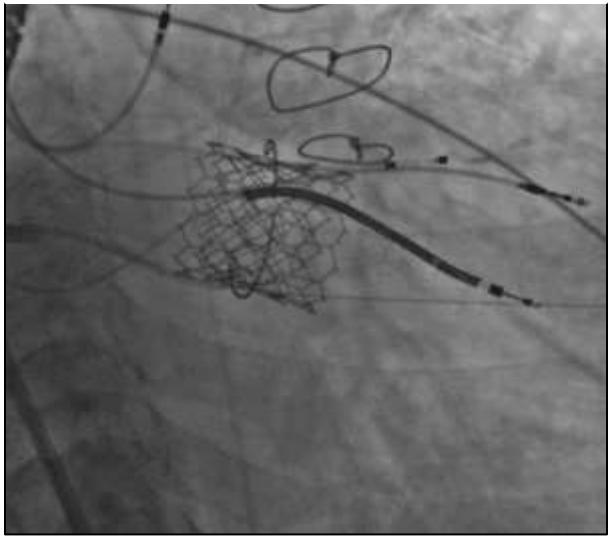
Transcatheter valve-in-valve-in-ring performed with a 2nd 29mm Sapien3 valve



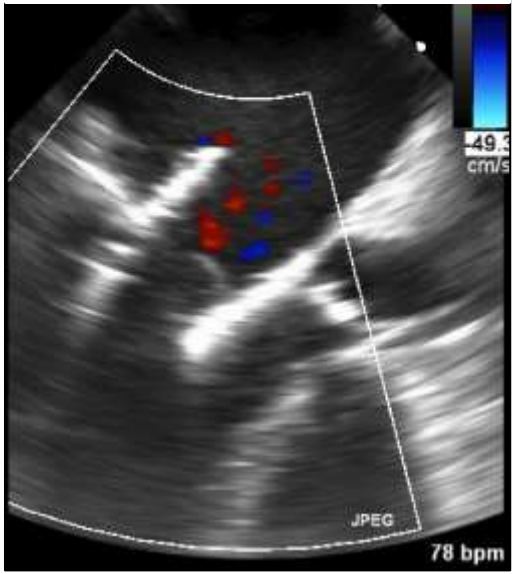


PVL closure with AVP2 plug performed

PVL closure performed with AVP2 plug

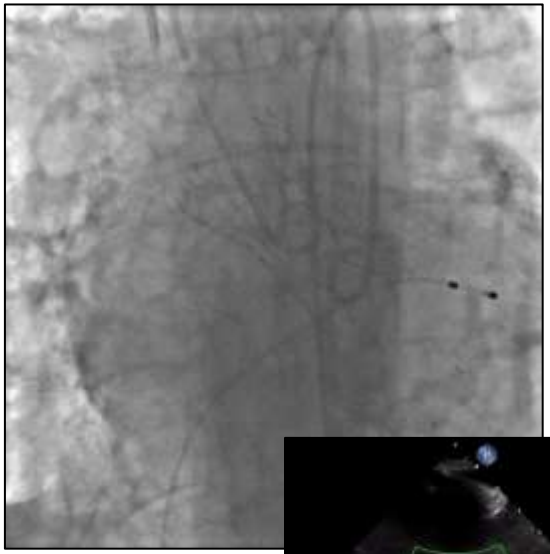


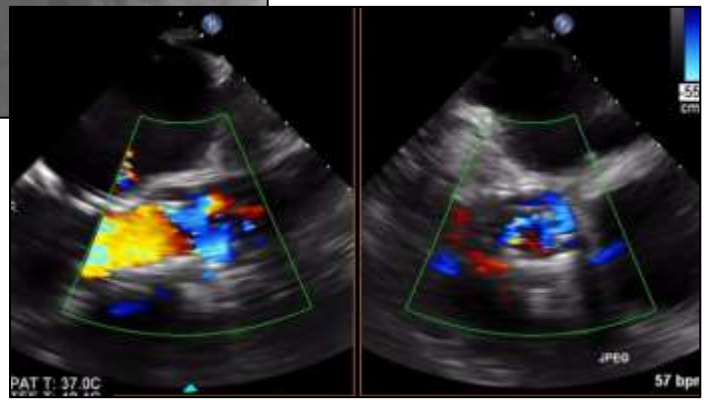
Final result
Mild PVL

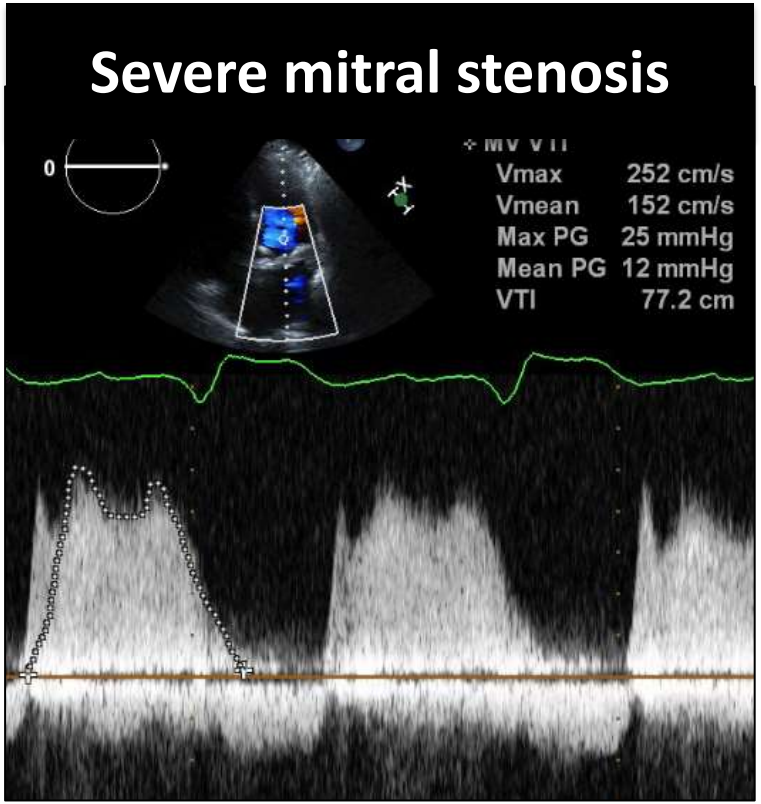


79 y/o male with severe AS s/p TAVR

Continued to experience heart failure



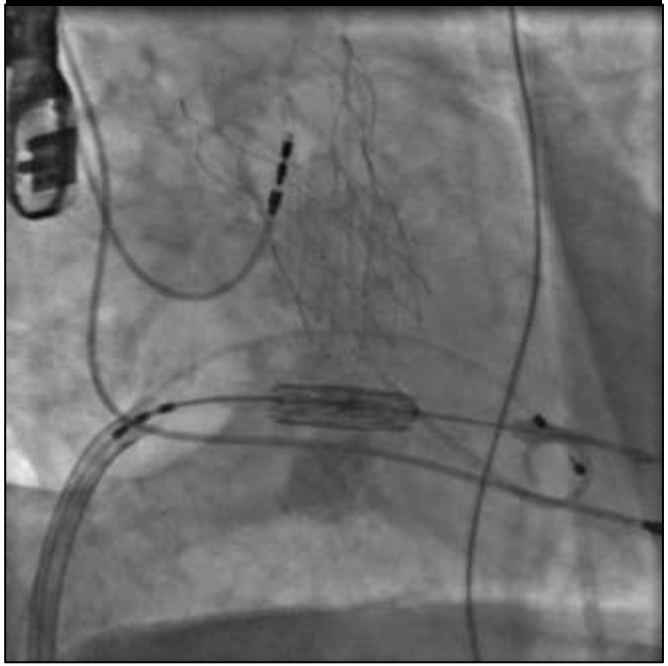




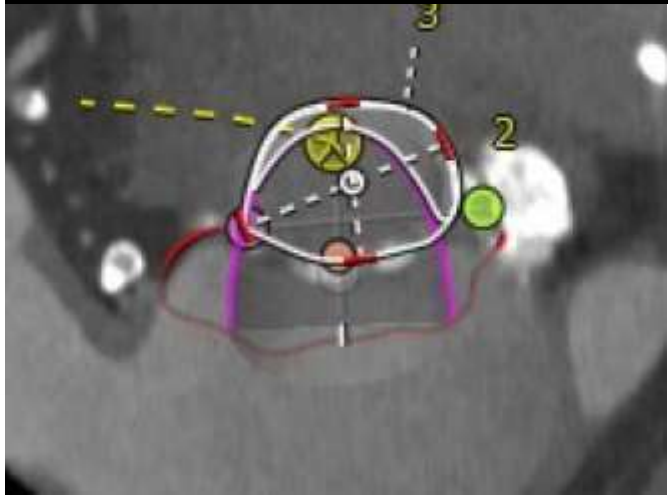
Transseptal Sapien in MAC performed

LVOT obstruction noted after TMVR, managed with alcohol septal ablation

26mm Sapien 3 in mitral annular calcium

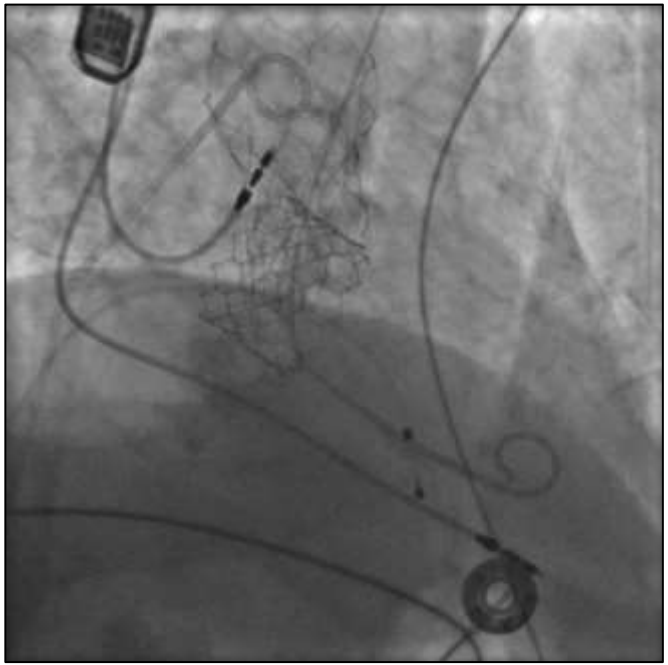


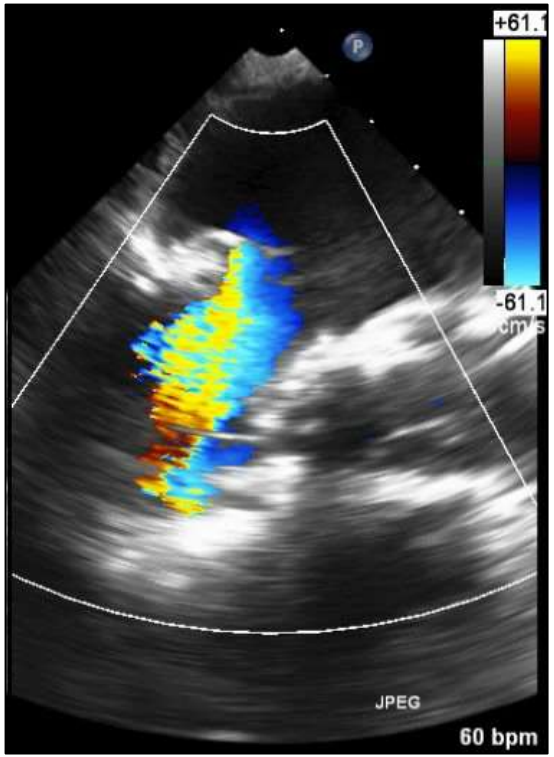
Post-hoc CT analysis revealed a small neo-LVOT area
96.8mm²

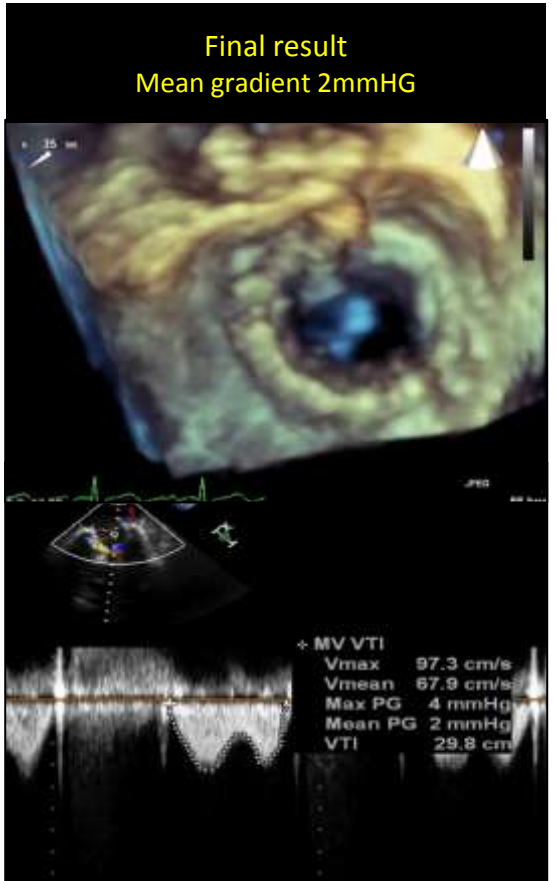


Final result s/p 26mm Sapien 3 in MAC and alcohol septal ablation

No significant MR







Background

- Mitral valve disease is the most common valvular disease and surgery is the gold standard treatment
- Increasing number of patients need MV reoperations due to massive shift from mechanical to bioprosthetic valves and frequent recurrence of MR after MV repair, but reoperations are often considered as high risk
- Patients with severe MAC are poor candidates for conventional surgery
- TMVR is an emerging alternative treatment for these population, but limited data exists regarding its procedural and clinical outcomes

Objective

- We aimed to evaluate and compare the procedural and clinical outcomes of patients undergoing TMVR for degenerated bioprostheses (valve-in-valve [ViV]), failed annuloplasty rings (valve-in-rings [ViR]) and severe MAC (valve-in-MAC [ViMAC])

Methods

- We created an international multicenter registry of TMVR including 40 European and American centers
- Procedural and clinical outcomes of ViV, ViR and ViMAC were evaluated and compared according to MVARC

Baseline Characteristics

	Overall (n = 521)	ViV (n = 322)	ViR (n = 141)	ViMAC (n = 58)	P value
Age, years	73 ± 12	73 ± 13	72 ± 10	75 ± 11	0.28
Female	54%	59%	37%	71%	< 0.001
STS score, %	9.0 ± 7.0	9.2 ± 7.2	8.1 ± 6.4	10.1 ± 6.9	0.12
NYHA class IV	32%	32%	26%	47%	0.02
Creatinine, mg/dl	1.6 ± 1.3	1.5 ± 1.3	1.6 ± 1.2	1.8 ± 1.6	0.16
PVD	11%	12%	11%	12%	0.95
Prior stroke	16%	18%	12%	14%	0.28
COPD	30%	29%	27%	45%	0.03
Prior CABG	33%	29%	49%	19%	< 0.001
Prior MI	16%	12%	26%	12%	0.001

Echocardiographic Data

	Overall (n = 521)	ViV (n = 322)	ViR (n = 141)	ViMAC (n = 58)	P value
LVEF, %	53 ± 14	55 ± 12	44 ± 16	58 ± 11	< 0.001
Mean transmitral gradient, mmHg	11 ± 6	12 ± 6	7 ± 5	12 ± 5	< 0.001
Mechanism of failure					
MR	46%	37%	77%	19%	< 0.001
MS	33%	41%	6%	57%	
Combined	21%	23%	16%	24%	

Procedural Characteristics

	Overall (n = 521)	ViV (n = 322)	ViR (n = 141)	ViMAC (n = 58)	P value
Access site					
Transapical	60%	60%	65%	45%	0.09
Transseptal	40%	39%	36%	53%	
Device type					
Sapien/XT/S3 valves	90%	94%	85%	81%	< 0.001
Lotus	6%	4%	6%	16%	
Planned concomitant AVR	4%	4%	1%	12%	0.001
Balloon pre-dilatation	9%	11%	4%	16%	0.01
Balloon post-dilatation	9%	4%	16%	19%	< 0.001

Procedural Outcomes

	Overall (n = 521)	ViV (n = 322)	ViR (n = 141)	ViMAC (n = 58)	P value
Conversion to surgery	2.3%	0.9%	2.8%	8.6%	0.004
Valve embolization	1.7%	0.9%	1.4%	6.9%	0.01
LV perforation	0.8%	1.2%	0.0%	0.0%	0.58
Need for second valve	5.4%	2.5%	12.1%	5.2%	< 0.001
LVOT obstruction	7.1%	2.2%	5.0%	39.7%	< 0.001
Technical Success *	87.1%	94.4%	80.9%	62.1%	< 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

Procedural Outcomes

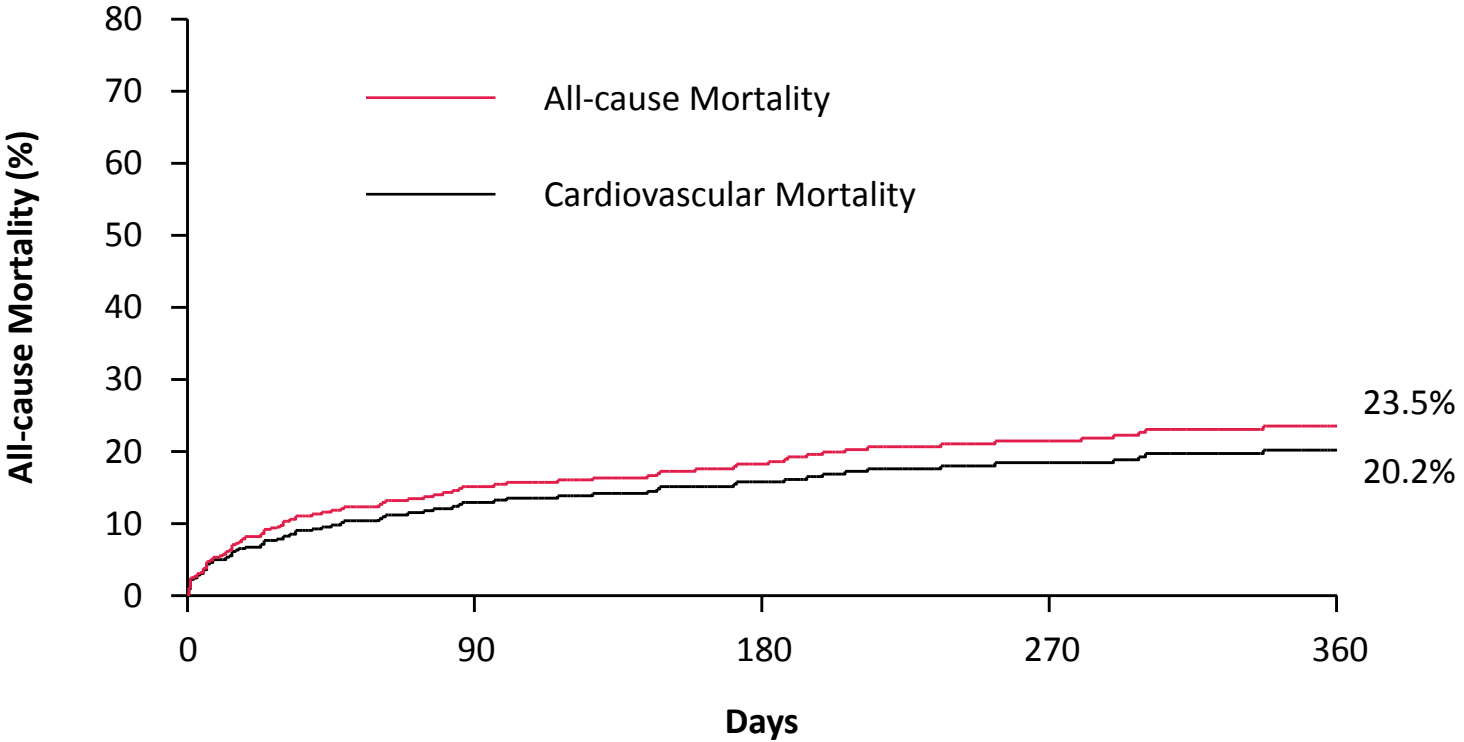
	Overall (n = 521)	ViV (n = 322)	ViR (n = 141)	ViMAC (n = 58)	P value
Echocardiography					
LVEF, %	51 ± 14	53 ± 13	44 ± 15	58 ± 12	< 0.001
Mean gradient, mmHg	6 ± 3	6 ± 3	7 ± 3	5 ± 3	0.019
MR ≥ moderate	10.0%	5.6%	18.4%	13.8%	< 0.001
Re-intervention	14.0%	10.9%	17.7%	22.4%	0.02
Paravalvular leak closure	3.5%	2.2%	7.8%	0.0%	0.006
Alcohol septal ablation	1.9%	0.6%	0.7%	12.1%	< 0.001
ASD closure	6.9%	7.1%	5.0%	10.3%	0.38
Surgical mitral valve replacement	1.9%	1.9%	2.1%	1.7%	0.98
Device success	77%	85%	70%	53%	< 0.001

Clinical Outcomes

	Overall (n = 521)	ViV (n = 322)	ViR (n = 141)	ViMAC (n = 58)	P value
Mortality at 30 days	10.4%	6.2%	9.9%	34.5%	< 0.001
Stroke	1.7%	2.2%	0.0%	3.4%	0.15
Bleeding, life-threatening or fatal	3.5%	2.2%	6.4%	3.4%	0.07
Major vascular complication	2.7%	1.6%	3.5%	6.9%	0.05
AKI (stage 2 or 3)	6.5%	4.3%	9.2%	12.1%	0.03
Procedural success	65.8%	73.6%	58.2%	41.4%	< 0.001

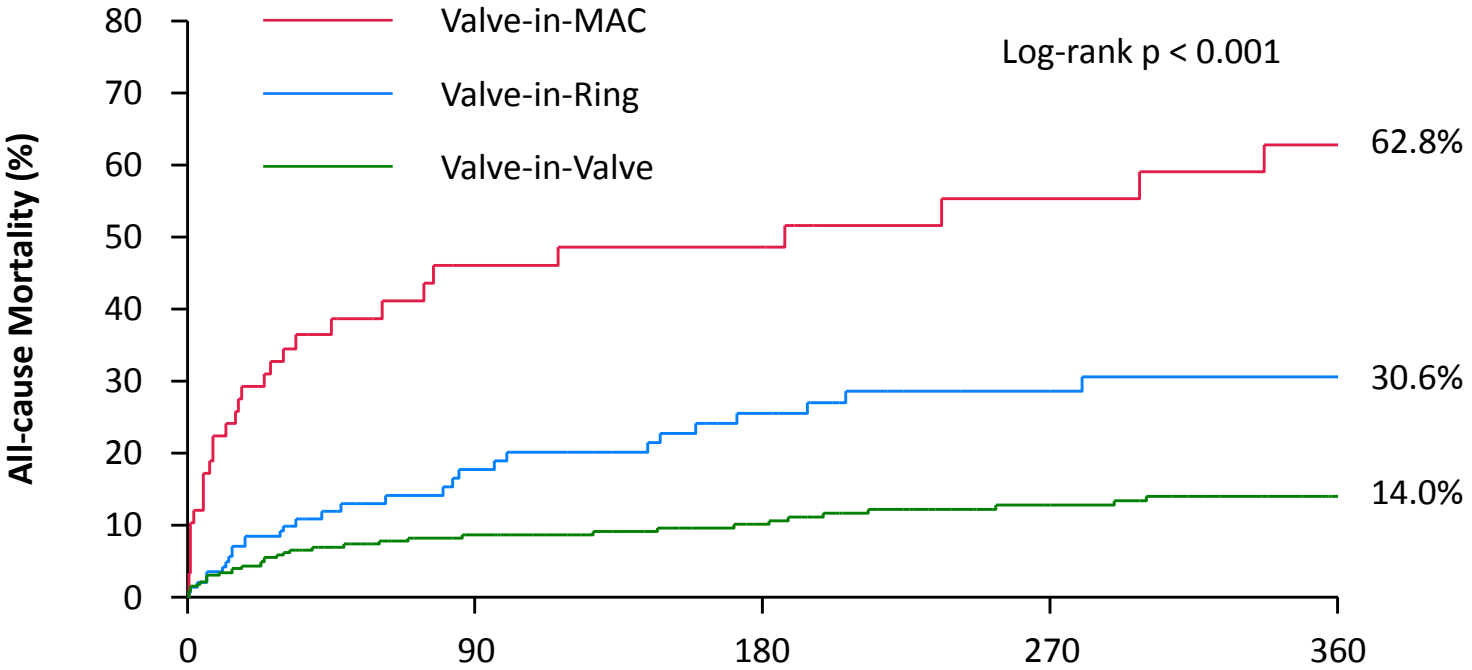
Mid-term Mortality

Overall All-cause and CV Mortality



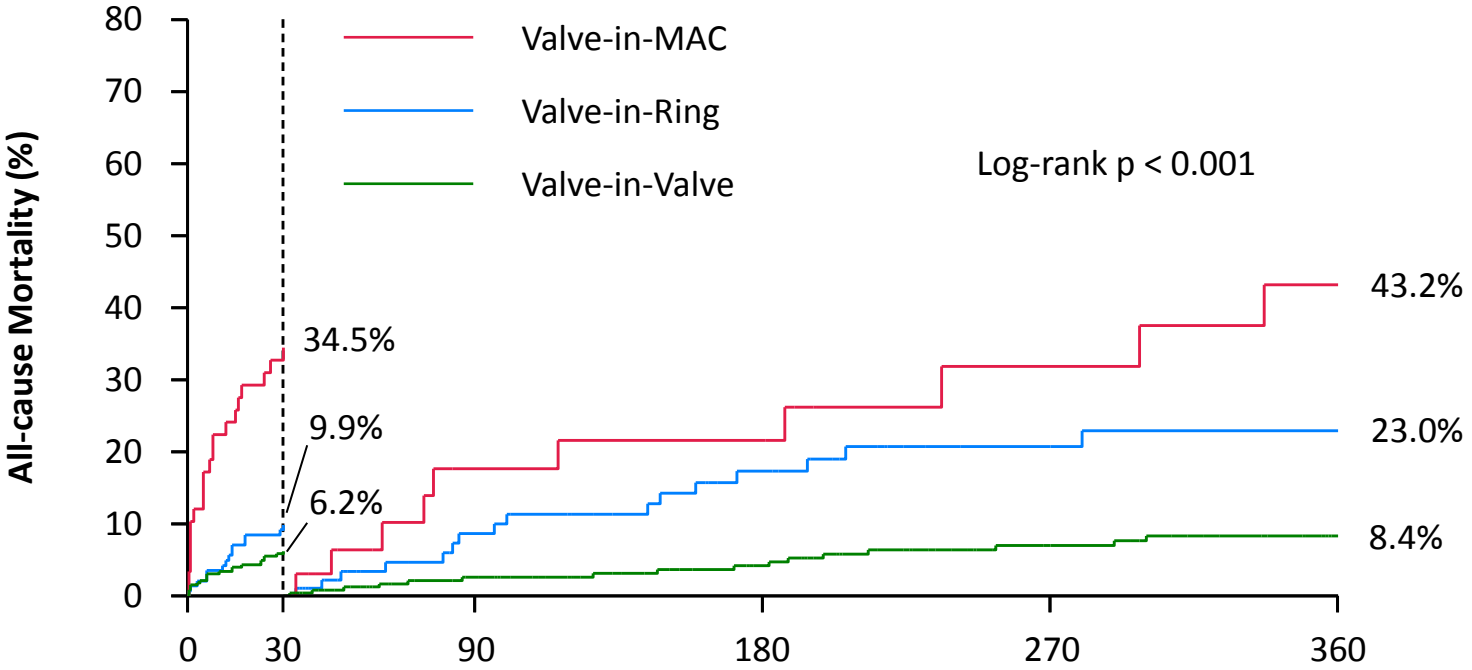
No. at Risk			
	521	253	171

All-cause Mortality According to TMVR



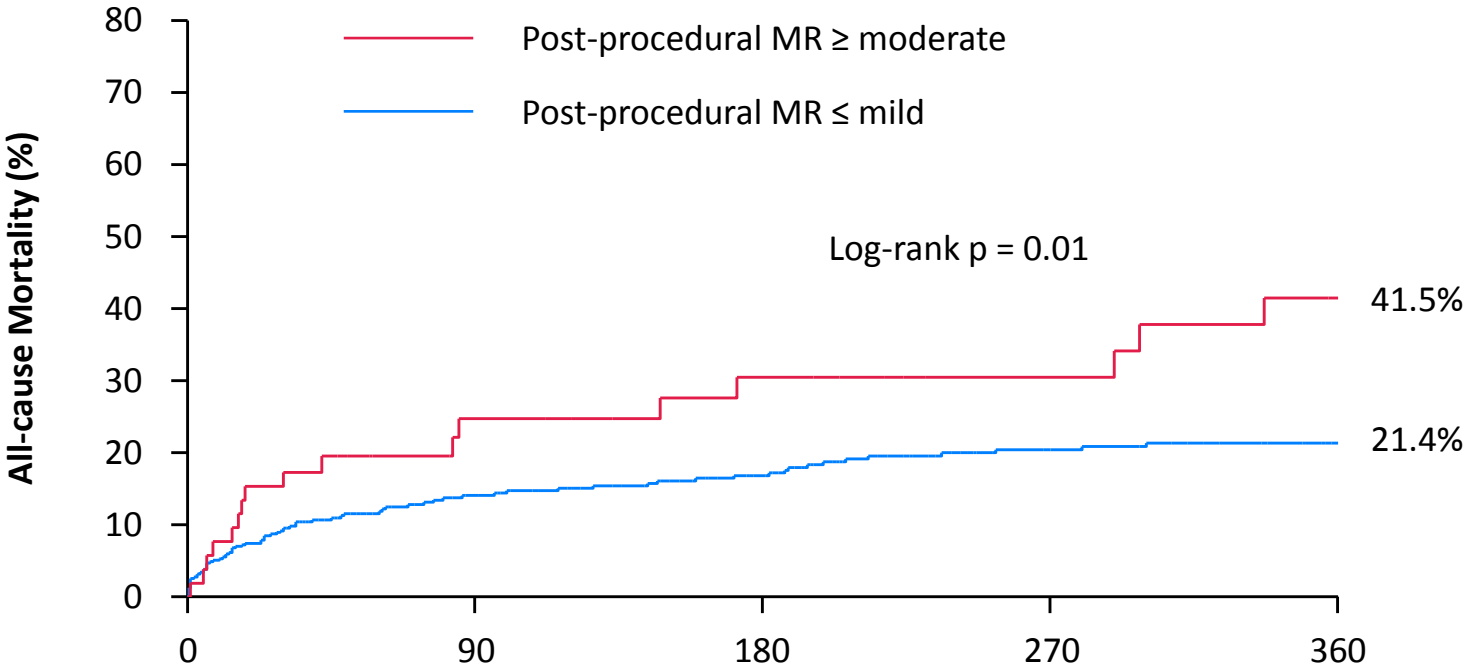
No. at Risk			
Valve-in-MAC	58	20	10
Valve-in-Ring	141	53	34
Valve-in-Valve	322	180	127

Landmark Analysis of All-cause Mortality



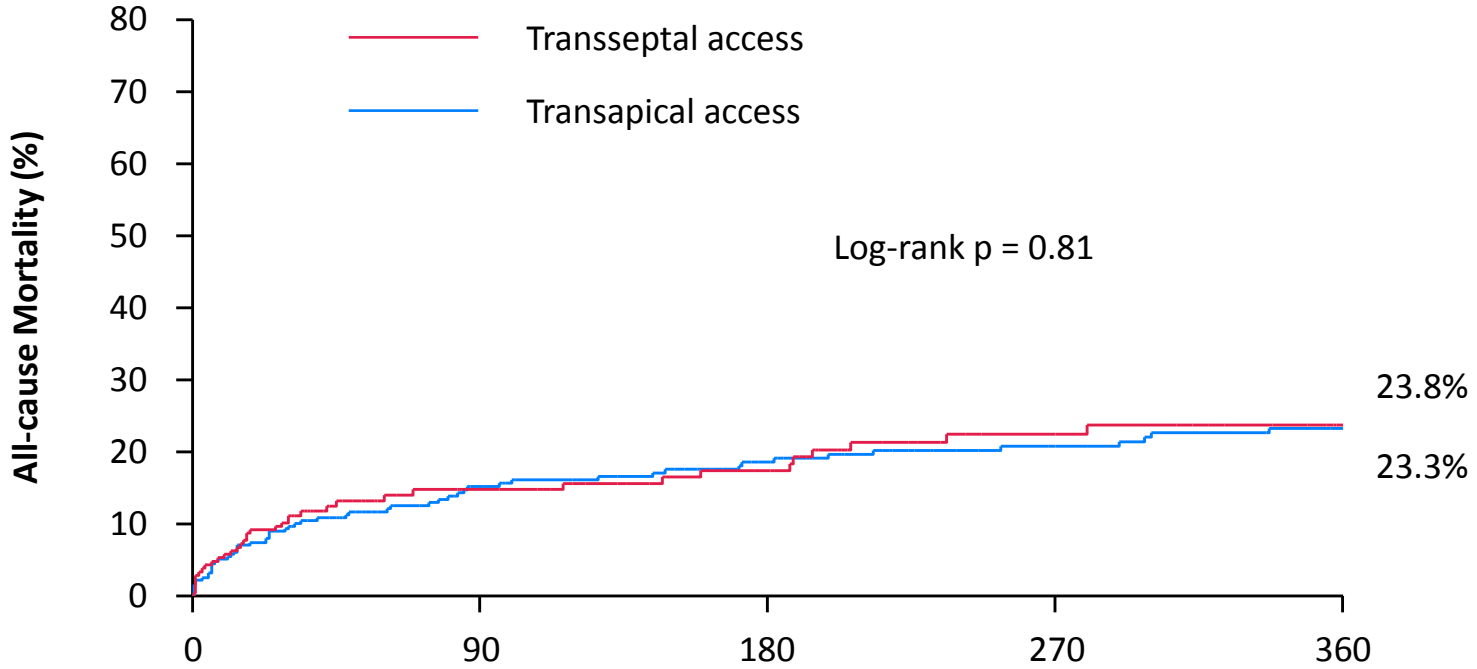
No. at Risk			
Valve-in-MAC	58	20	10
Valve-in-Ring	141	53	34
Valve-in-Valve	322	180	127

All-cause Mortality According to Post-procedural MR



No. at Risk			
MR ≥ moderate	52	25	15
MR ≤ mild	469	228	156

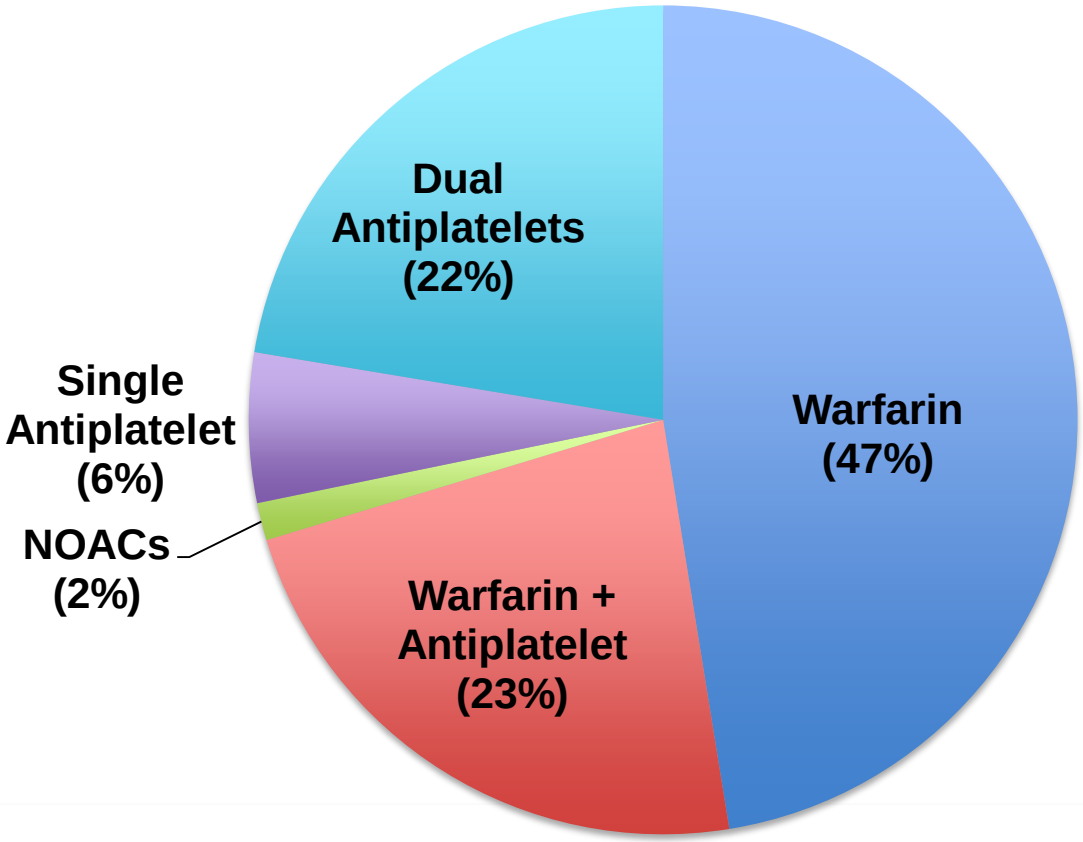
All-cause Mortality According to Access Sites



No. at Risk			
Transseptal	206	91	49
Transapical	310	160	120

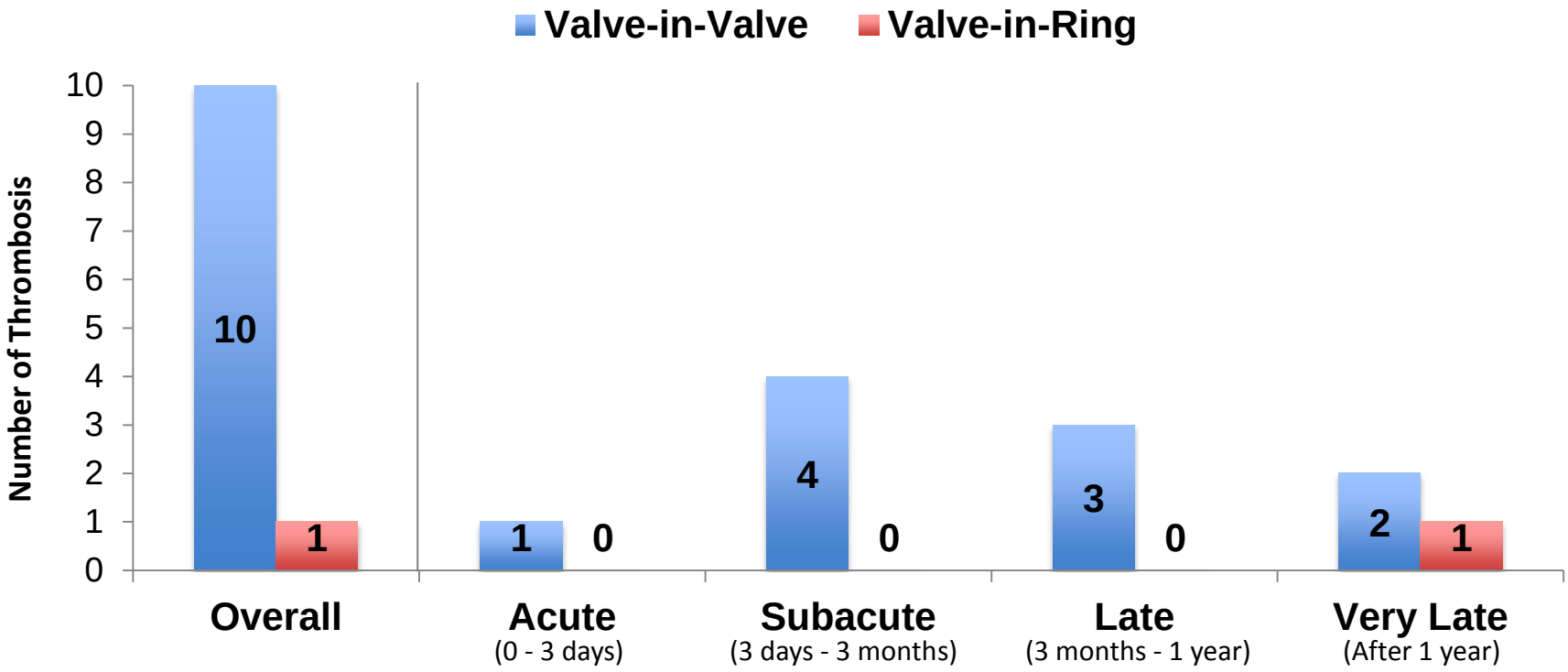
Valve Thrombosis

Antithrombotic Treatment

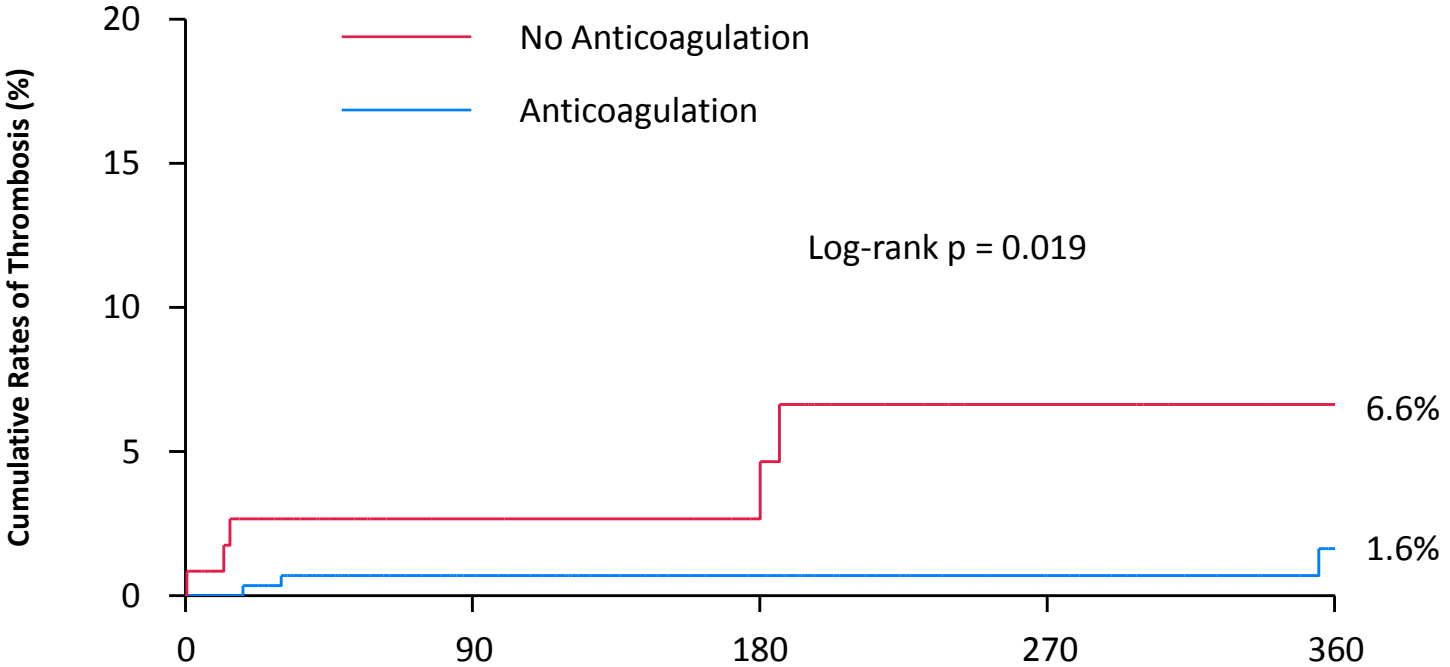


n = 411

Valve Thrombosis



Valve Thrombosis and Anticoagulation



No. at Risk			
No Anticoagulation	116	51	34
Anticoagulation	295	154	102

Conclusions

- Excellent outcomes of TMVR for patients with degenerated mitral bioprosthetic valves (ViV) despite high surgical risk
- Suboptimal procedural outcomes of ViR and ViMAC:
  second valve implantation, LVOT obstruction and post-procedural MR
- Higher mid-term mortality with ViR and ViMAC due to adverse events and underlying mitral valve disease
- Higher incidence of valve thrombosis without anticoagulation
- Optimal patient selection and procedure refinement likely to improve the outcomes of TMVR

Can we improve…

- Procedural outcomes?
- Residual MR?
- Residual gradients?
- Thrombosis rates?
- Mortality?

Yes, we can!

How?

Patient Selection

CT

MViV and MViR:

Insights from Registries and Trials

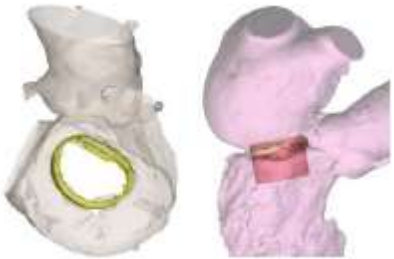
Mayra Guerrero MD
Professor of Medicine
Department of Cardiovascular Medicine
Mayo Clinic Hospital

TVT 2019, Chicago, IL
June 14th, 2019

Cardiac CT & Procedural Planning

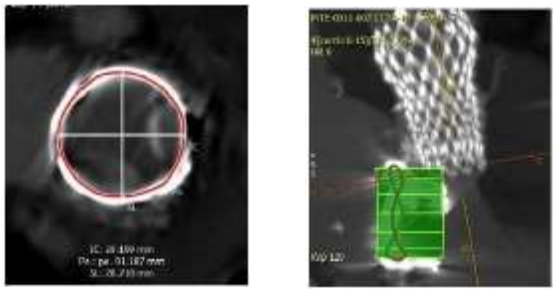
- THV size selection based on mitral annular area
- Risks of LVOT obstruction and embolization were evaluated
- Access route (transeptal preferred if adequate anatomy)
- Deployment angle for procedural planning

Valve in Ring



Compared with ViV app recommendation:
Sizing agreement in 80%
Different size chosen in **20%** (smaller=2, larger=4)

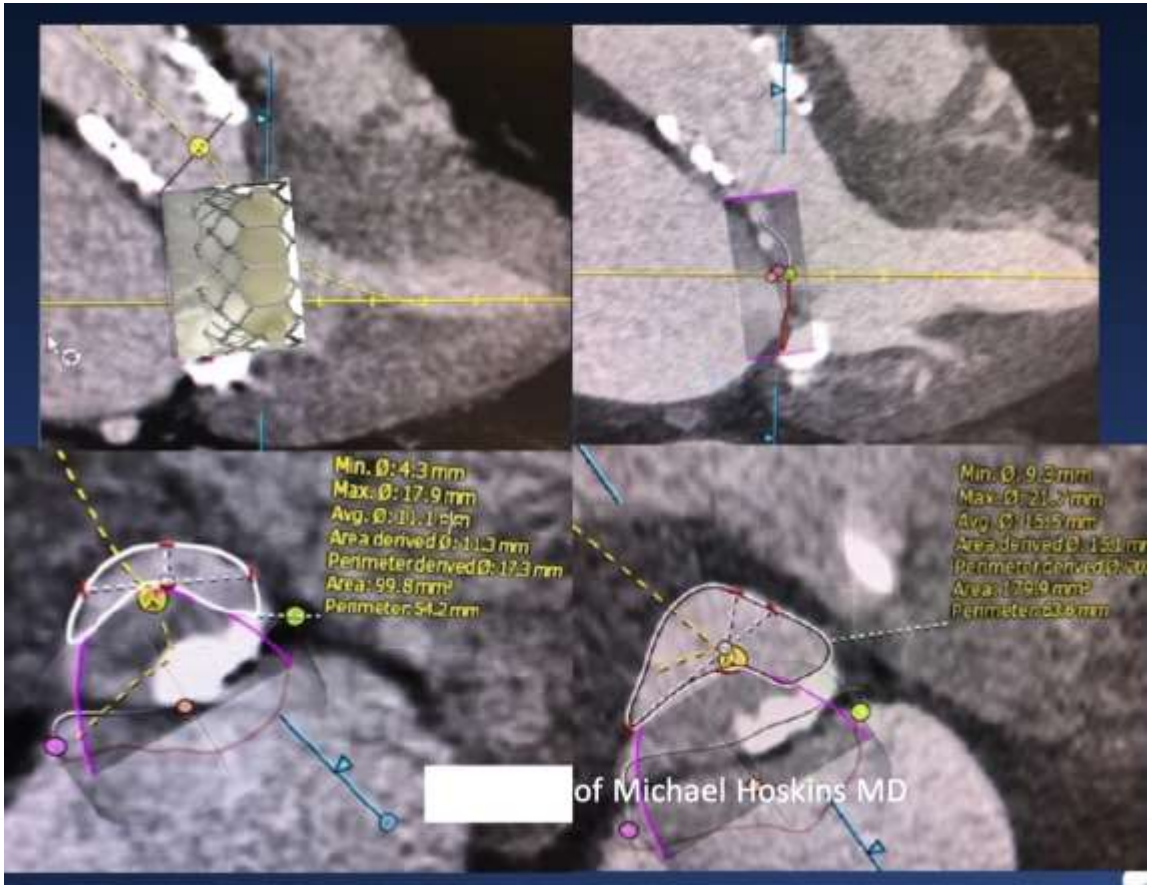
Valve in Valve



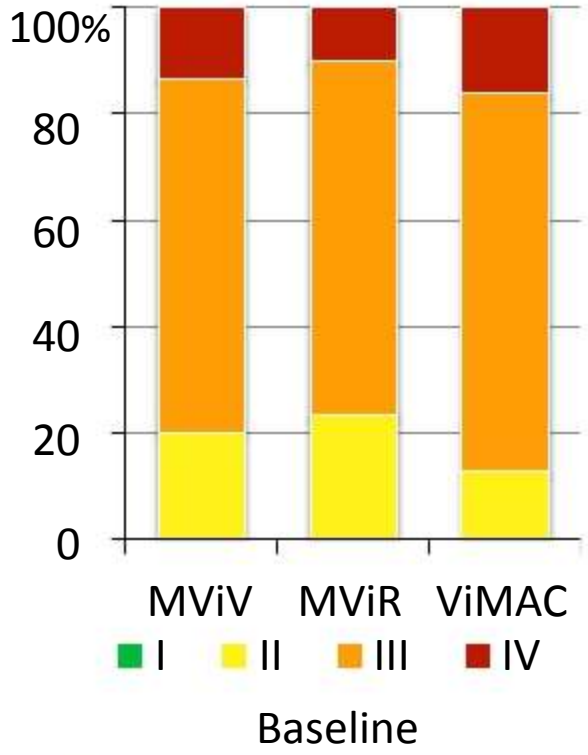
Compared with ViV app recommendation:
Sizing agreement in 57%
Difference size chosen in **43%** (1 size smaller in 13 patients)

CT is the Boss: Pre Post

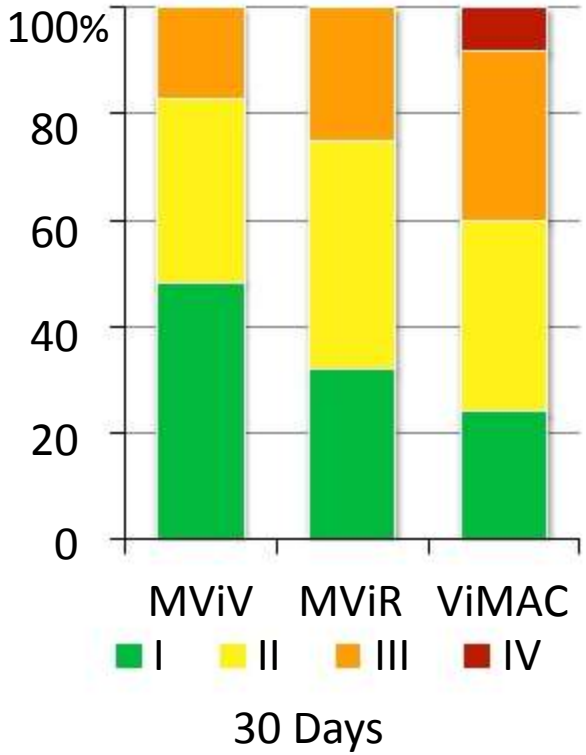
- **Determines Angle of Deployment**
- **Risk of LVOT Obstruction**
- **Size of Valve**



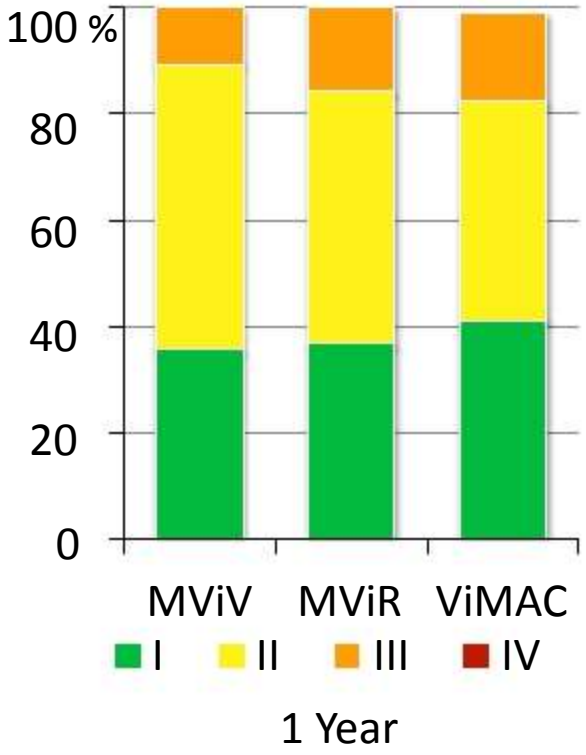
NYHA Class



Baseline



30 Days



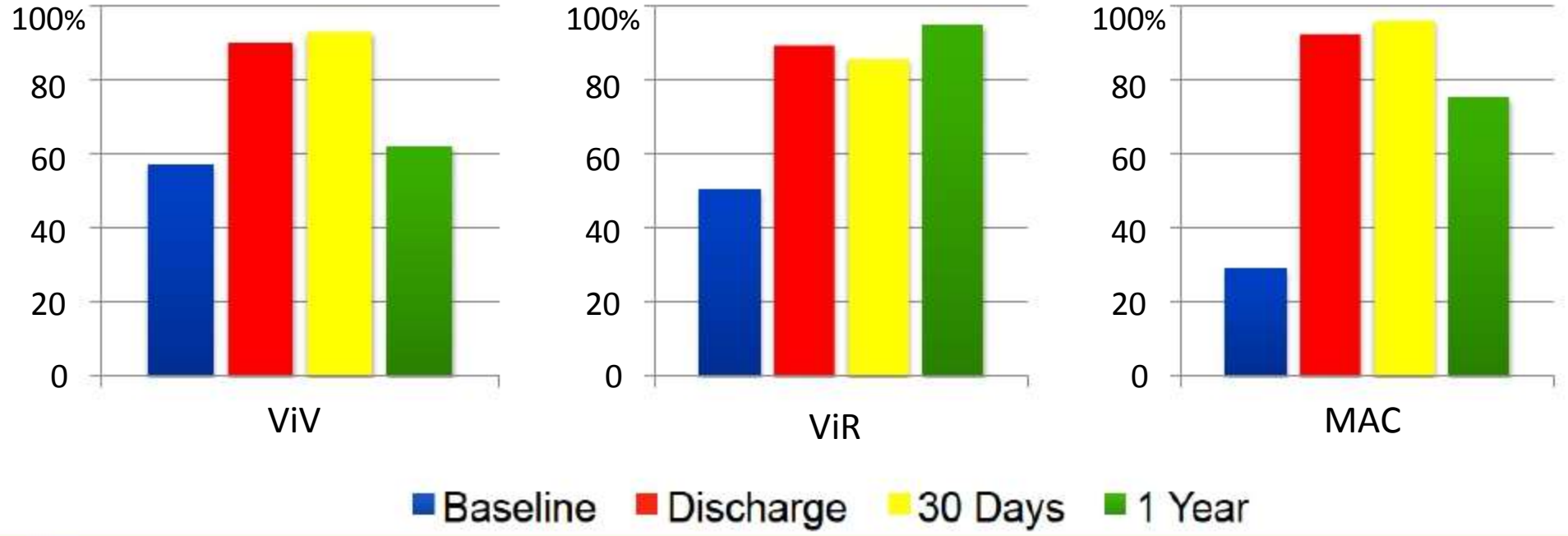
1 Year

Courtesy Mayra Guerrero MD

Anticoagulation Therapy

A minimum of 3 months of anticoagulation after TMVR was recommended

(warfarin, INR 2-3)



Percentage of patients on anticoagulation

Valve Thrombosis at 1 year

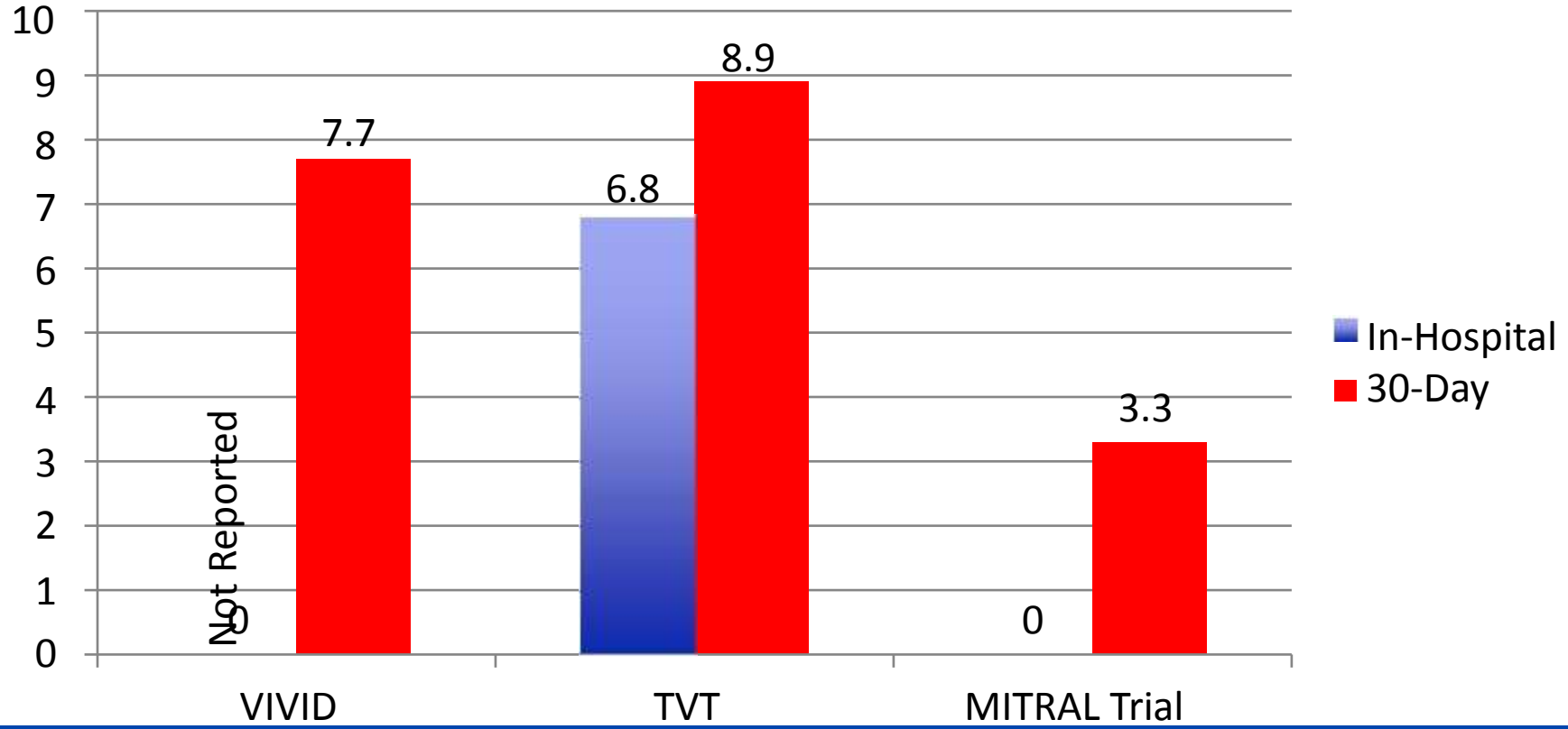
	ViV	ViR	MAC
ValveThrombosis	0	0	1(3.3%)*

1/90 (1.1%) in entire cohort.

- Subclinical: Incidental finding on 1-year echo in a patient not receiving anticoagulation. Mean MVG 4.5 mmHg, trivial central MR unchanged from post-procedure. Successfully treated with warfarin without sequela.

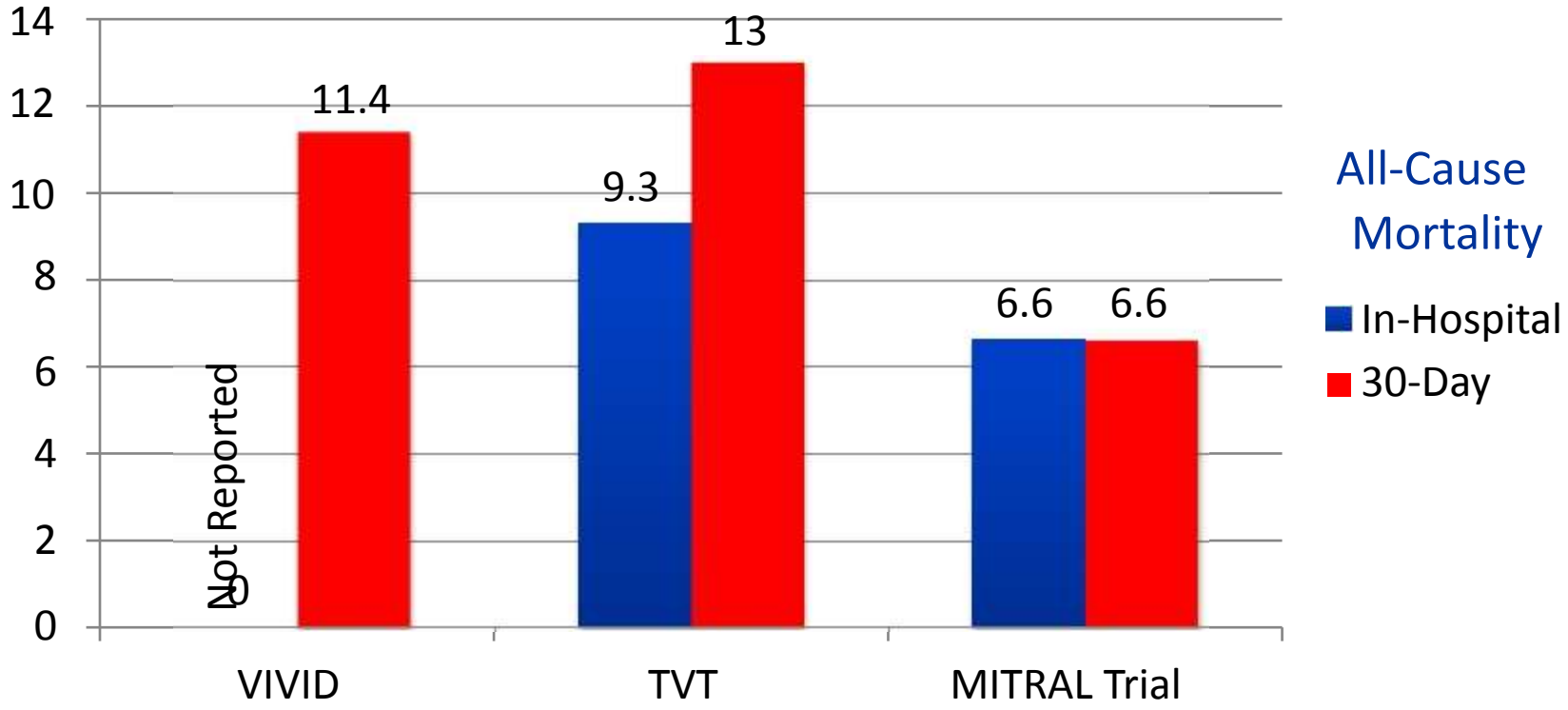
Mitral Valve-in-Valve Early Experience

30 day Mortality



Mitral Valve-in-Ring Early Experience

No FDA approval yet

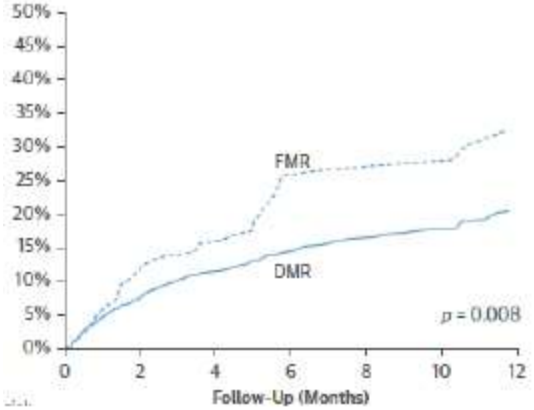


Transseptal 18.5%

Transseptal 38.3%

Transseptal 100%

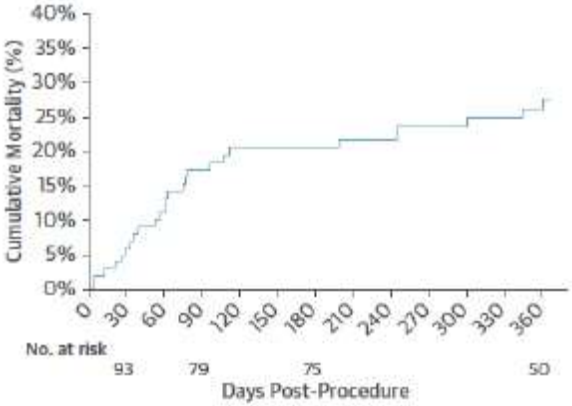
1-Year Mortality



31.2%

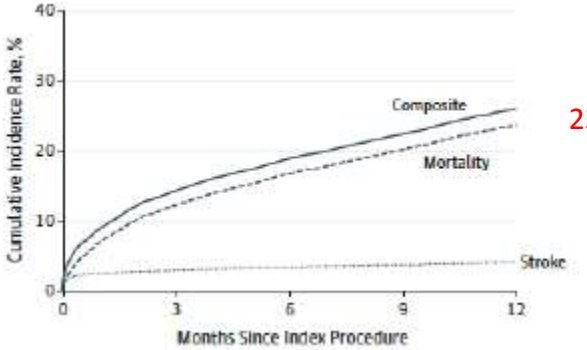
24.7%

MitraClip TVT Registry (STS MVr 6.1%, MVR 9.2%)



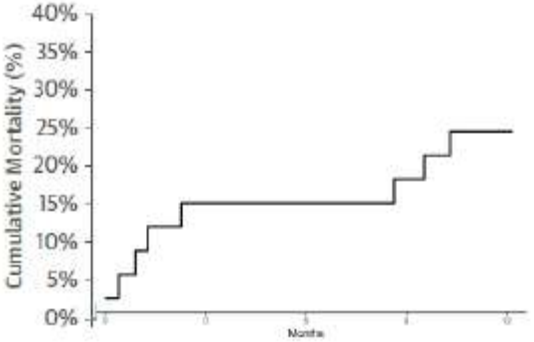
26%

Tendyne First 100 patients (STS score 7.8%)



23.7%

TAVR Outcomes TVT Registry n=12,182 (STS 7.1%)



26.7%

MITRAL Trial ViR arm, n=30 (STS 8.7%)

Sorajja, et al JACC 2017
Sorajja, et al JACC 2019
Holmes, et al JAMA 2015
Guerrero, et al. EuroPCR 2019

Courtesy Mayra Guerrero MD

Summary

- Contemporary outcomes of MViV and MViR are superior to prior registries
- Patients who survive have sustained improvement of symptoms at 1 year
- Low thrombosis rate was observed at 1 year (1.1%)
- Valve performance is maintained at 1 year in all groups
- Mean MVG was higher with 23mm SAPIEN 3 valves particularly in MViR (highest in small rigid ring)

Courtesy Mayra Guerrero MD

Conclusions

- Transeptal MViV was associated with excellent outcomes at 1-year.
  It should be standard of care for all patients who have favorable anatomy

- Transseptal MViR had 1-year mortality similar to MitraClip in TVT Registry.
  It is a reasonable alternative for high risk patients in patients who have favorable anatomy *(not small S3 in rigid rings)*

