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

Danny Dvir, MD

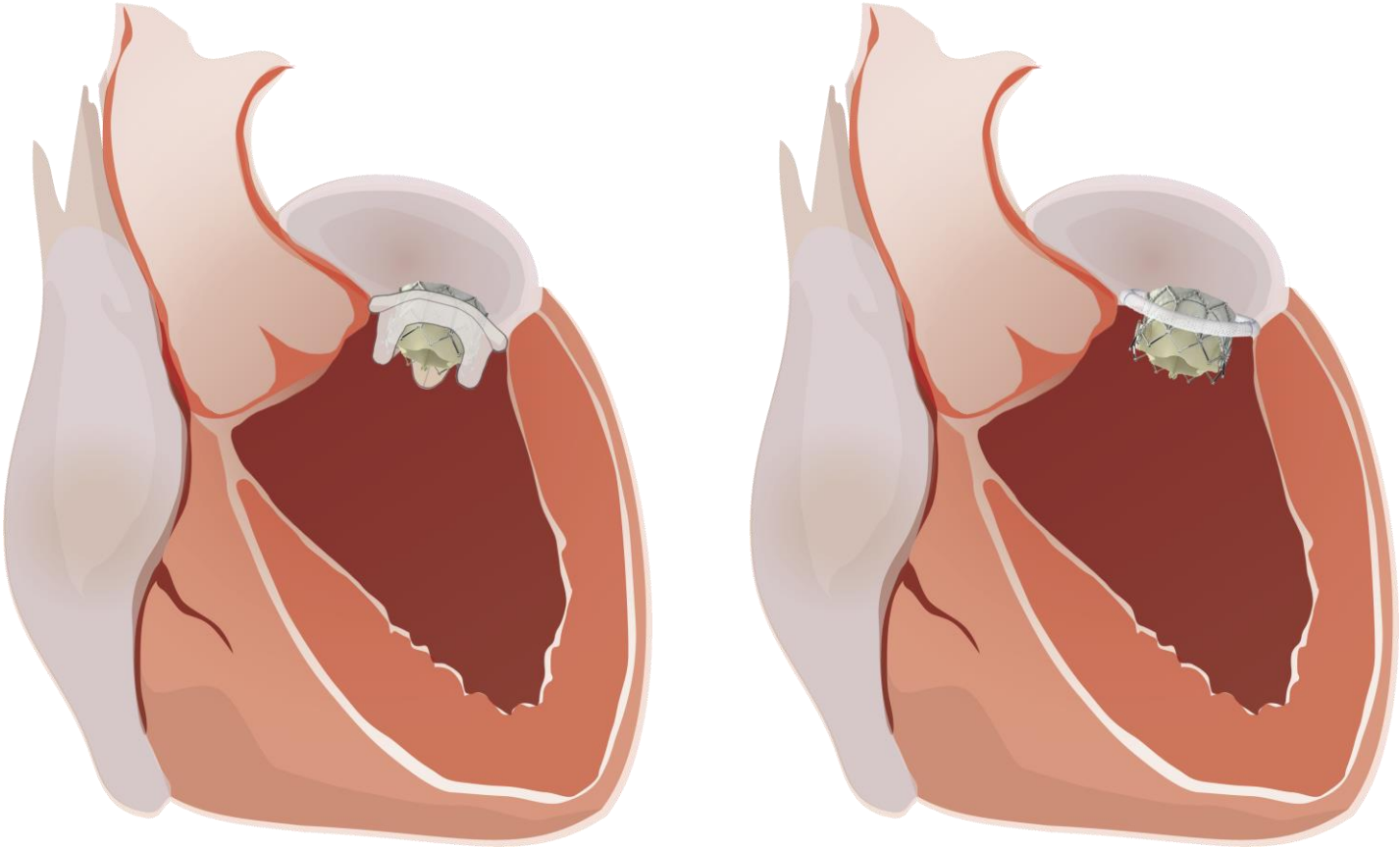
On behalf of VIVID registry investigators

Introduction

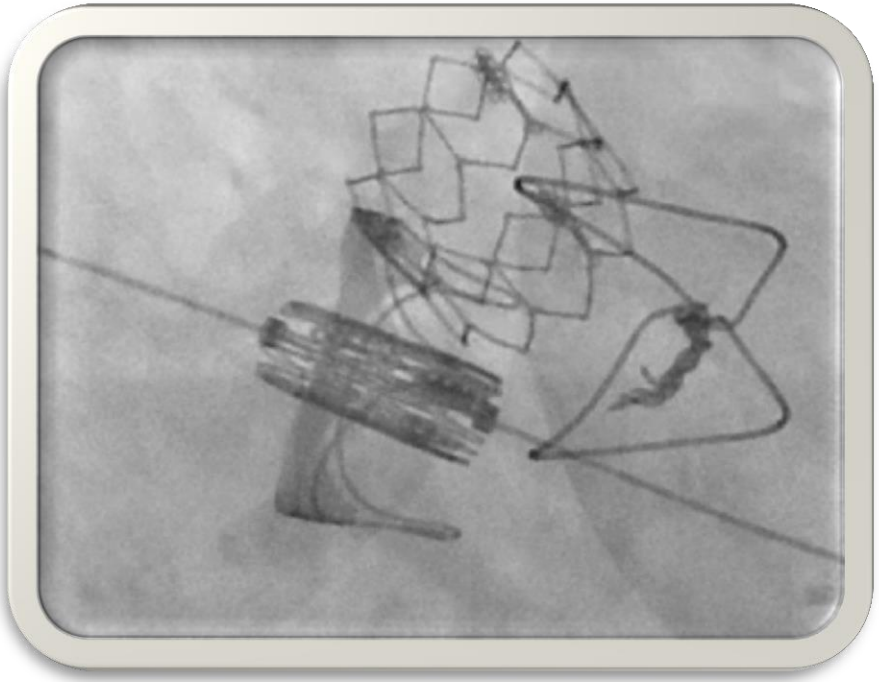
- Bioprosthetic valves are increasingly implanted in open-heart surgeries.
- These valves commonly fail, resulting in a need for a high risk repeat cardiac operation.
- Transcatheter *aortic* Valve-in-Valve may obviate the need for reoperation. VIVID registry. *JAMA* 2014;312(2):162-70.

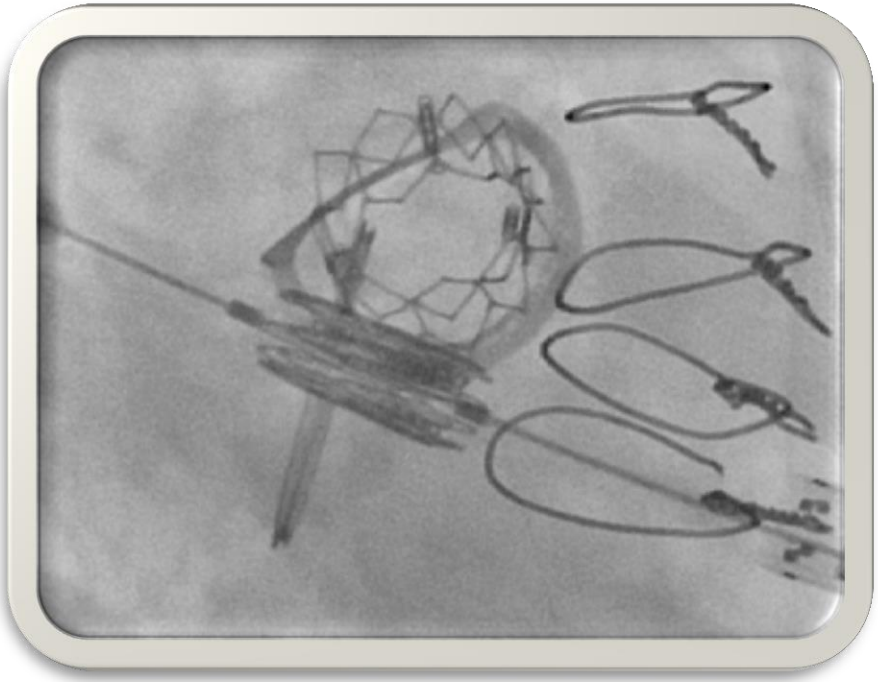
Mitral Valve-in-Valve / Valve-in-Ring

- Transcatheter *Mitral* valve-in-valve / valve-in-ring implantation is a less-invasive approach and possibly an alternative for redo operation.



Mitral Valve-in-Valve / Valve-in-Ring





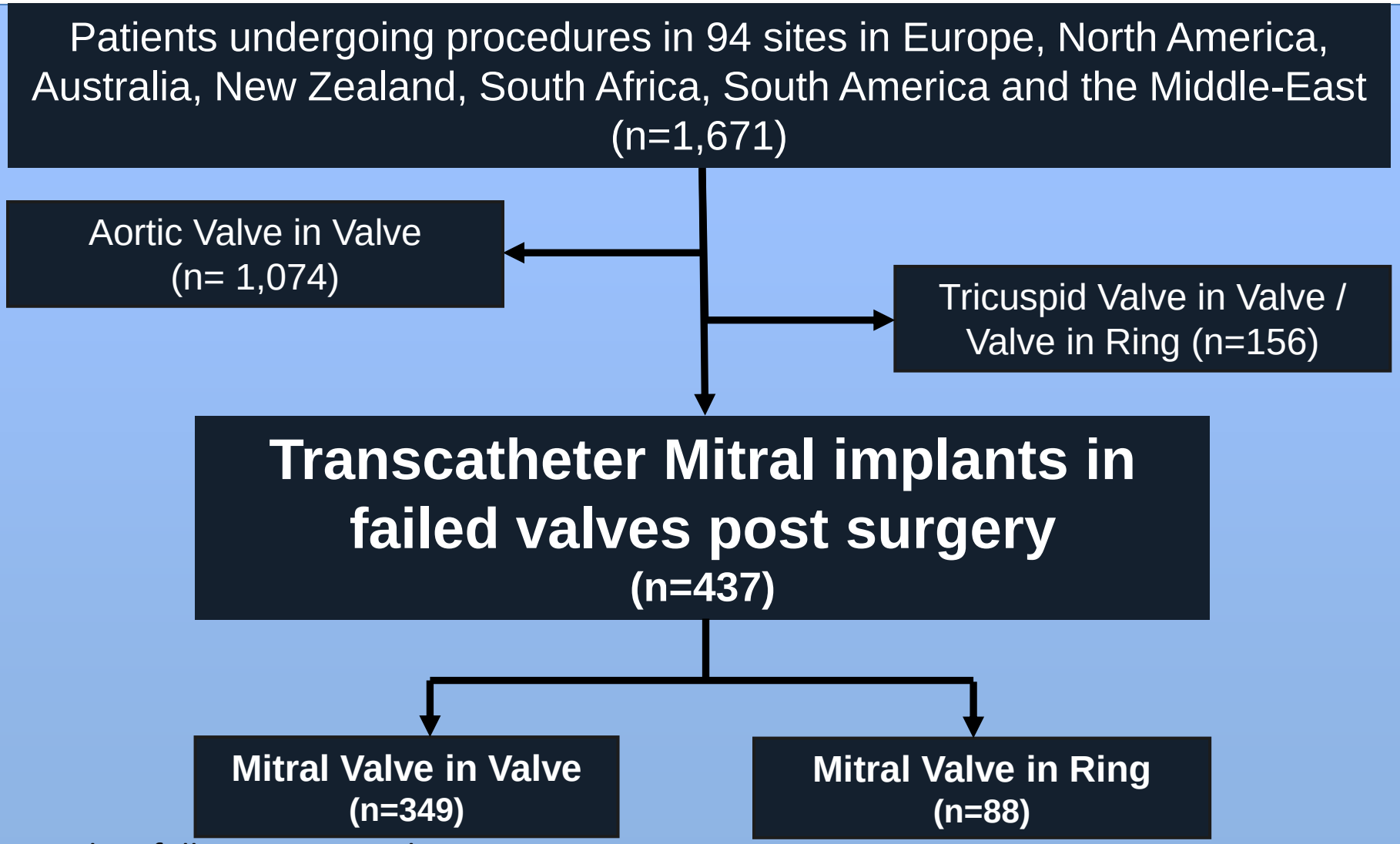
Objective

- To evaluate the efficacy and safety of ***Mitral* Valve-in-Valve and Valve-in-Ring** procedures**.**

- ***Primary study endpoint:***

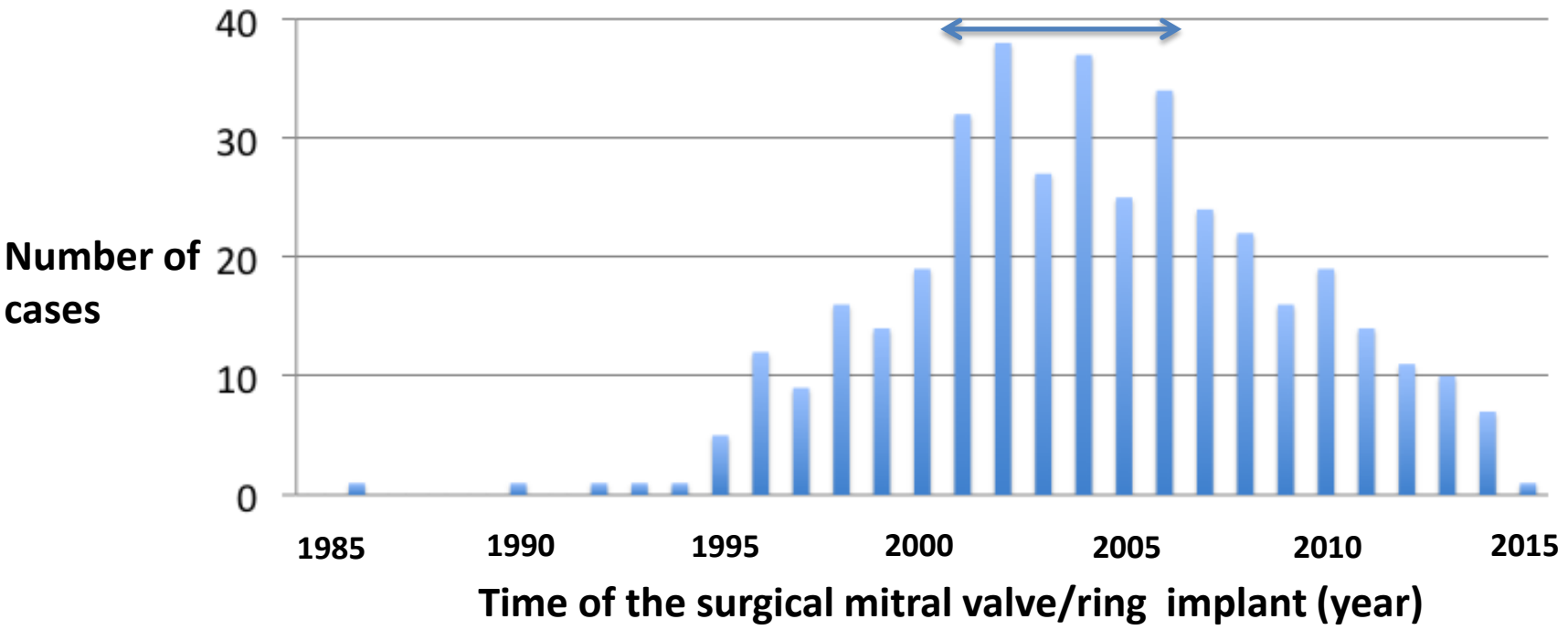
  30-day survival free from moderate or above mitral valve regurgitation or clinically-evident LVOT-obstruction.

VIVID Registry



- Median follow up is 408 days.
- Long-term functional class and echocardiographic assessment are assessed.

Index cardiac surgery



- Median 9 years since last cardiac surgery (IQR 5-12).
- 1-5 previous cardiac surgeries per patient.
- 70.9% of patients had 1 previous cardiac surgery.

Surgical Mitral Bioprosthesis (n= 349)

Type	n	%	Size	n	%
Edwards Pericardial / Porcine	171	52.9	23 mm	2	0.6
Medtronic Mosaic	67	19.2	25 mm	42	12
Medtronic Hancock	49	14	27mm	128	36.7
St Jude Epic	26	7.4	29 mm	110	31.5
St Jude Biocor	14	4	31 mm	48	13.8
Braile Porcine	4	1.1	33 mm	9	2.6
Other / Unknown	18	5.2	Other / unknown	10	2.9

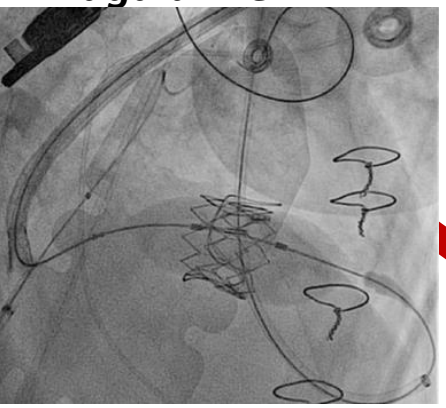
Surgical Mitral Ring (n= 88)

Type	n	%	Size	n	%
Edwards Physio I / II	50	56.8	26 mm	11	12.5
Medtornic Duran	7	8	28 mm	29	33
St Jude Seguin	6	6.8	30 mm	14	15.9
Edwards Classic	5	5.7	32 mm	9	10.2
Medtronic other	4	4.5	34 mm	6	6.8
Sorin Carbomedics	2	2.2	36 mm	2	2.3
Other / Unknown	14	15.9	Other / unknown	17	19.3

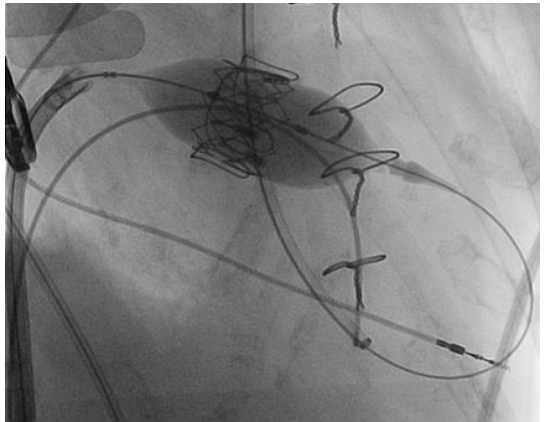
Access during Mitral VinV / VinR procedures (n=437)

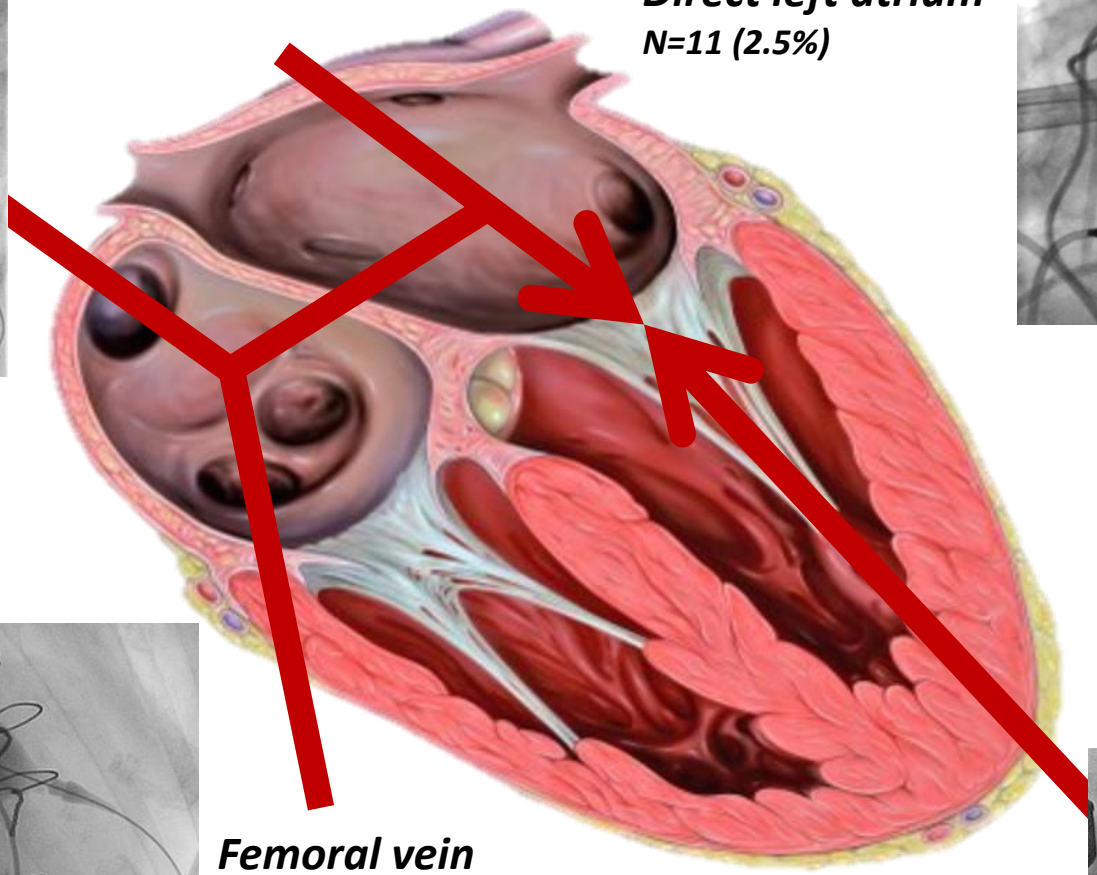
Valve-in-Valve International Data VIVID

Jugular Vein



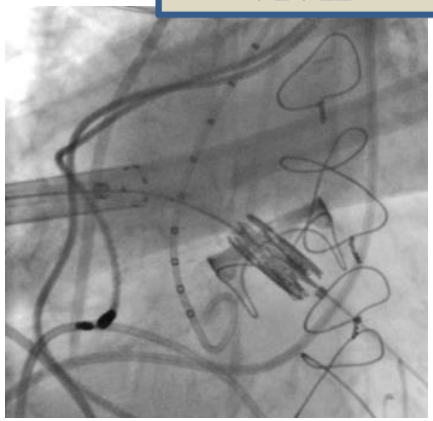
Total trans-septal
n=81 (18.5%)



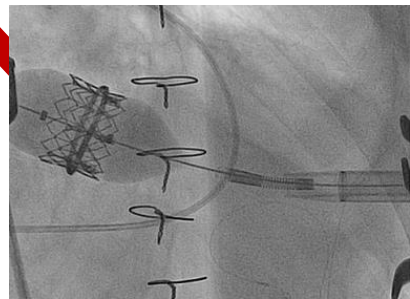


Femoral vein

Direct left atrium
N=11 (2.5%)



Transapical
n=345 (78.9%)



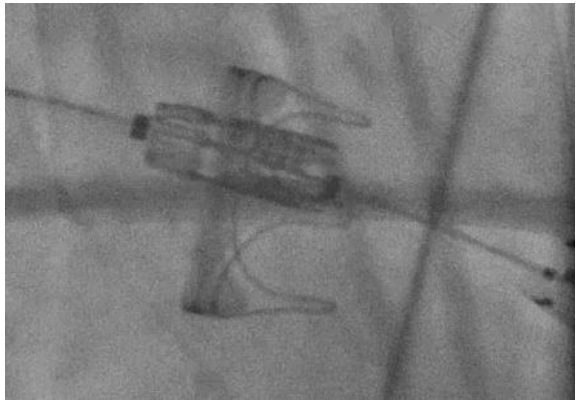
Transcatheter devices (n=437)

Valve-in-Valve International Data VIVID

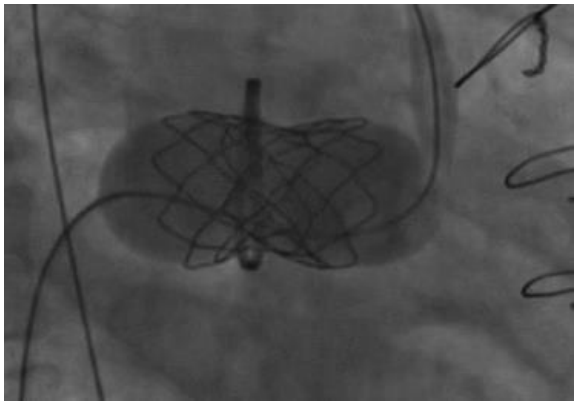
Transcatheter devices (n=437)

Valve-in-Valve International Data VIVID

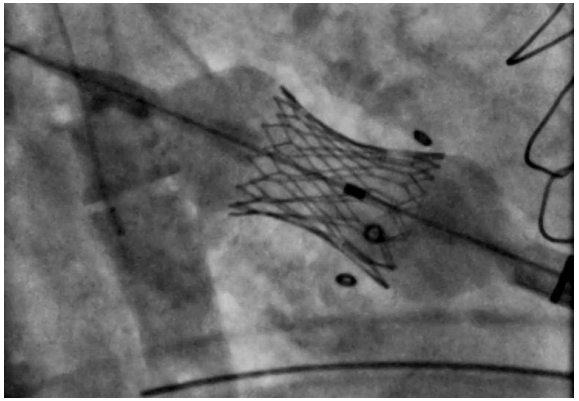
Edwards Cribier / SAPIEN / XT
(Edwards Lifesciences)
n= 374, 85.6%



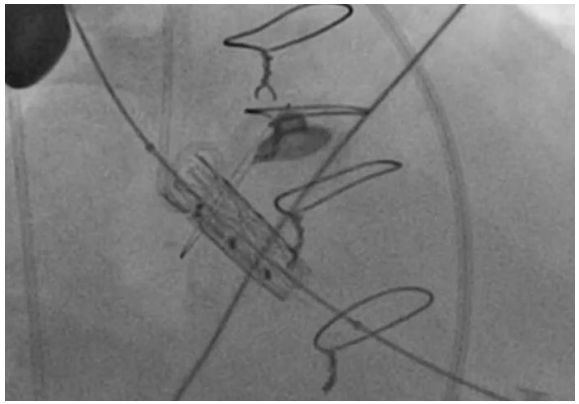
Melody
(Medtronic)
n=28, 6.4%



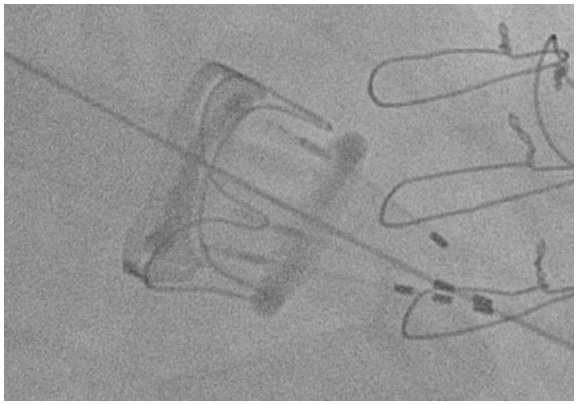
SAPIEN 3
(Edwards Lifesciences)
n= 17, 3.9%



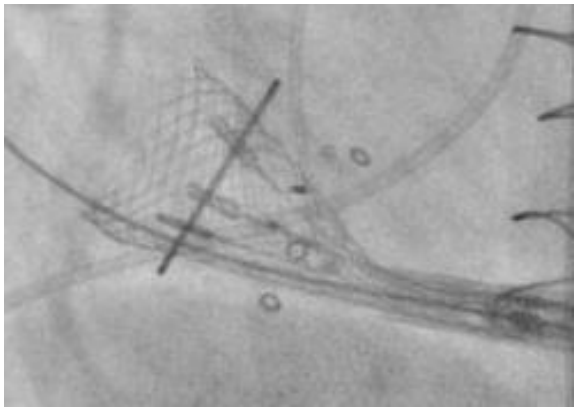
Inovare
(Braile)
n= 12, 2.7%



Direct Flow
(Direct Flow Medical)
n= 3, 0.7%

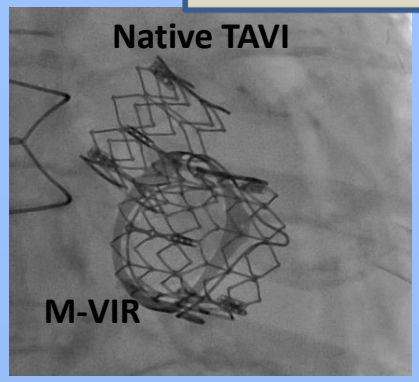


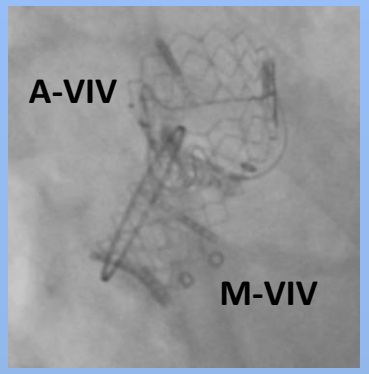
Lotus
(Boston Scientific)
n= 3, 0.7%

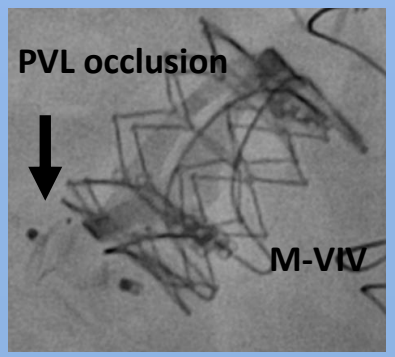


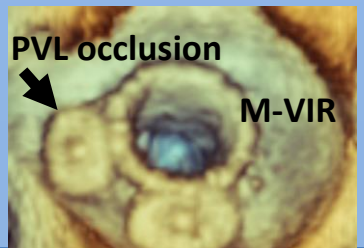
Combined procedures (n= 57, 13%)
Mitral VIV / VIR and…

- Native aortic valve TAVI (n=22)
- Aortic valve-in-valve (n=20)
- Mitral paravalvular leak closure (n=12)
- Tricuspid valve-in-valve/ring (n=3)









Baseline characteristics

	Total n=437	Mitral Valve-in-Valve n=349	Mitral Valve-in-Ring n=88	P Value
Age (yrs)	74.1 ± 12.6	75.3 ± 12	69.4 ± 13.7	<0.001
Female	60%	63%	47.7%	0.02
LogEuroSCORE	27 ± 18.9	27.1± 19.1	26.6 ± 18	0.84
STS score (%)	12.9 ± 11.6	13.4 ± 12.3	11.0 ± 8.1	0.12
Height (cm)	165.2 ± 9.6	164.7 ± 9.6	167.8 ± 9.3	0.008
Weight (kg)	68.8 ± 15.9	67.7 ± 15.6	72.9 ± 16.4	0.007
BMI (kg/m^2)	25.1 ± 5.1	24.9 ± 4.8	26 ± 6.1	0.08

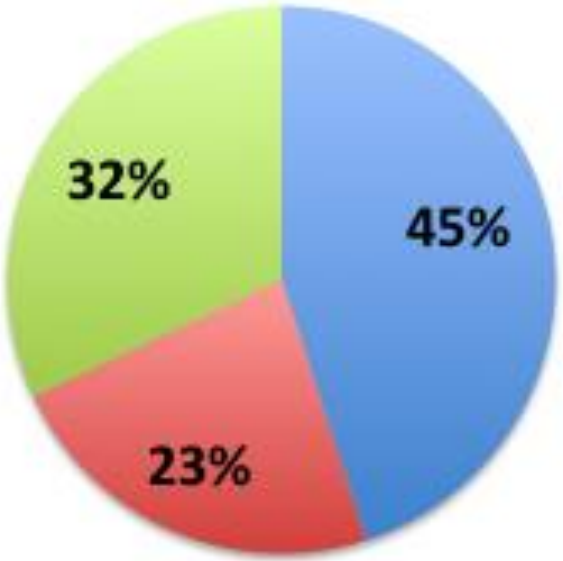
Baseline characteristics

	Total n=437	Mitral Valve-in-Valve n=349	Mitral Valve-in-Ring n=88	P Value
Diabetes Mellitus	25.2%	23.2%	33%	0.06
Peripheral Vascular Disease	15.6%	15.2%	17%	0.64
Chronic Renal Failure	54.2%	50%	70.5%	<0.001
Atrial fibrillation / flutter	59.3%	58.7%	61.4%	0.73
Previous stroke	18.3%	19.2%	14.8%	0.36
NYHA III/IV	95%	94.6%	96.7%	0.44
Permanent Pacemaker	27.5%	23.5%	43.2%	<0.001
Chronic lung disease	24.9%	24.1%	28.4%	0.65

Mechanism of failure

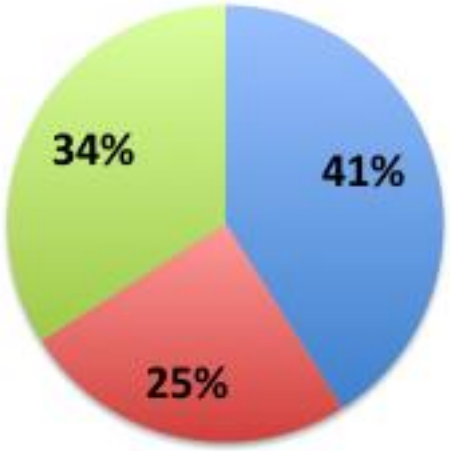
Valve-in-Valve International Data VIVID

Total
n= 437



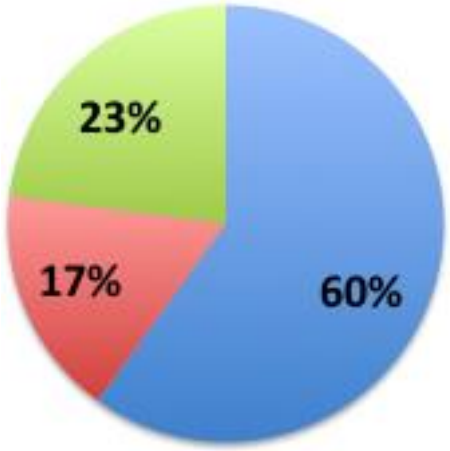
Regurgitation
Stenosis
Combined

Valve in Valve
n= 349



p= 0.04

Valve in Ring
n= 88



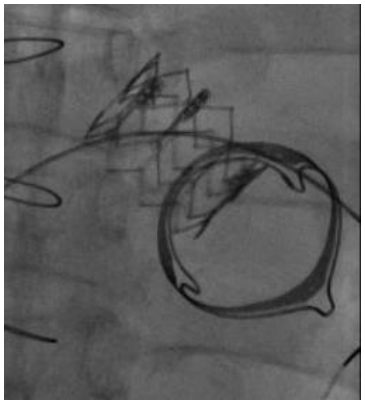
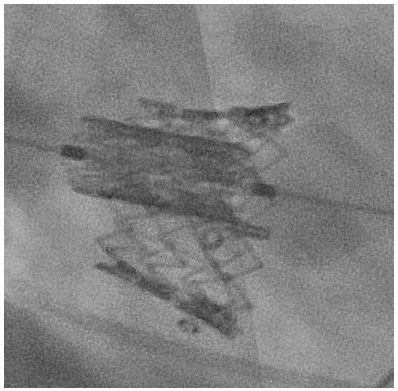
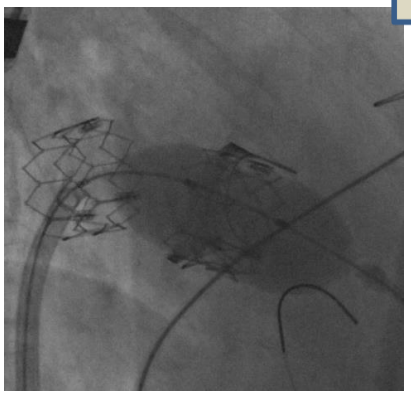
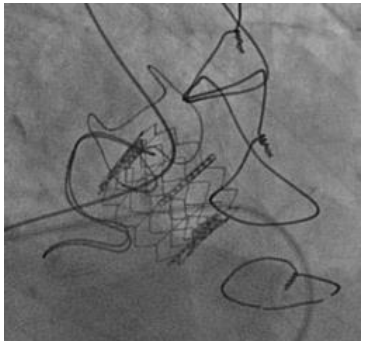
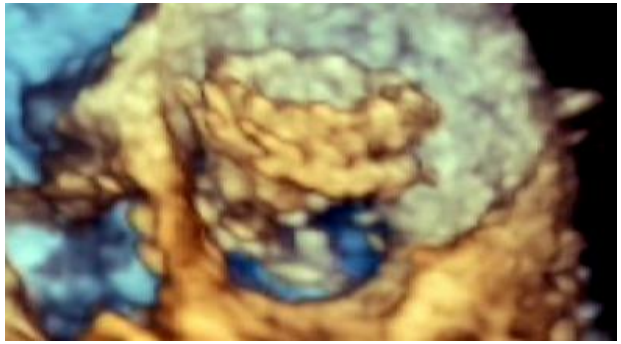
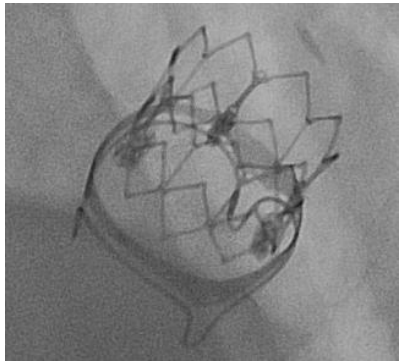
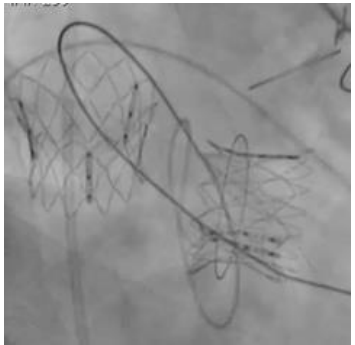
Baseline Echocardiographic parameters

	Total n=437	Mitral Valve-in-Valve n=349	Mitral Valve-in-Ring n=88	P Value
LVEF (%)	52.1 ± 13.9	54.2 ± 12.3	43.8 ± 16.7	<0.001
MV max gradient (mmHg)	23.1 ± 10.3	24.2 ± 8.8	18.6 ± 14.1	0.001
MV mean gradient (mmHg)	11 ± 5.7	11.5 ± 5.2	9.3 ± 7	0.001
MV area (cm^2)	1.52 ± 0.9	1.39 ± 0.7	1.96 ± 1.1	<0.001
PA systolic pressure (mmHg)	62.1 ± 18.8	62.3 ± 19.1	61.7 ± 17.8	0.38

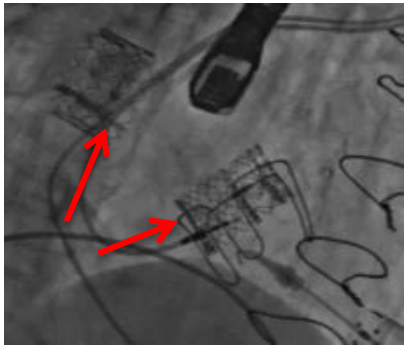
Procedural characteristics

	Total n=437	Mitral Valve-in-Valve n=349	Mitral Valve-in-Ring n=88	P Value
Transesophageal echocardiogram	97.3%	97.1%	97.7%	0.84
General anesthesia	98.9%	98.9%	98.9%	0.97
Pre-inflation	24%	21.5%	34.1%	0.02

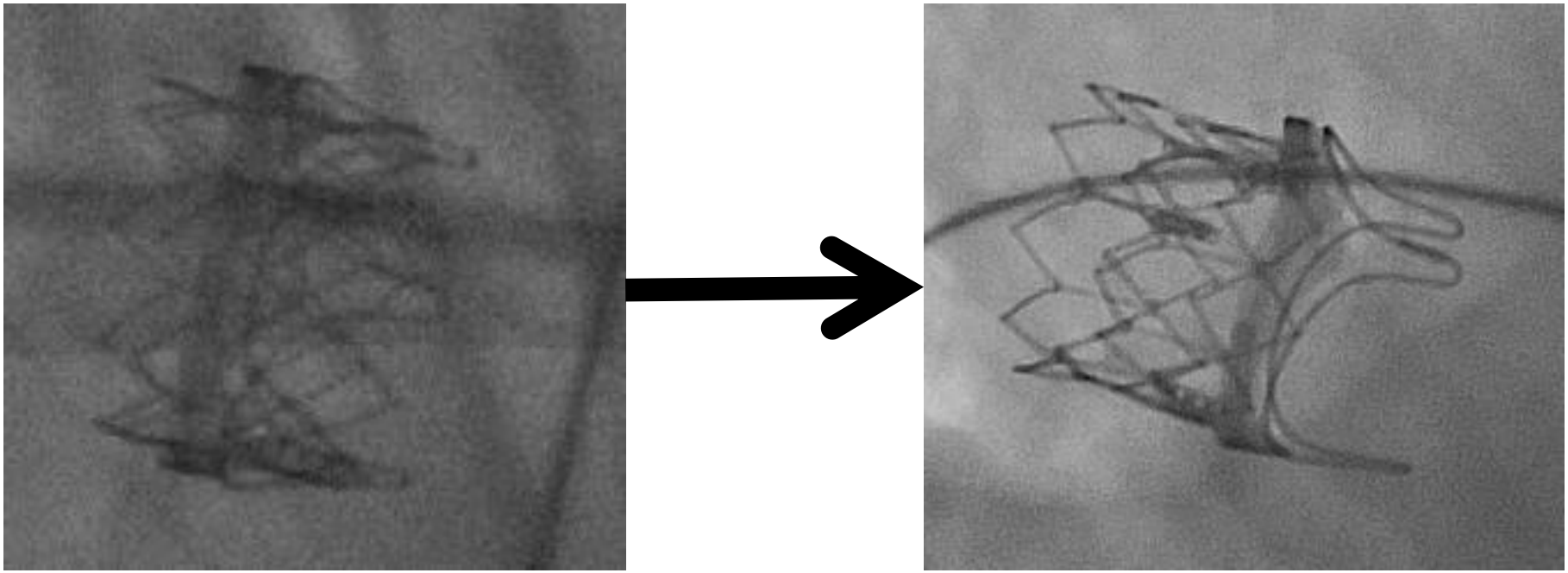
Malpositioning

29 malpositioning events (6.6%).
20 Implantation of another transcatheter device (4.6%).



Delayed malpositioning

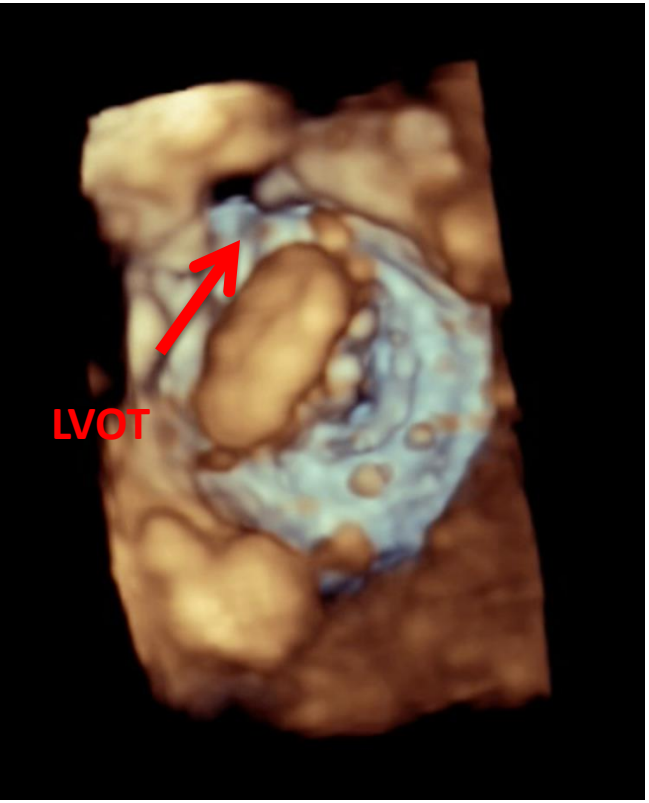


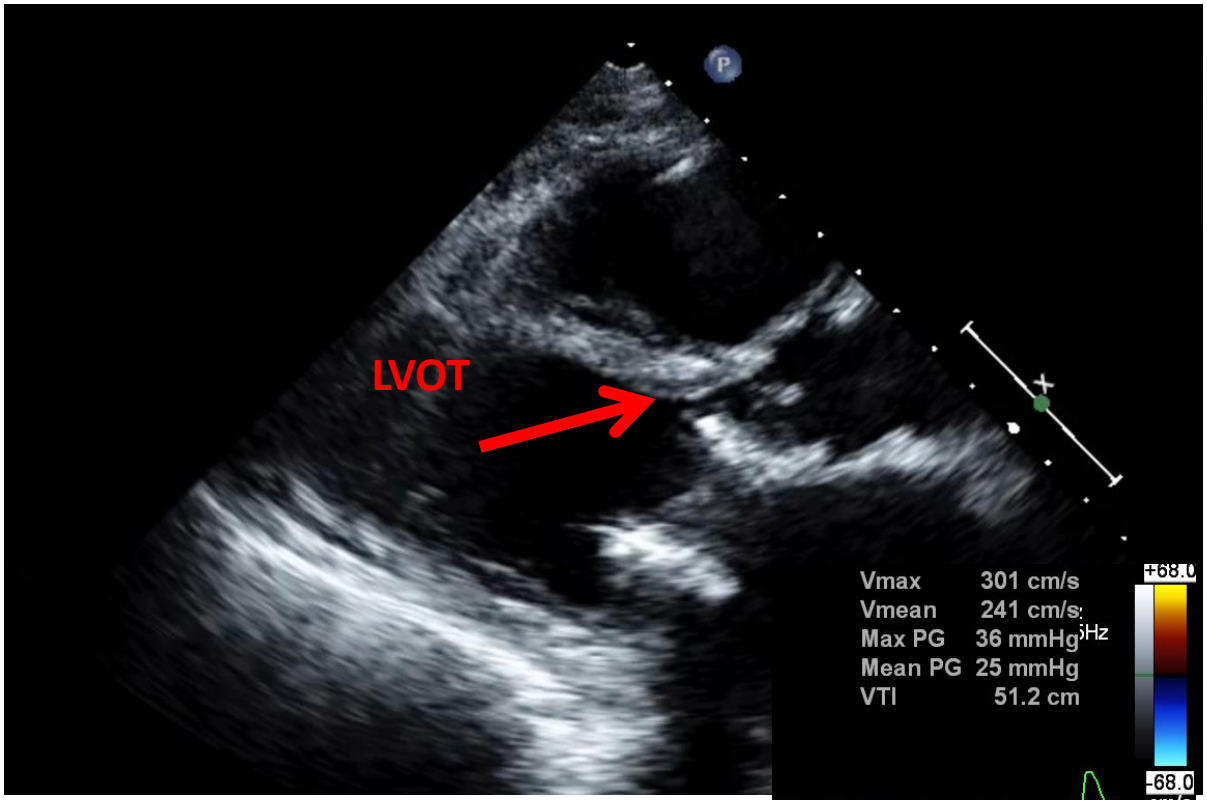
Mitral Valve-in-Valve

After 2 months

Delayed malpositioning (>1 week) in 1.1%.

LVOT obstruction





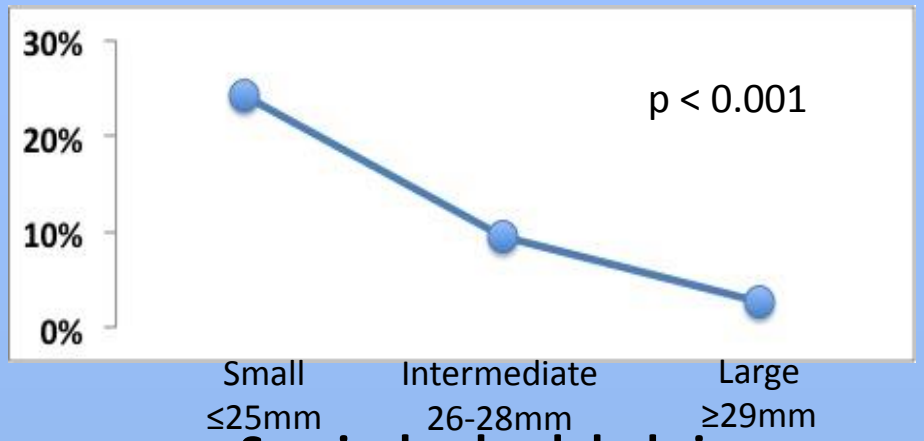
3.7% in the studied population.
More common after Valve-in-Ring
(8% vs. 2.6% in Valve-in-Valve , p=0.03).

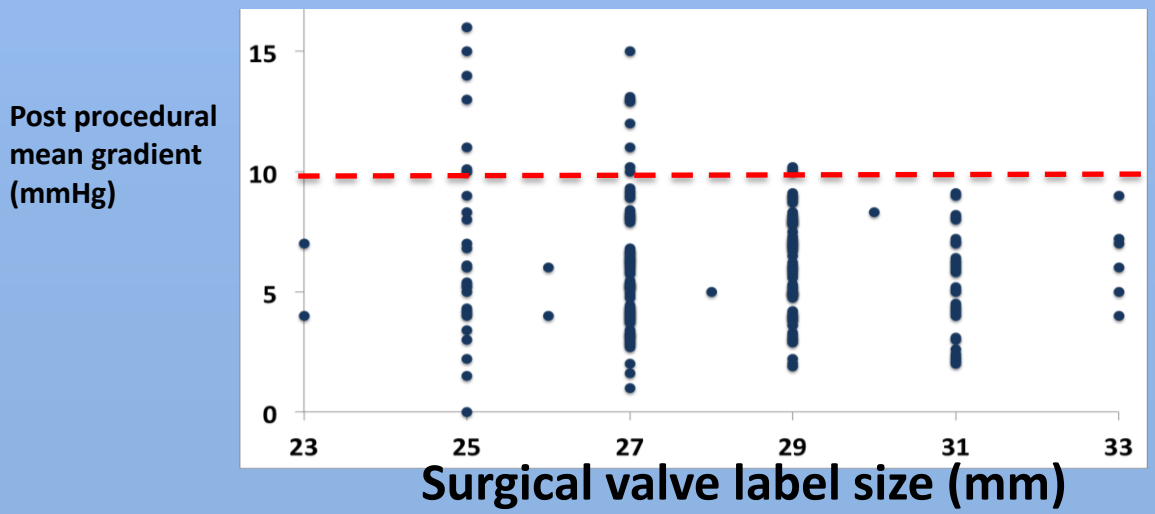
Residual stenosis

Valve-in-Valve International Data VIVID

Multivariate analysis for elevated gradients:
the main independent predictor is having **small surgical valve size**:
Odds Ratio 3.7 (CI 1.79-7.69, p<0.001)

Rate of elevated gradient after mitral valve-in-valve (mean ≥10mmHg)





Procedural characteristics

	Total n=437	Mitral Valve-in-Valve n=349	Mitral Valve-in-Ring n=88	P Value
Post-inflation	7.1%	3.2%	22.7%	**<0.001**
Regurgitation (≥ moderate)	5%	2.6%	14.8%	**<0.001**
Mean gradient (mmHg)	5.9 ± 2.7	5.9 ± 2.7	5.7 ± 2.8	0.61
Valve area (cm^2)	2.07 ± 0.7	1.99 ± 0.7	2.33 ± 0.9	0.02

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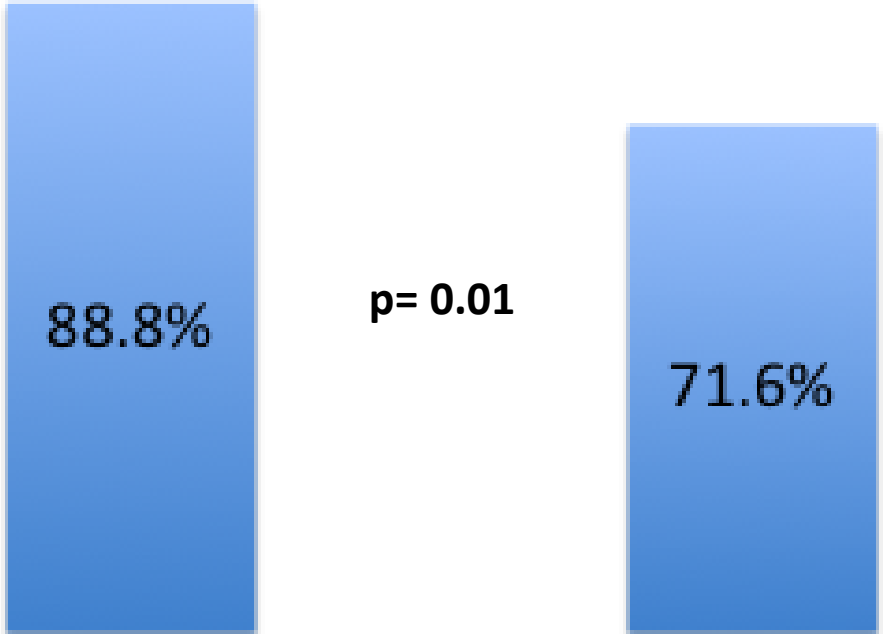
Valve-in-Valve International Data VIVID

Procedural characteristics

	Total n=437	Mitral Valve-in-Valve n=349	Mitral Valve-in-Ring n=88	P Value
Major stroke	2.5%	2.9%	1.1%	0.33
Acute kidney injury (VARC II/III)	14.4%	10.6%	29.5%	<0.001
30-day Death	8.5%	7.7%	11.4%	0.15
30-day Cardiovascular death	6.9%	6%	10.2%	0.62

Composite end point*



*Composite end point included 30-day survival free from significant MR (moderate or more) or clinically-evident LVOT obstruction. The composite of adverse events occurred in 39 patients undergoing valve-in-valve and 25 patients that underwent valve-in-ring.

Summary / Conclusions

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

- Most procedures were performed in very high-risk patients and were clinically effective; However, **small surgical valves (label ≤ 25)** were associated with elevated post procedural gradients.

- **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.

- Study results have numerous implications for the interventional community, for surgeons, who deploy bioprostheses / rings, and for the cardiovascular industry, that designs transcateheter strategies for mitral valve and ring implantations.

Thank you

registry@valveinvalve.com