Mitral VIV and VIR Current Evidence

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☑ I have the following potential conflicts of interest to report:

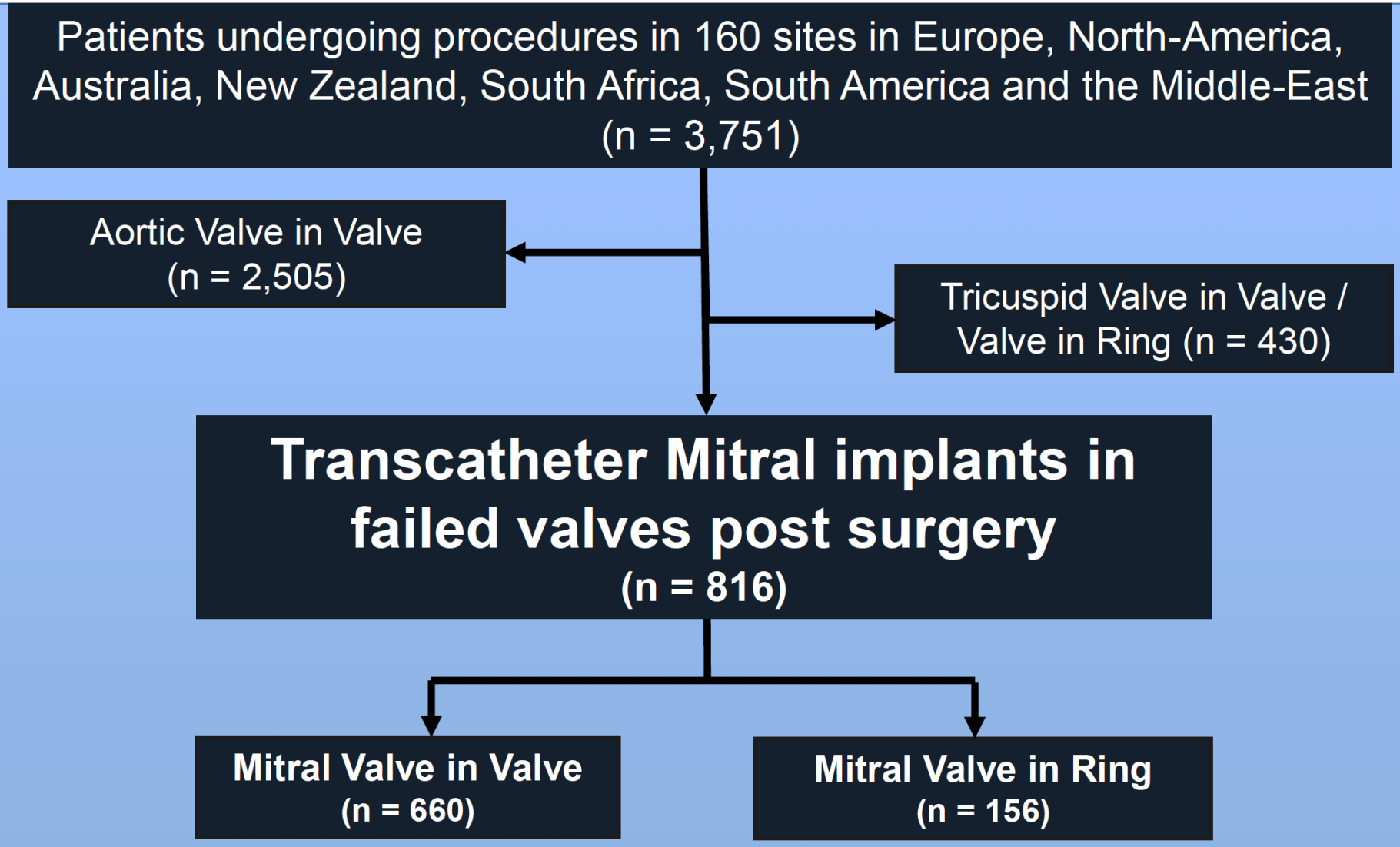
: Consultant: *Edwards Lifesciences*
Medtronic Inc
Abbott
4Tech
4C
Cephea

Three major sources for evidence

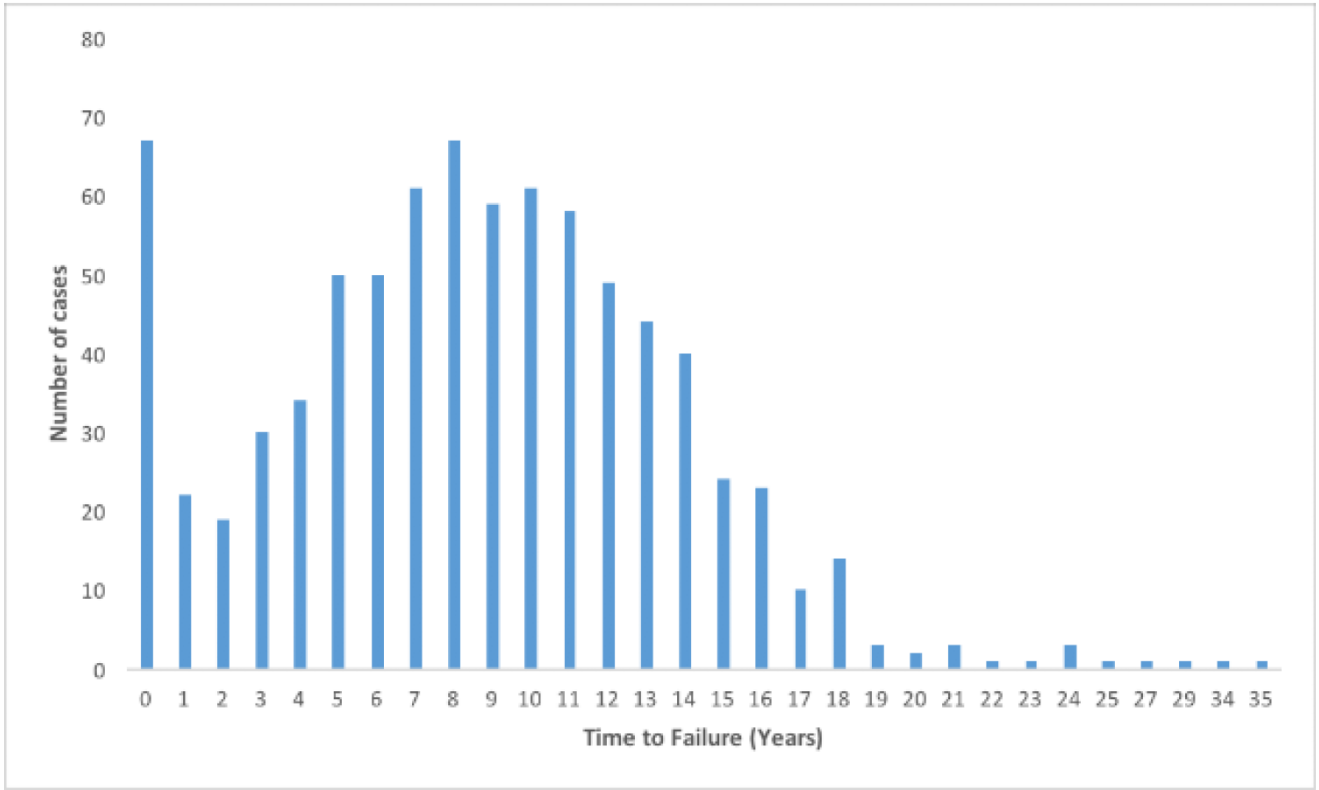
- VIVID registry
- MITRAL study
- TMVR registry

VIVID Registry

Valve-in-Valve International Data
VIVID



Index cardiac surgery



- Median 8.5 years since last cardiac surgery (IQR 5-12).

Surgical Mitral Bioprosthesis (n = 660)

Type	n	%	Size	n	%
Edwards Pericardial / Porcine	307	46.5	23 mm	5	0.8
Medtronic Hancock	103	15.6	25 mm	74	11.2
Medtronic Mosaic	92	13.9	27 mm	210	31.8
St Jude Epic	55	8.3	29 mm	177	26.8
Labcor	8	1.2	31 mm	109	16.5
Sorin	8	1.2	33 mm	13	2
Other / Unknown	87	13.2	Other / unknown	72	10.9

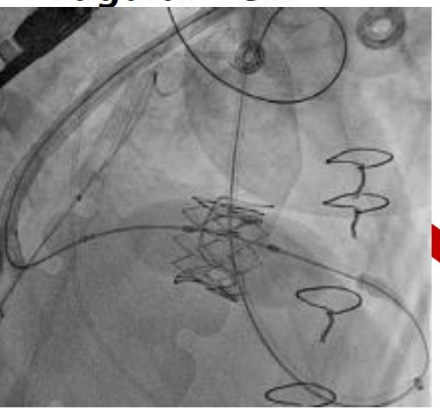
Surgical Mitral Ring (n = 156)

Type	n	%	Size	n	%
Edwards Physio I / II	95	60.9	26 mm	17	10.9
Medtornic Duran	8	5.1	28 mm	45	28.8
Edwards Classic	8	5.1	30 mm	17	10.9
St. Jude Seguin	7	4.5	32 mm	16	10.3
Medtronic CG Future	5	3.2	34 mm	6	3.8
Cosgrove	4	2.6	36 mm	2	1.3
Other / Unknown	29	18.6	Other / unknown	53	33.9

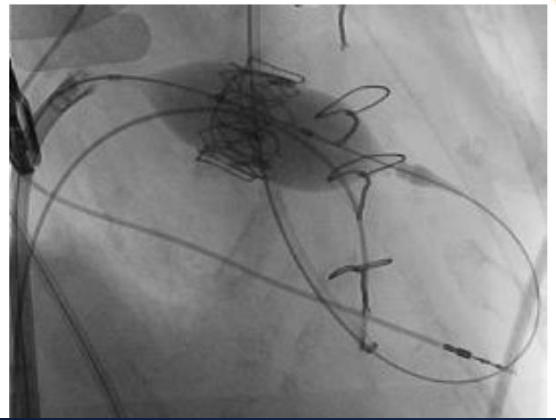
Access during Mitral VinV / VinR procedures

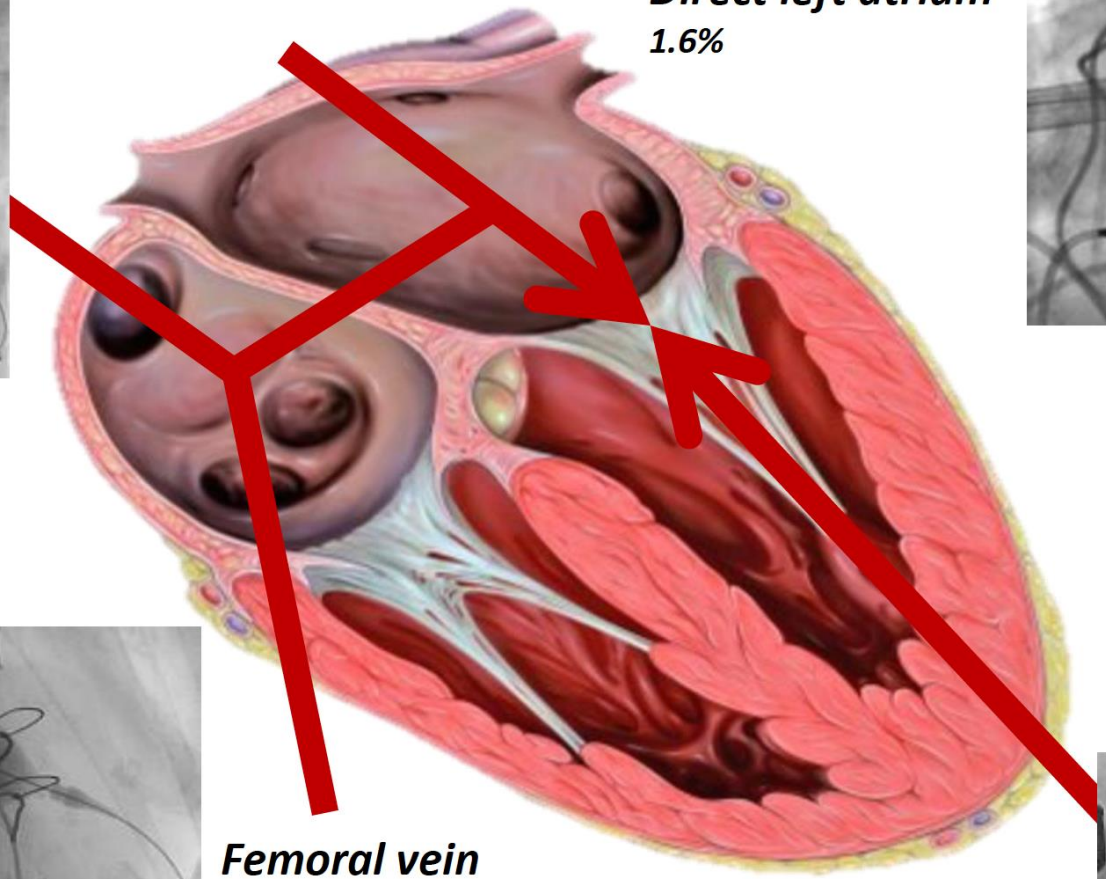
Valve-in-Valve International Data VIVID

Jugular Vein



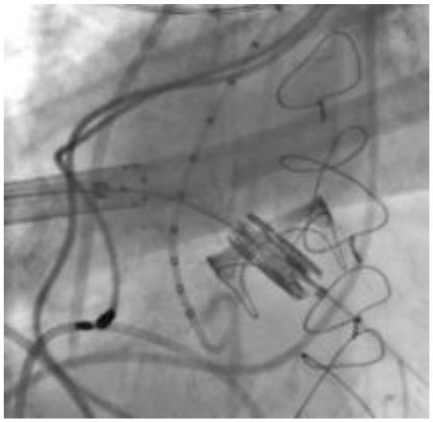
Total trans-septal
21.3%



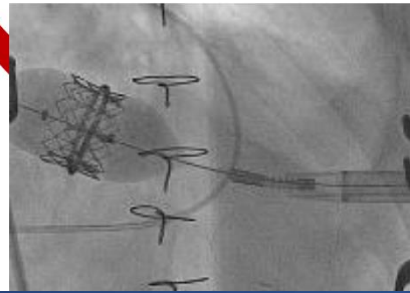


Femoral vein

Direct left atrium
1.6%



Transapical
75.9%



Baseline characteristics

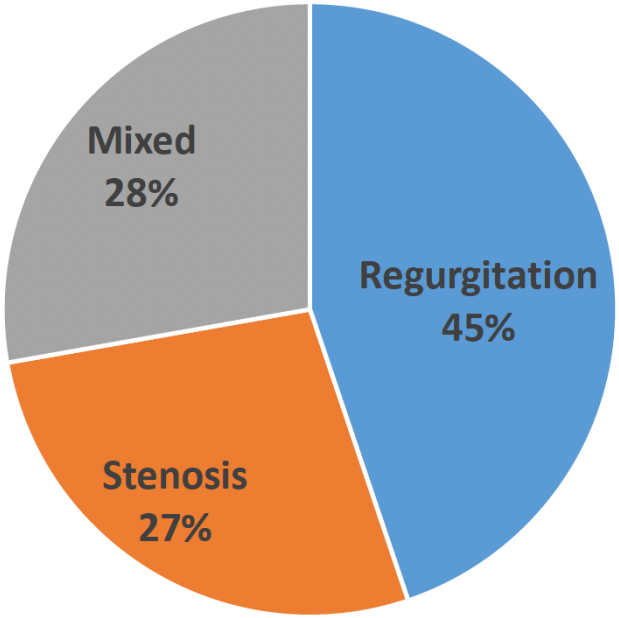
Valve-in-Valve International Data VIVID

	Total N = 816	Mitral Valve-in-Valve N=660	Mitral Valve-in-Ring n=156	P Value
Age (yrs)	73.9 ± 12	74.5 ± 12	71.3 ± 11.8	0.03
Female	486 (59.9%)	408 (62.2%)	78 (50%)	0.005
LogEuroSCORE	31.2 ± 18.4	31 ± 18.4	32 ± 18.4	0.58
EuroSCORE II	15.7 ± 10.9	15.3 ± 10.8	17.5 ± 11.5	0.048
STS score (%)	12.2 ± 10.7	12.5 ± 11.2	11.1 ± 8.5	0.13
Height (cm)	165.2 ± 9.4	164.6 ± 9.4	167.9 ± 8.8	< 0.001
Weight (kg)	68.5 ±15.2	67.5 ± 14.8	72.6 ± 16.2	< 0.001

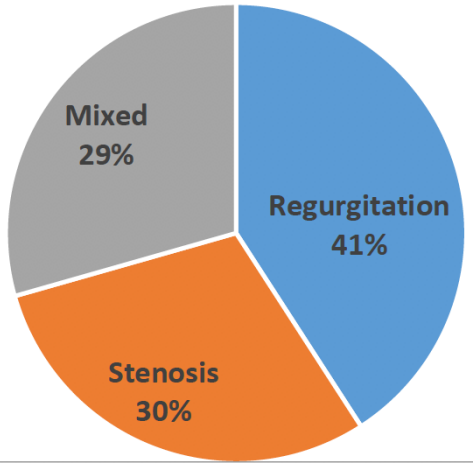
Mechanism of failure

Valve-in-Valve International Data VIVID

Total
n= 816

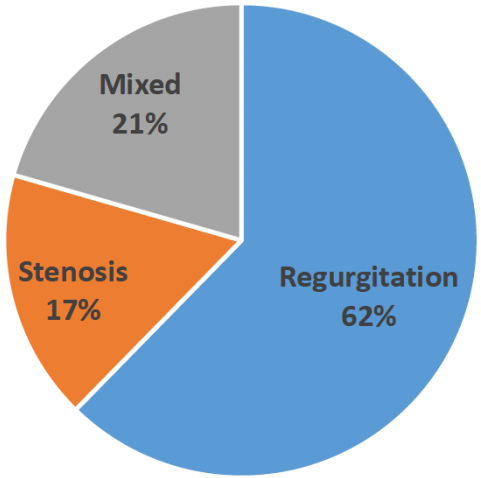


Valve in Valve
n= 646



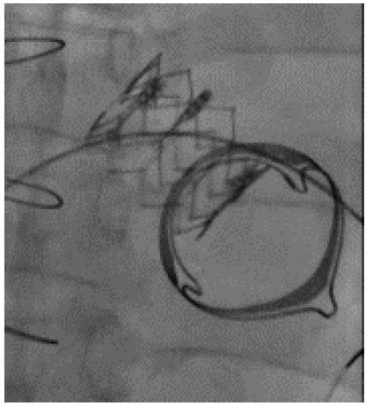
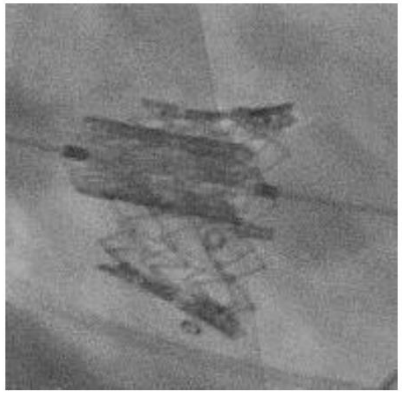
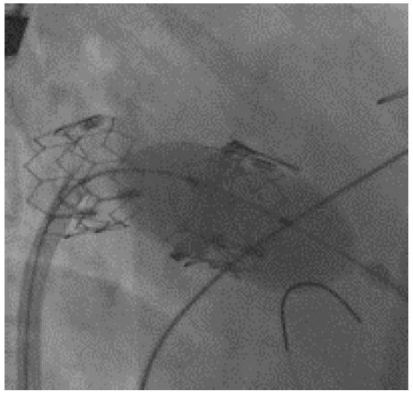
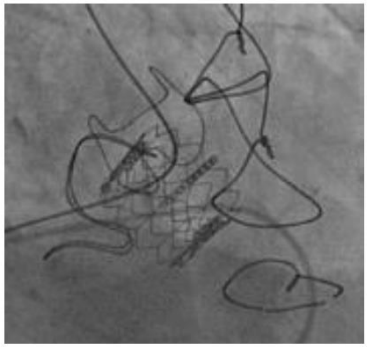
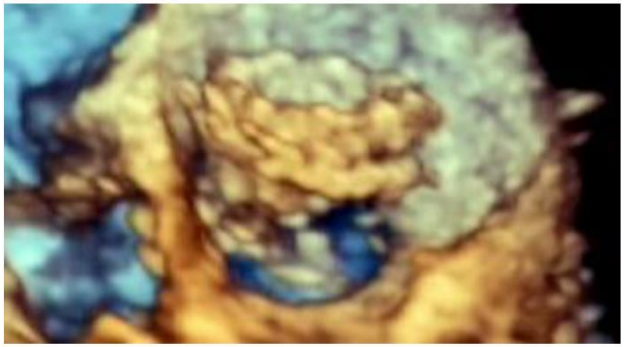
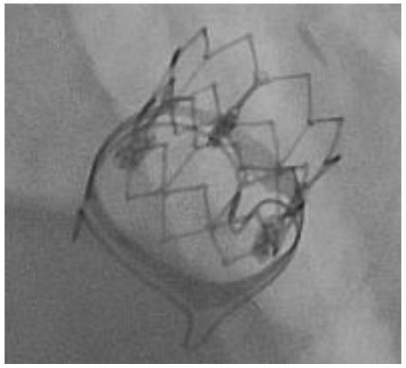
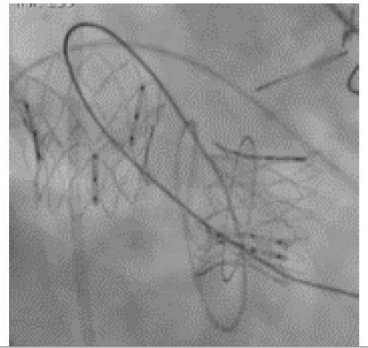
p < 0.001

Valve in Ring
n= 146

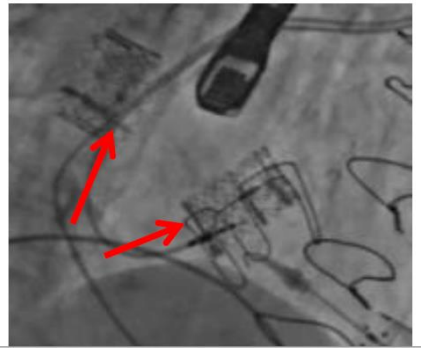


Valve-in-Valve International Data VIVID

Malpositioning

26 malpositioning events (3.4%).



Valve-in-Valve
International Data
VIVID

Procedural characteristics

	Total N = 816	Mitral Valve-in-Valve N=660	Mitral Valve-in-Ring n=156	P Value
Major stroke	9 (1.2%)	9 (1.5%)	0 (0%)	0.15
Acute kidney injury (VARC II/III)	77 (10.2%)	58 (9.5%)	19 (13.5%)	0.16
Major vascular complications	19 (2.5%)	16 (2.5%)	3 (2.1%)	0.65
Bleeding complications	70 (9%)	60 (9.5%)	10 (6.8%)	0.3

Majority Cases were TA

Summary / Conclusions

Valve-in-Valve International Data VIVID

- VIVID registry displays the first large comprehensive analysis of transcatheter ***mitral*** valve implantation, including **Valve-in-Valve** and **Valve-in-Ring**.

- **Mitral Valve-in-Ring** was associated with **worse clinical results** in comparison with Valve-in-Valve, including more post procedural mitral regurgitation and LVOT obstruction. Almost one third of patients undergoing Valve-in-Ring experienced the composite adverse event end point at 30-days.

MITRAL (Mitral Implantation of TRAnscatheter valves)

30-Day Outcomes of Transcatheter MV Replacement in Patients With Severe Mitral Valve Disease Secondary to Mitral Annular Calcification or Failed Annuloplasty Rings

Mayra Guerrero, MD, FACC, FSCAI
On behalf of the
MITRAL trial investigators

Primary and Secondary Endpoints

Primary Safety Endpoints

- Technical Success at Exit from Cath Lab/OR*
- Procedural Success at 30 days*

Primary Effectiveness Endpoint

- Patient Success at 1 year*

Secondary Safety and Effectiveness Endpoints

- Composite of various adverse events at 30 days and 1 year

Patient Flow

Valve-in-Ring Arm

Ring Type	n
Edwards Physio	9
Edwards Classic	4
St. Jude Seguin	3
Medtronic CG Future Ring	3
Medtronic CG Future Band	2
Edwards Physio 2	2
Edwards ET Logix	1
St. Jude Tailor Band	1
Medtronic Simulus SemiRigid	1
Duran AnCore	1
Sorin Memo 3D	1
Sorin Annuloflex	1
Cosgrove Band	1

36 patients presented in case review call* → 6 patients excluded:
3= Risk of Embolization
(2 Cosgrove bands, 1 Perigard band)
2= Risk of LVOTO
1= Dehiscense with para-ring leak

↓

30 patients enrolled

↓

30 patients treated

Failure mode	n(%)
Regurgitation	17 (56.7%)
Stenosis	10 (33.3%)
Both	3 (10%)

Rigid rings = 5
Incomplete rings/bands = 4

Patient Characteristics

ViR Failure mode	n(%)
Regurgitation	17 (56.7%)
Stenosis	10 (33.3%)
Both	3 (10%)

Characteristics	Valve-in-Ring n (%), or mean (±SD)
Age	72 (±9.0)
Female	**10 (33.33%)**
NYHA	
II	7 (23.33%)
III	20 (66.67%)
IV	3 (10%)
Diabetes	8 (26.67%)
COPD	4 (13.33%)
Home Oxygen	3 (10%)
Atrial Fibrillation	19 (63.33%)
Renal Failure	10 (33.33%)
Prior CABG	18 (60%)
Prior AVR	**4 (13.33%)**
STS score	**9.1 (±6.6)**

ViR Procedural Outcomes

100% Transseptal Access

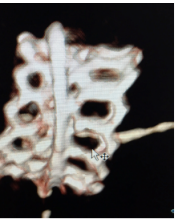
Outcomes	In-Hospital n=30	30 Days n=29*
All-Cause Mortality	2 (6.6%)	2 (6.8%)
Cardiovascular death	1 (3.3%)	1 (3.4%)
Non-Cardiac death	1 (3.3%)	1 (3.4%)

VIR Primary Safety End points

	n (%)
Technical success at exit from Cath Lab (n=30)	**21 (70%)**
Need for second valve* (position too atrial causing MR=5, leaflet infolding at ventricular edge of THV causing MR=1) * In early experience: Operator's first ViR in MITRAL trial=3, second implant=3)	6 (20%)
2 (+) Mitral Regurgitation (1 treated with paravalvular leak closure)	3 (10%)
Procedural Success at 30 days (n=29, last implant 10-3-17)	**18/29 (62%)**
Death at 30 days	2 (6.8%)
Reintervention (1 PVL closure attempt followed by surgical MVR)	1 (3.4%)
Mean MVG >10 mmHg (2 were on HD)	4 (13.8%)
MVA < 1.5 cm2	3 (10.3%)
Intracranial hemorrhage (spontaneous bleed in undiagnosed preexisting brain tumor)	1 (3.4%)

Outcomes of 2nd Valve Requirement

	Alive at 30 Days	Procedural Success Criteria Met	NYHA Class at 30 days
1	Yes	Yes	1
2	Yes	Yes	3
3	Yes	Yes	2
4	Yes	Yes	2
5	Yes	Yes	2
6	Yes	Yes	3



ViR Conclusions

- Transseptal access for ViR can be achieved in most patients (100% in this cohort)
- TS ViR is associated with low 30 day mortality and low complication rate
- Technical success limited by need for second valve improved with experience
- Need for second valve was not associated with poor outcomes
- THV design changes (longer inner skirt) may further improve technical success
- Patients treated with TS ViR experienced significant improvement of symptoms
- These results suggest that TS ViR is a reasonable alternative for high risk patients

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

Sung-Han Yoon

On Behalf of TMVR Registry Investigators

Baseline Characteristics

	ViV (n = 322)	ViR (n = 141)
Age, years	73 ± 13	72 ± 10
Female	59%	37%
STS score, %	9.2 ± 7.2	8.1 ± 6.4
NYHA class IV	32%	26%
Creatinine, mg/dl	1.5 ± 1.3	1.6 ± 1.2
PVD	12%	11%
Prior stroke	18%	12%
COPD	29%	27%
Prior CABG	29%	49%
Prior MI	12%	26%

Procedural Characteristics

	ViV (n = 322)	ViR (n = 141)
Access site		
Transapical	60%	65%
Transseptal	39%	36%
Device type		
Sapien/XT/S3 valves	94%	85%
Lotus	4%	6%
Planned concomitant AVR	4%	1%
Balloon pre-dilatation	11%	4%
Balloon post-dilatation	4%	16%

Procedural Outcomes

	ViV (n = 322)	ViR (n = 141)
Conversion to surgery	0.9%	2.8%
Valve embolization	0.9%	1.4%
LV perforation	1.2%	0.0%
Need for second valve	2.5%	12.1%
LVOT obstruction	2.2%	5.0%
Technical Success *	94.4%	80.9%

* 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

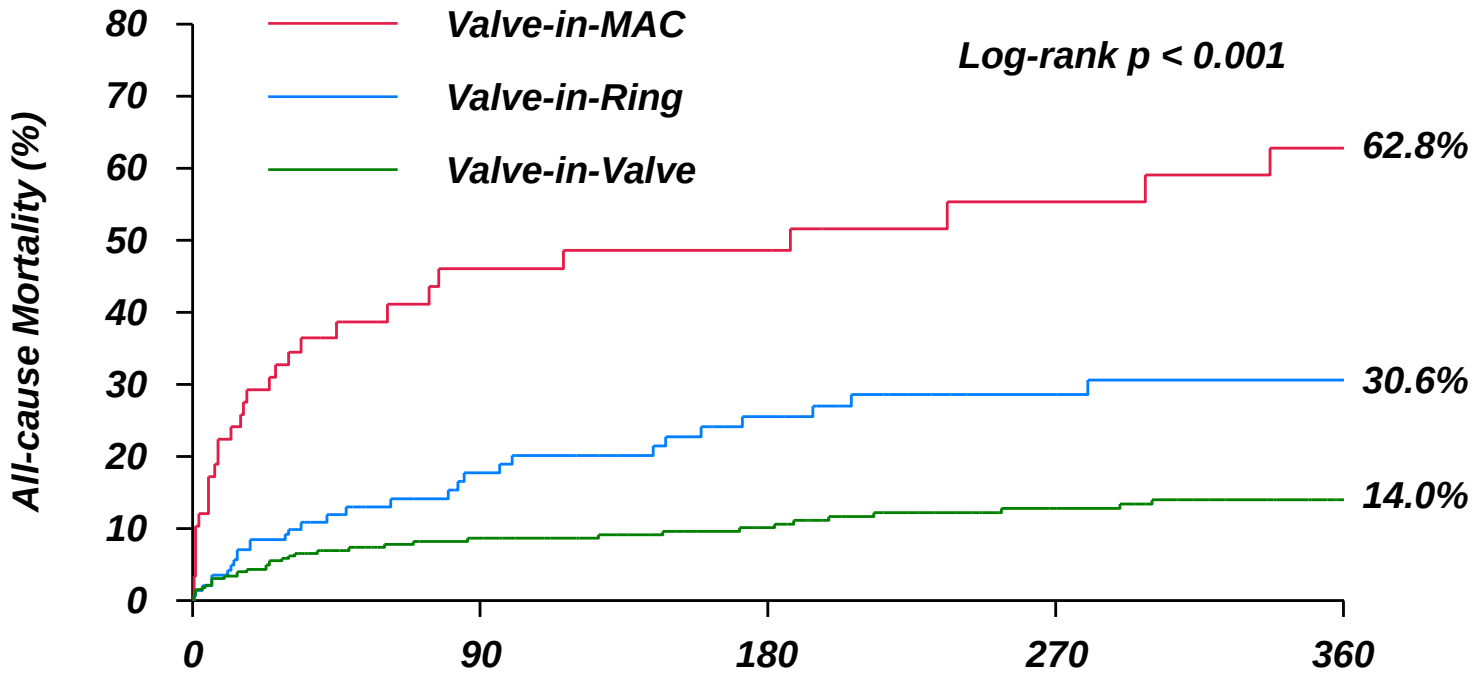
	ViV (n = 322)	ViR (n = 141)
Echocardiography		
LVEF, %	53 ± 13	44 ± 15
Mean gradient, mmHg	6 ± 3	7 ± 3
MR ≥ moderate	5.6%	18.4%
Re-intervention	10.9%	17.7%
Paravalvular leak closure	2.2%	7.8%
Alcohol septal ablation	0.6%	0.7%
ASD closure	7.1%	5.0%
Surgical mitral valve replacement	1.9%	2.1%
Device success	85%	70%

Clinical Outcomes

	ViV (n = 322)	ViR (n = 141)
Mortality at 30 days	6.2%	9.9%
Stroke	2.2%	0.0%
Bleeding, life-threatening or fatal	2.2%	6.4%
Major vascular complication	1.6%	3.5%
AKI (stage 2 or 3)	4.3%	9.2%
Procedural success	73.6%	58.2%

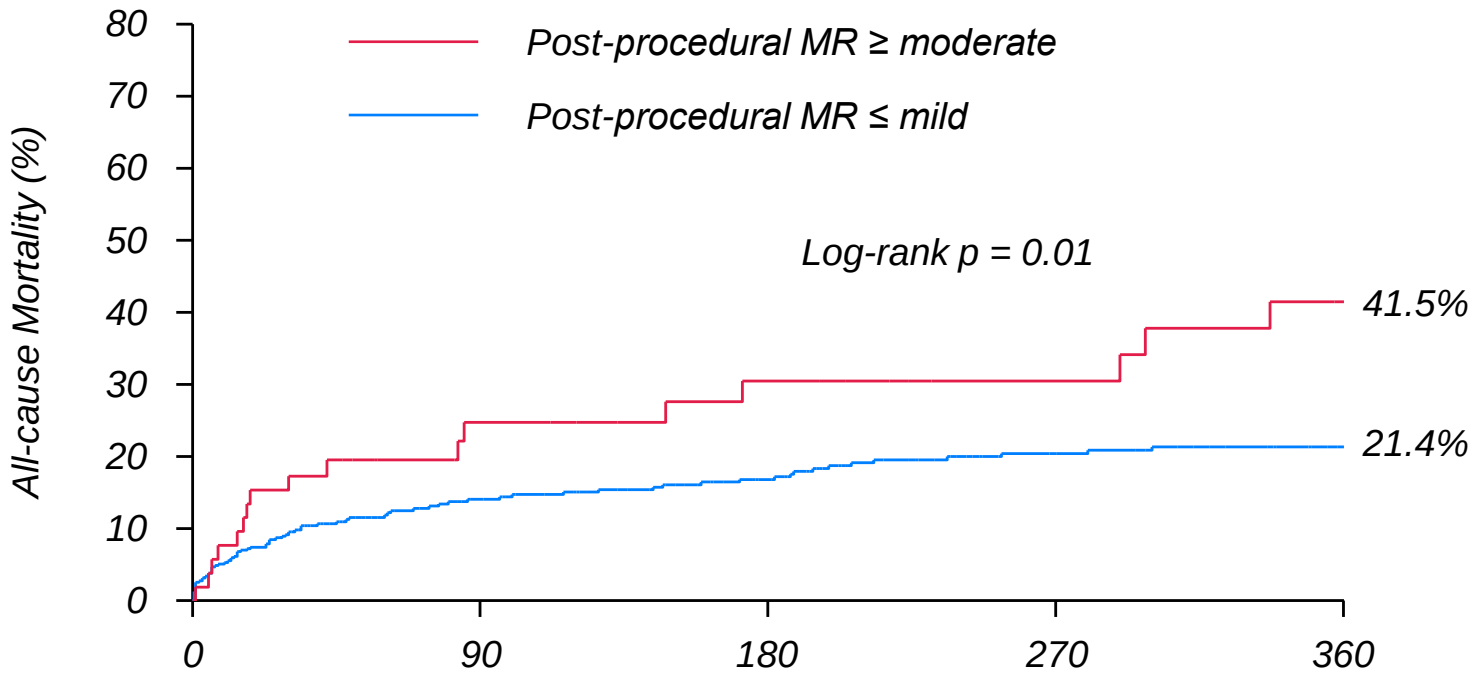
Mid-term Mortality

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

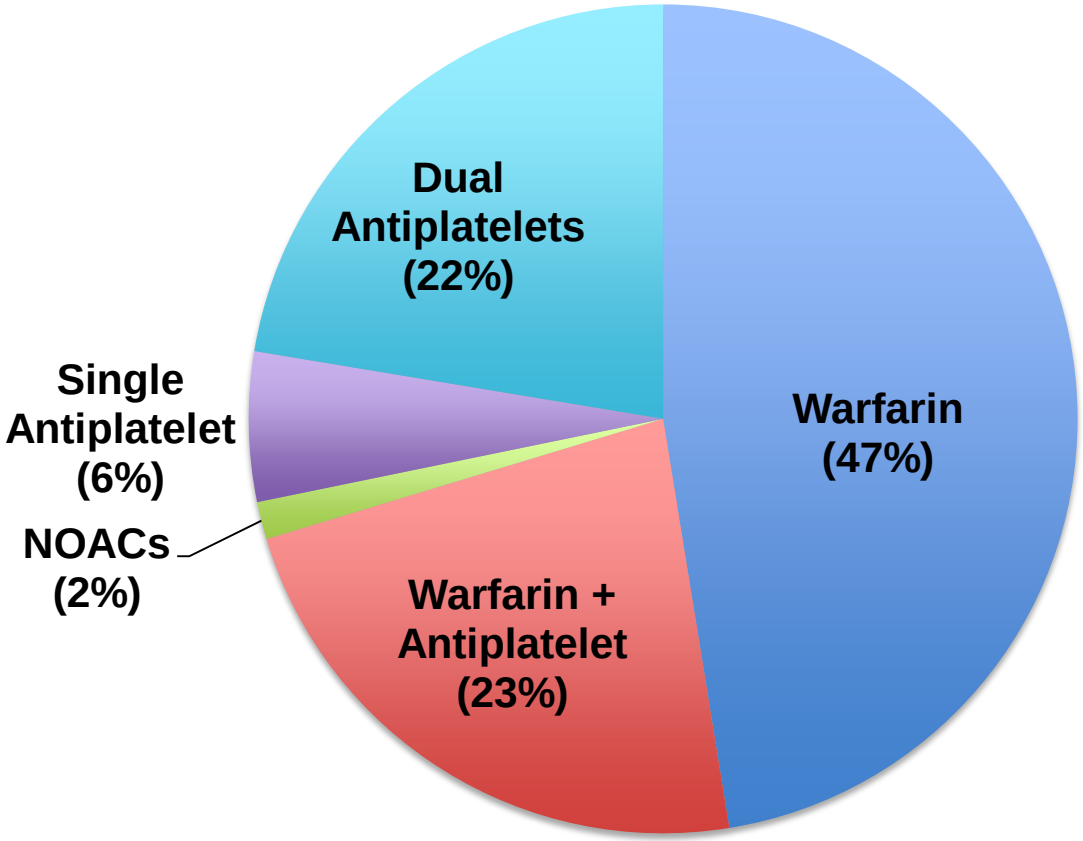
All-cause Mortality According to Post-procedural MR



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

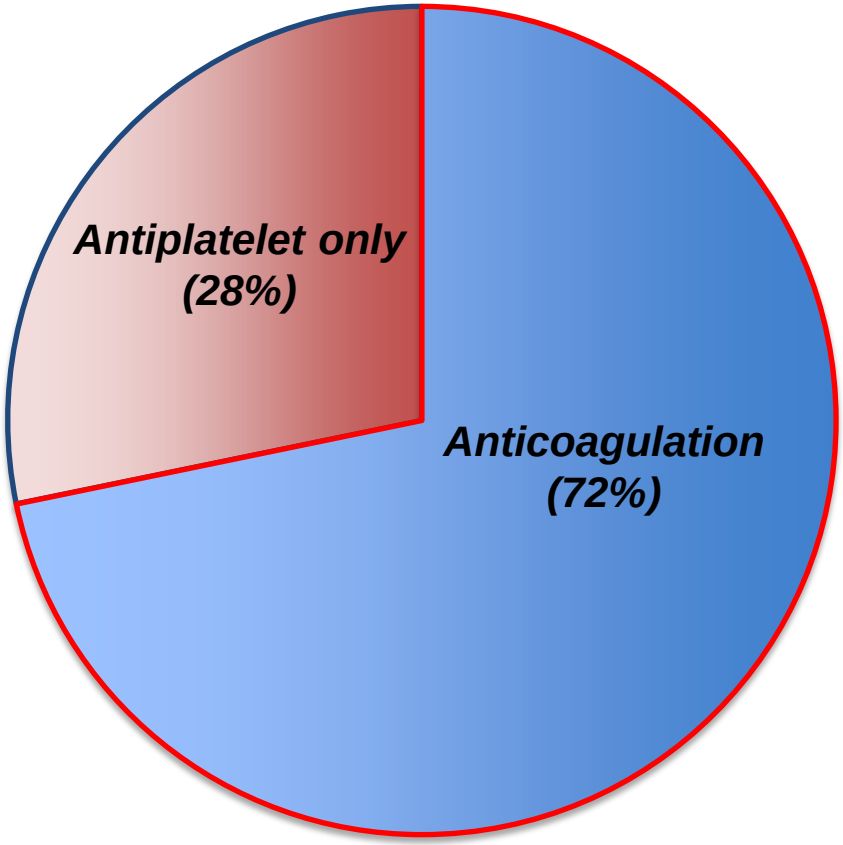
Valve Thrombosis

Antithrombotic Treatment



n = 411

Antithrombotic Treatment



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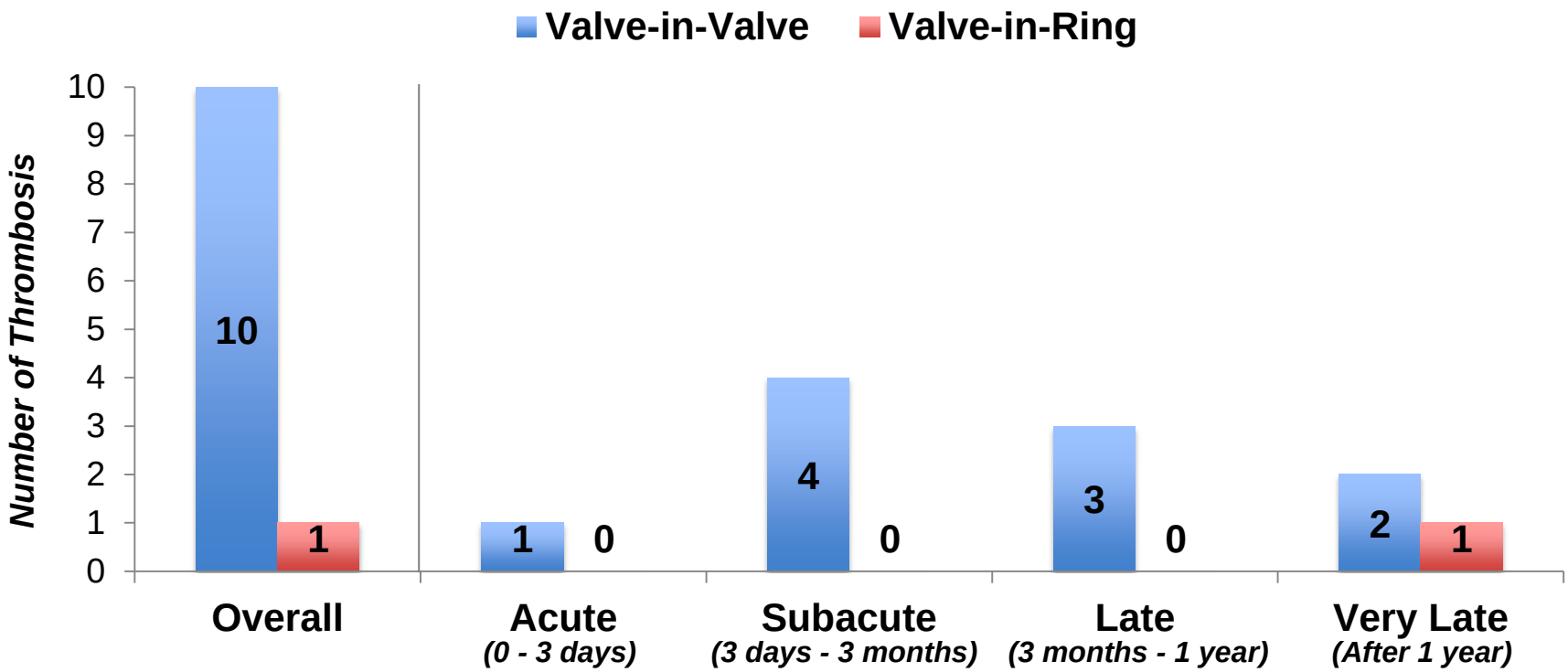
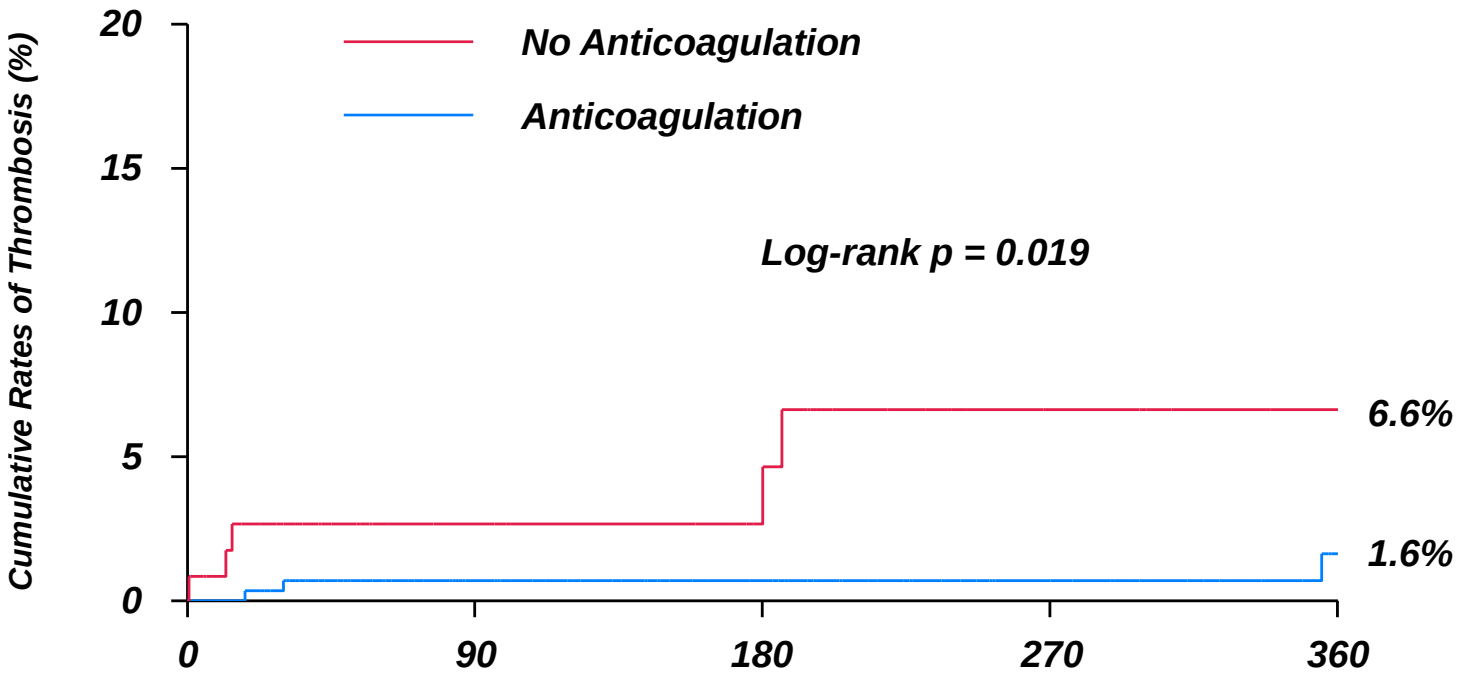
Valve Thrombosis



Valve Thrombosis and Anticoagulation



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

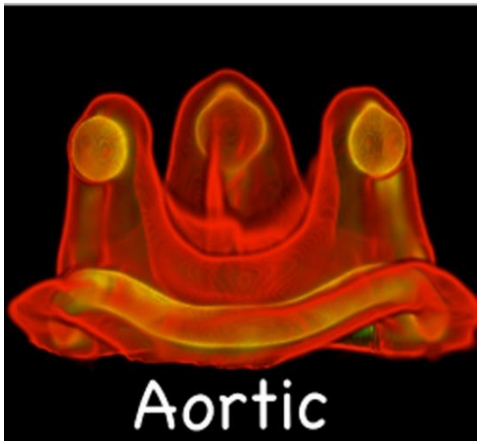
Conclusions

- 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 advanced device technology promise to improve the outcomes of TMVR

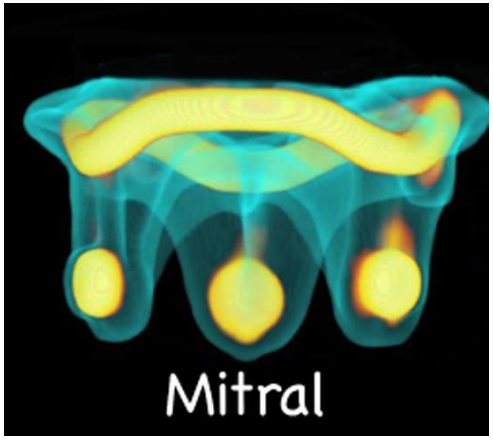
Conclusion 2

- Trans-septal approach may improve outcomes
- VIR – Not all rings are good for VIR
- LVOTO – bad news
- Anticoagulation is important

VIV Apps



App Store
Google market



- Correct Patient
- Correct VIV combination
- Correct position