

Emerging Indications in Transcatheter Aortic Valve Replacement

Amar Krishnaswamy, MD, FACC

Interventional Cardiology

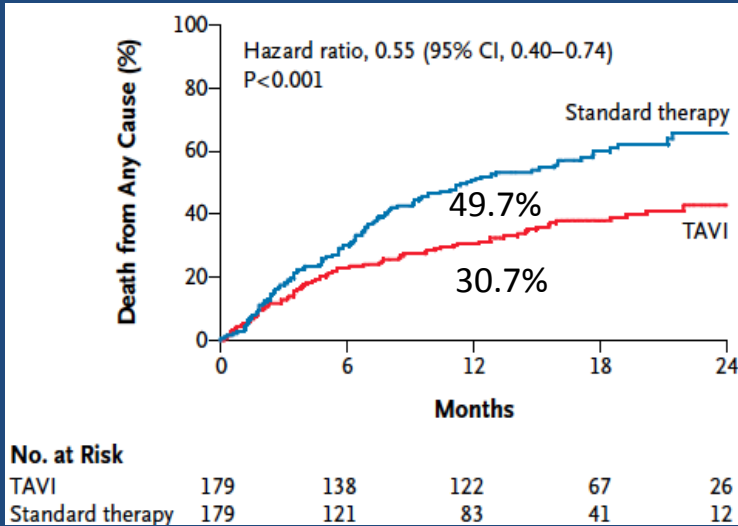
Assistant Professor of Medicine

Cleveland Clinic

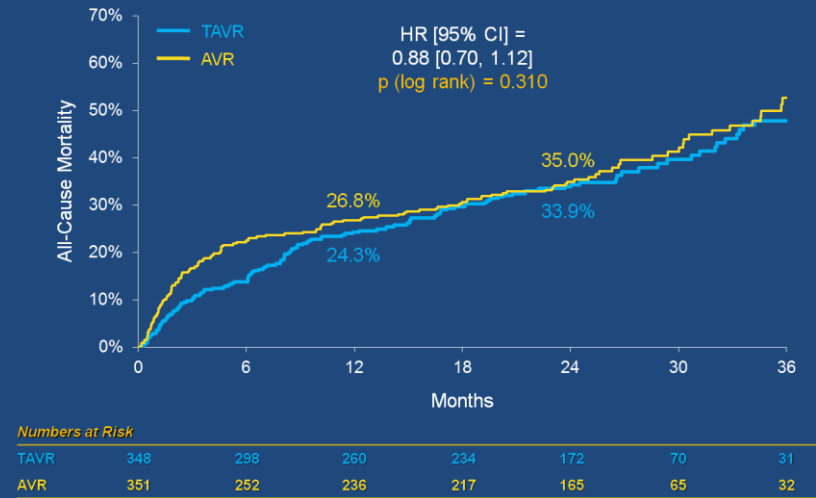
I HAVE NO DISCLOSURES

TAVR: Inoperable and High Risk

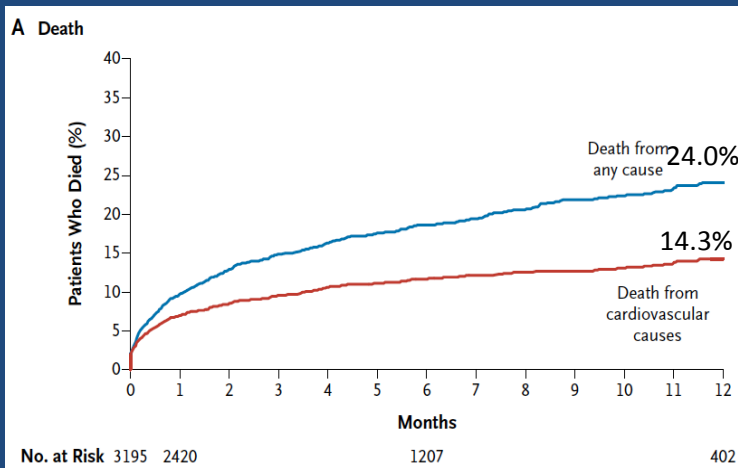
PARTNER IB – Inoperable Cohort



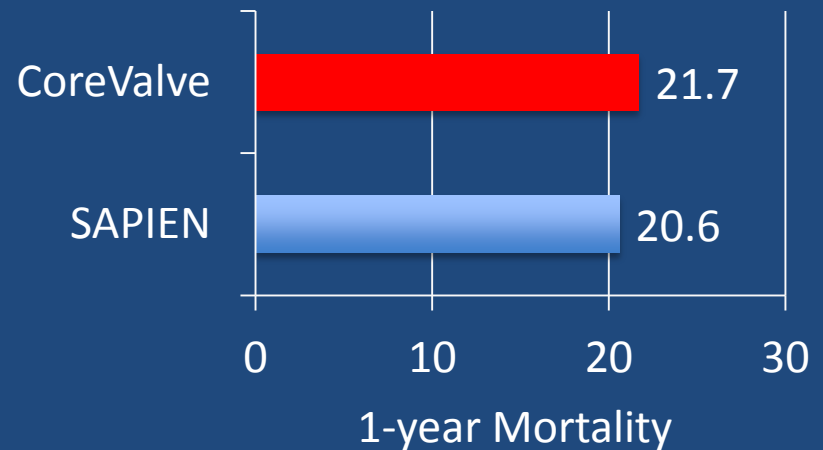
PARTNER IA – High Risk Cohort



FRANCE-2 – High Risk Patients



UK Registry – High Risk Patients



Emerging Indications

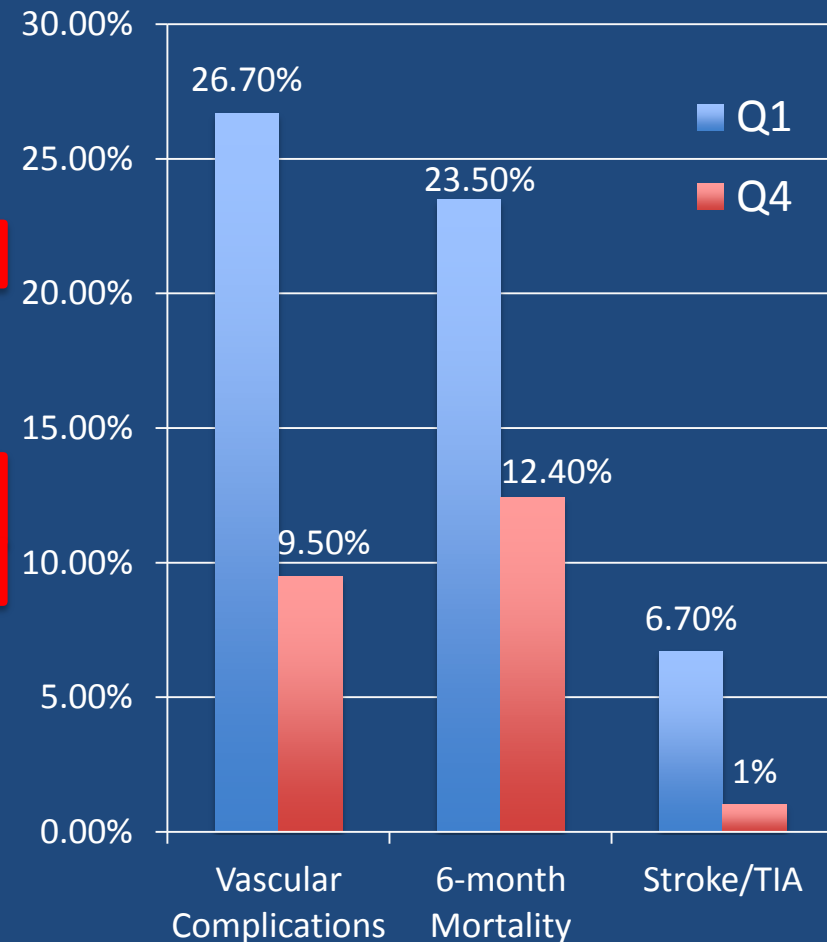
- Intermediate Risk Patients
- Valve-in-valve
- Bicuspid aortic stenosis
- Pure aortic regurgitation

Emerging Indications

- Intermediate Risk Patients
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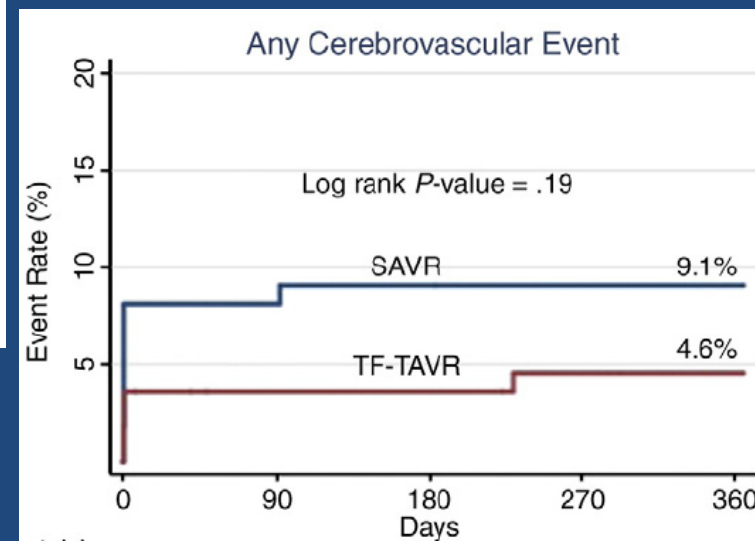
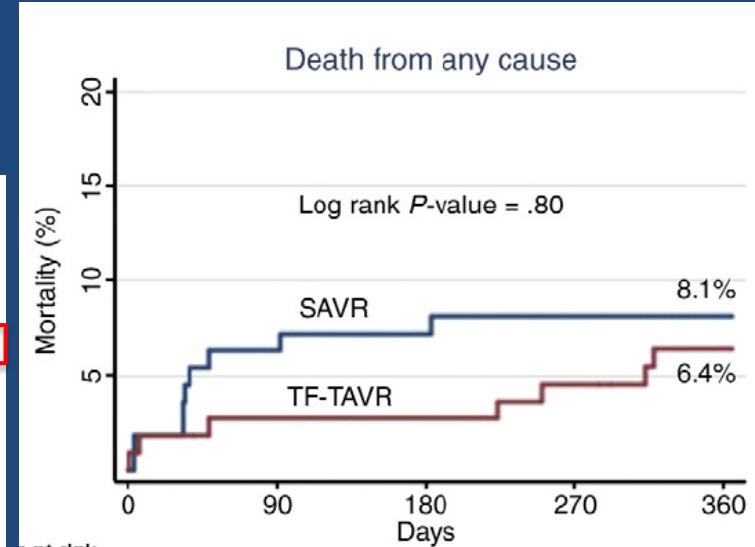
TAVR: Intermediate Risk Patients

	Quarter 1	Quarter 4	P-value
Patients	105	101	
Age (years)	81.1	78.9	0.09
Valve (%)			< 0.001
SAPIEN	13.3	40.6	
CoreValve	86.7	59.4	
Intubation	100%	69.2%	< 0.001
STS Score, %	7.13	4.8	< 0.001
Logistic EuroSCORE, %	25.44	17.8	< 0.001



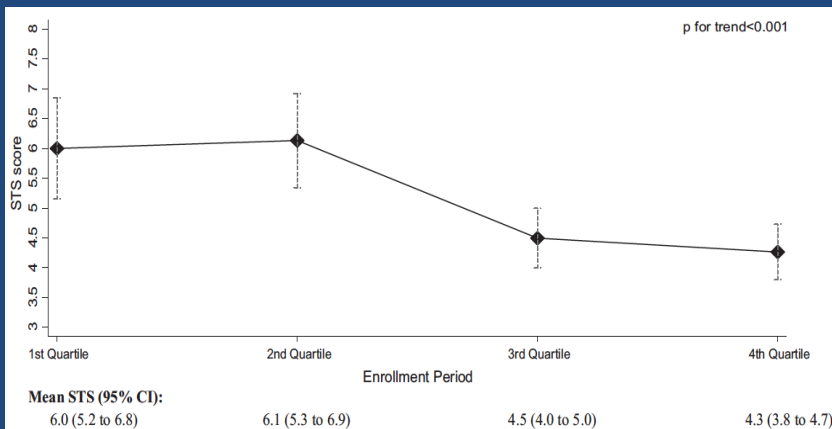
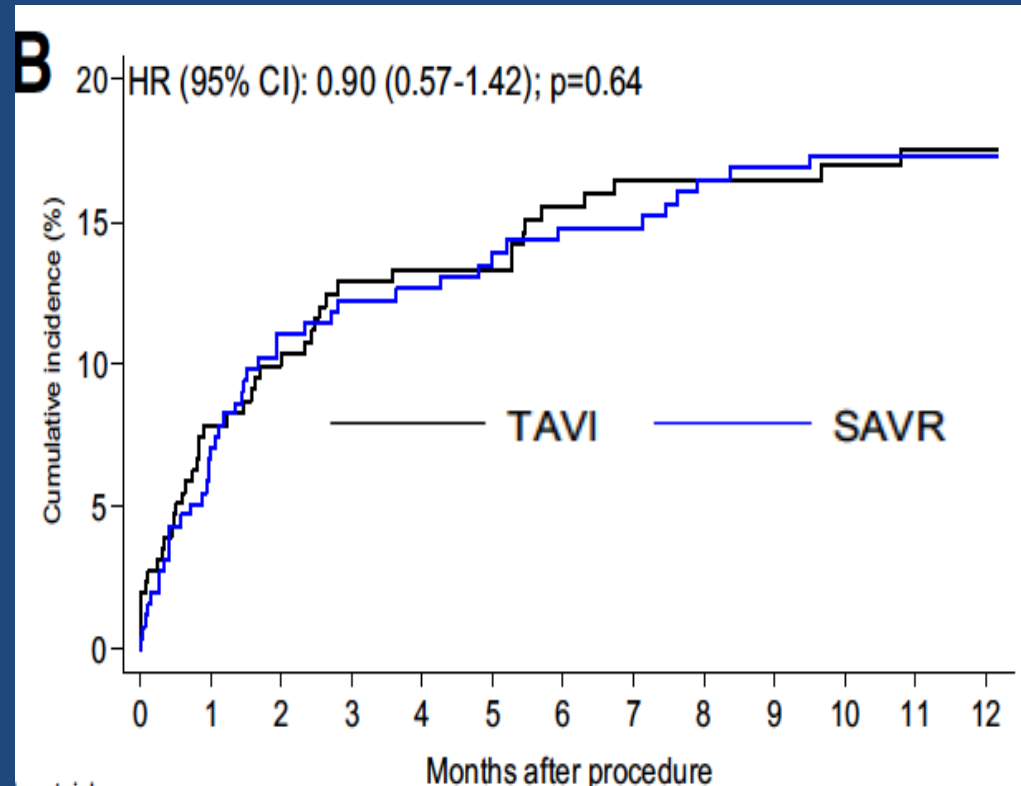
Intermediate Risk TAVR: Milan

Characteristic	TF-TAVR (n = 111)	SAVR (n = 111)	P
Age (y)	80.5 ± 6.9	79.4 ± 3.0	.10
Sex	49 (44.1)	49 (44.1)	1.00
STS-PROM	4.57 ± 2.28	4.60 ± 2.63	.93
STS morbidity and mortality	22.7 ± 8.1	23.8 ± 8.3	.30
Logistic EuroSCORE	23.2 ± 15.1	24.4 ± 13.4	.54
Additive EuroSCORE	10.5 ± 2.5	11.0 ± 2.3	.13
Coronary artery disease	44 (39.6)	51 (45.9)	.34
Previous myocardial infarction	16 (14.4)	16 (14.4)	1.00
Diabetes	21 (18.9)	24 (21.6)	.62
Cerebrovascular disease	16 (14.4)	20 (18.0)	.47
Left ventricular ejection fraction (%)	53.5 ± 12.5	53.6 ± 10.7	.94
Hypertension	78 (70.3)	77 (69.4)	.88
Peripheral vascular disease	29 (26.1)	38 (34.2)	.19
Chronic obstructive pulmonary disease	29 (26.1)	25 (22.5)	.53
Redo AVR	0 (0)	1 (0.9)	.32
Hemoglobin (g/dL)	12.6 ± 1.6	12.7 ± 1.5	.53
Creatinine (mg/dL)	1.06 ± 0.38	1.09 ± 0.61	.61
New York Heart Association Class III-IV	75 (67.6)	77 (69.4)	.99
Body mass index (kg/m ²)	25.5 ± 4.6	25.7 ± 3.9	.72



Intermediate Risk TAVR: Germany

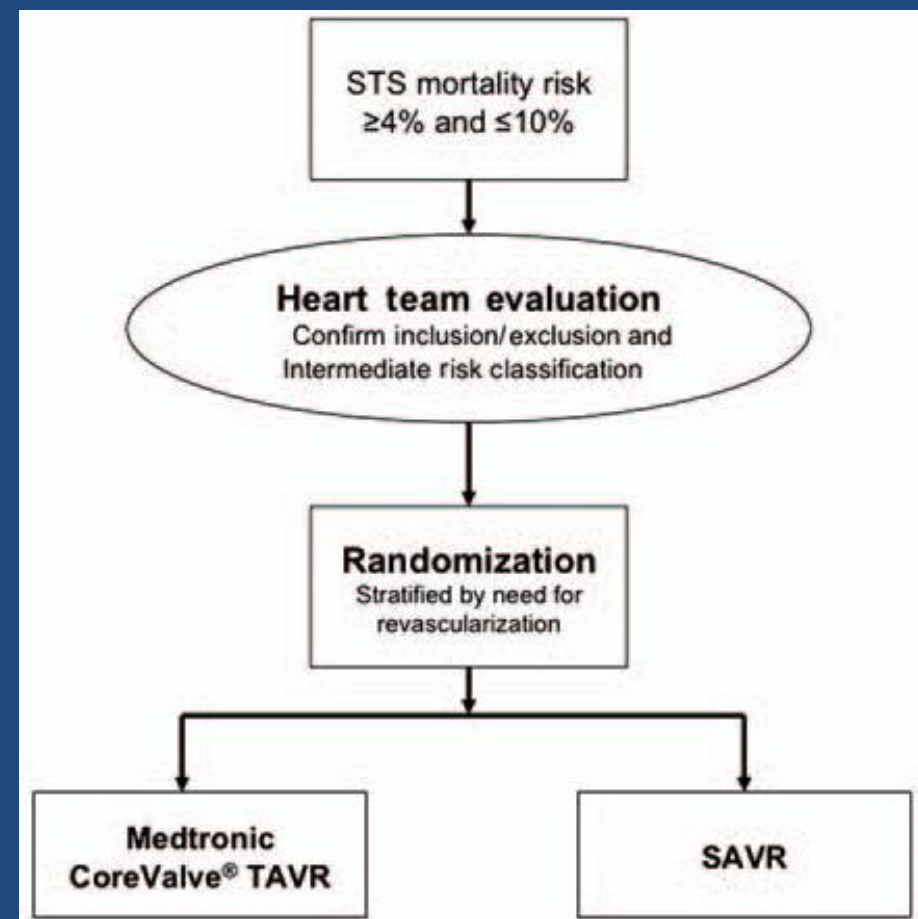
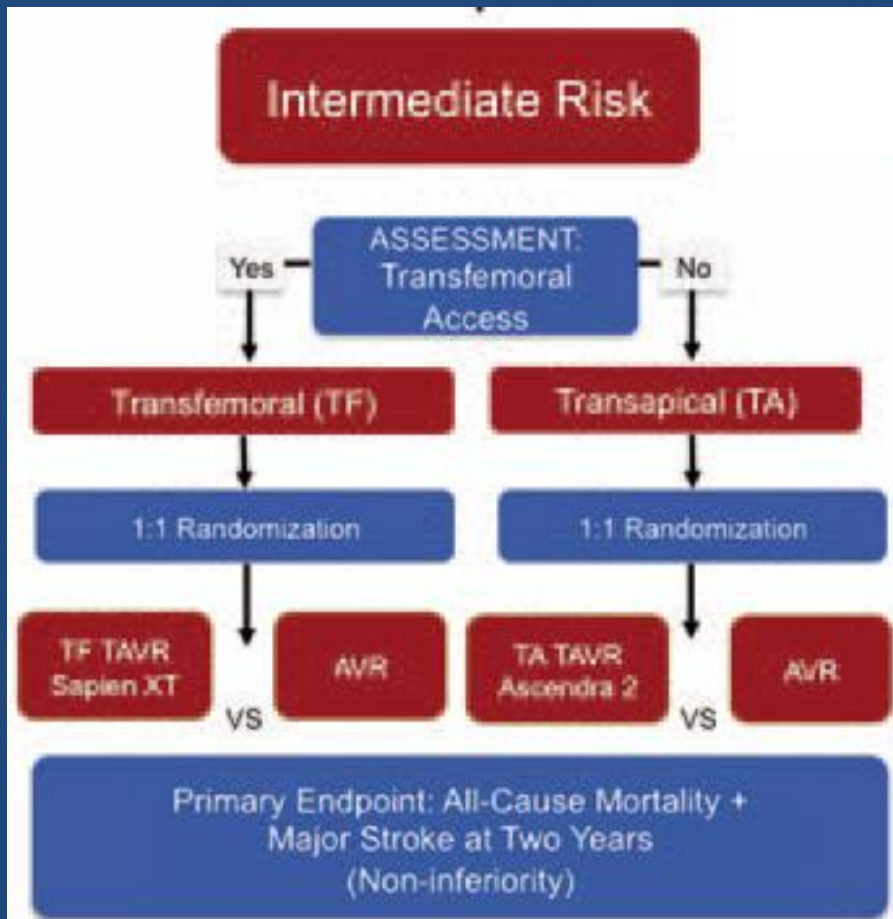
STS 3 – 8%	TAVI (n = 255)	SAVR (n = 255)	Diff	p Value
Age (yrs)	80.6 ± 5.7	79.7 ± 4.9	0.167	0.059
Female	156 (61.2)	151 (59.2)	0.040	0.651
Logistic EuroSCORE (%)	17.29 ± 9.1	17.62 ± 11.7	-0.031	0.723
NYHA				0.842
I	7 (3.1)	10 (4.4)	-0.070	
II	24 (10.6)	27 (11.9)	-0.042	
III	145 (63.9)	139 (61.2)	0.055	
IV	51 (22.5)	51 (22.5)	0.000	
Diabetes mellitus	79 (31.0)	60 (24.4)	0.147	0.1
Hypertension	198 (87.2)	183 (80.6)	0.180	0.055
Coronary artery disease	69 (61.6)	68 (60.7)	0.018	0.891
LVEF				0.404
>50%	166 (65.1)	152 (59.6)	0.113	
30%–50%	68 (26.7)	76 (29.8)	-0.070	
<30%	21 (8.2)	27 (10.6)	-0.081	



Intermediate Risk TAVR: Ongoing Randomized Trials

PARTNER IIA – Edwards SAPIEN

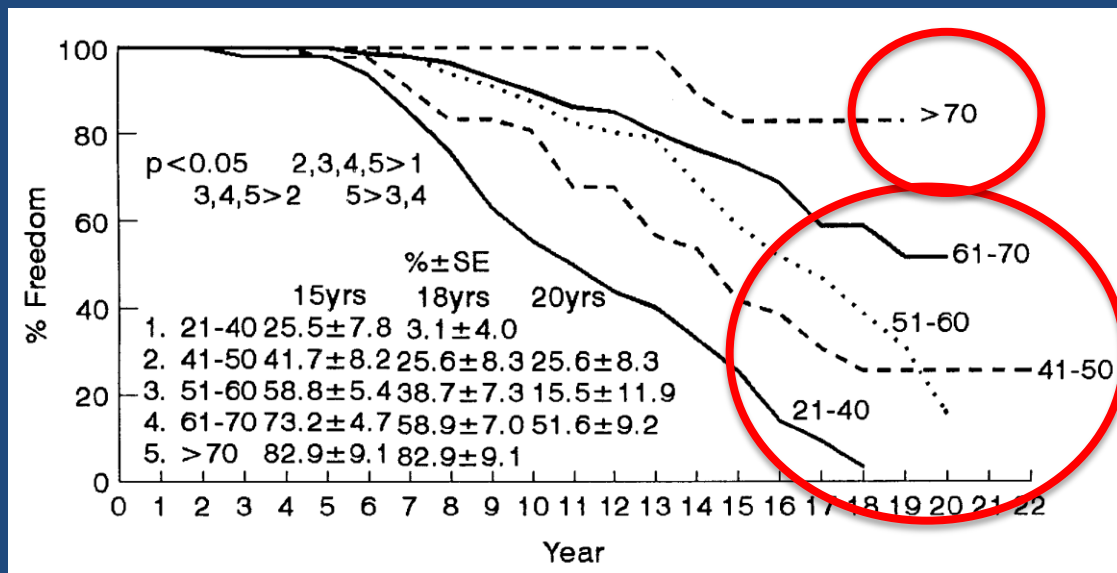
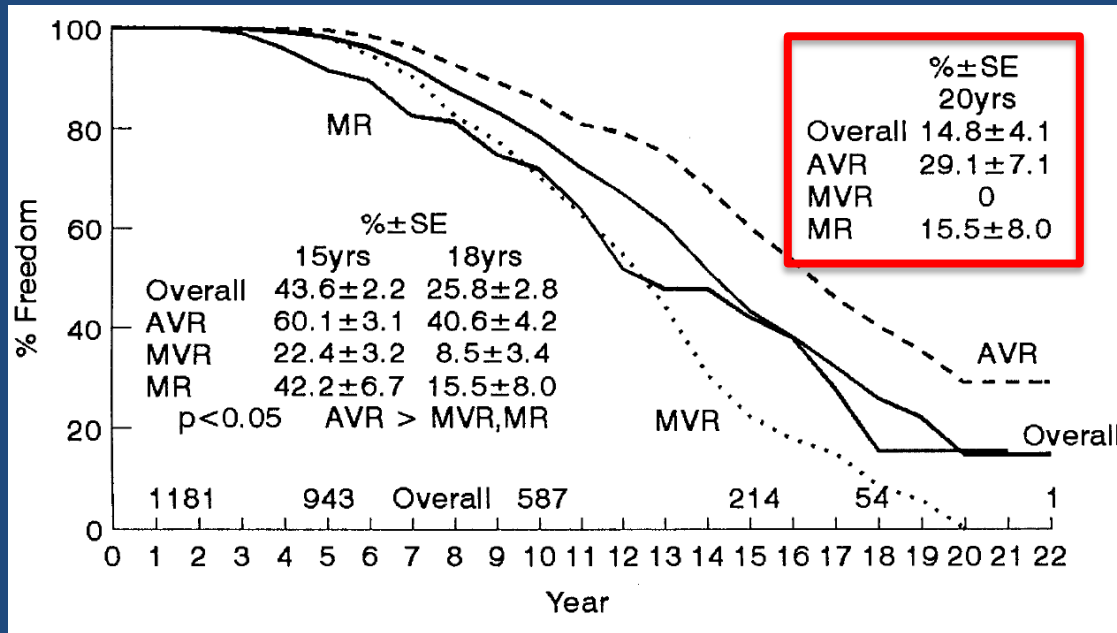
SURTAVI – Medtronic CoreValve



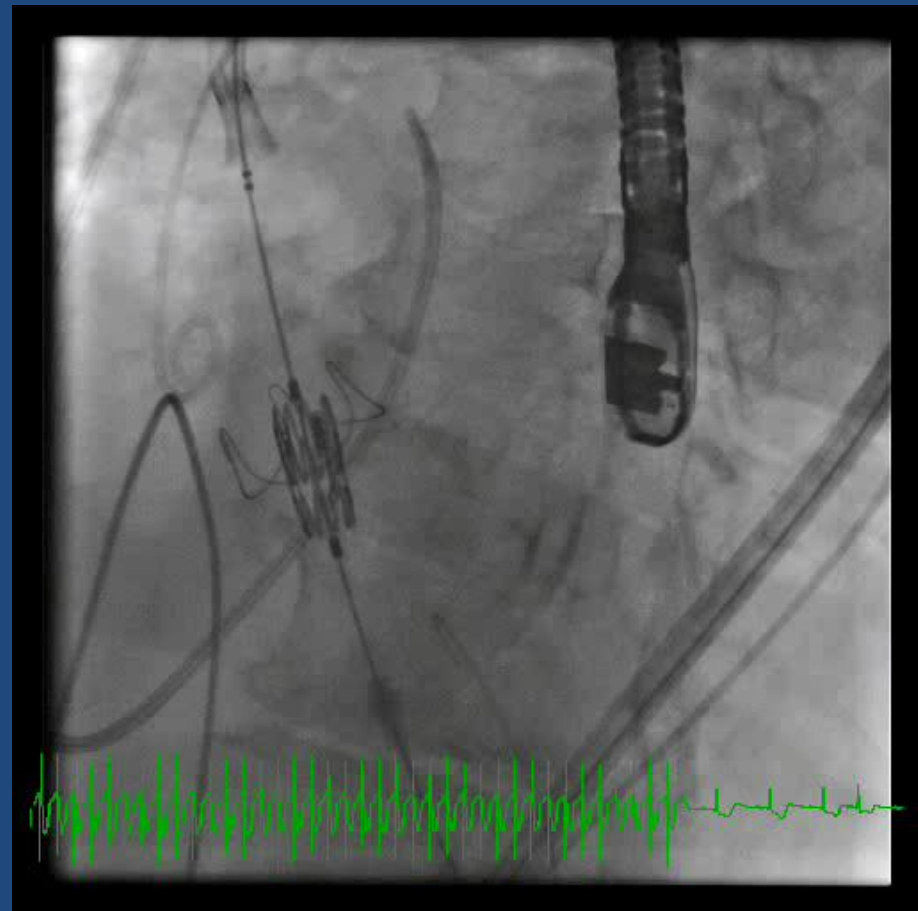
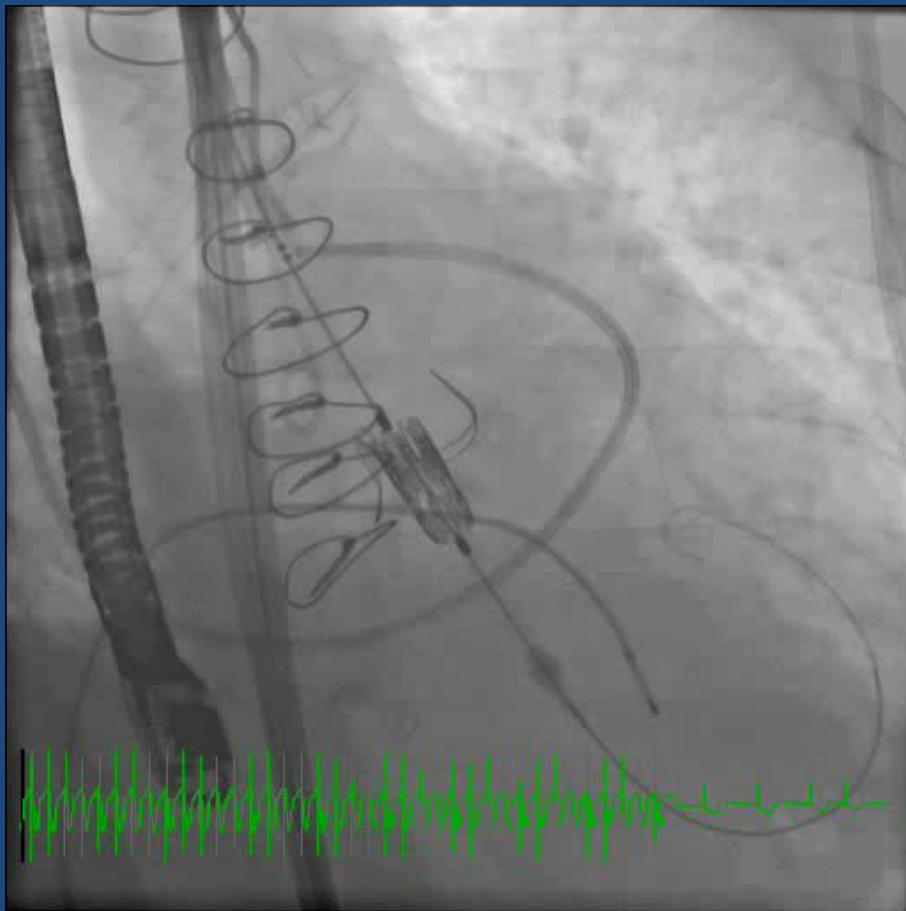
Emerging Indications

- Intermediate Risk Patients
- **Valve-in-valve**
- Bicuspid aortic stenosis
- Pure aortic regurgitation

Structural Valve Deterioration



Transfemoral Valve-in-Valve Implantation



Valvular Heart Disease

Transcatheter Aortic Valve Replacement for Degenerative Bioprosthetic Surgical Valves

Results From the Global Valve-in-Valve Registry

Danny Dvir, MD; John Webb, MD; Stephen Brecker, MD; Sabine Bleiziffer, MD;
David Hildick-Smith, MD; Antonio Colombo, MD; Fleur Descoutures, MD;
Christian Hengstenberg, MD; Neil E. Moat, FRCS; Raffi Bekerredjian, MD; Massimo Napodano, MD;
Luca Testa, MD, PhD; Thierry Lefevre, MD; Victor Guetta, MD; Henrik Nissen, MD, PhD;
José-María Hernández, MD; David Roy, MD; Rui C. Teles, MD; Amit Segev, MD;
Nicolas Dumonteil, MD; Claudia Fiorina, MD; Michael Gotzmann, MD; Didier Tchetche, MD;
Mohamed Abdel-Wahab, MD; Federico De Marco, MD; Andreas Baumbach, MD;
Jean-Claude Laborde, MD; Ran Kornowski, MD

Background—Transcatheter aortic valve-in-valve implantation is an emerging therapeutic alternative for patients with a failed surgical bioprosthesis and may obviate the need for reoperation. We evaluated the clinical results of this technique using a large, worldwide registry.

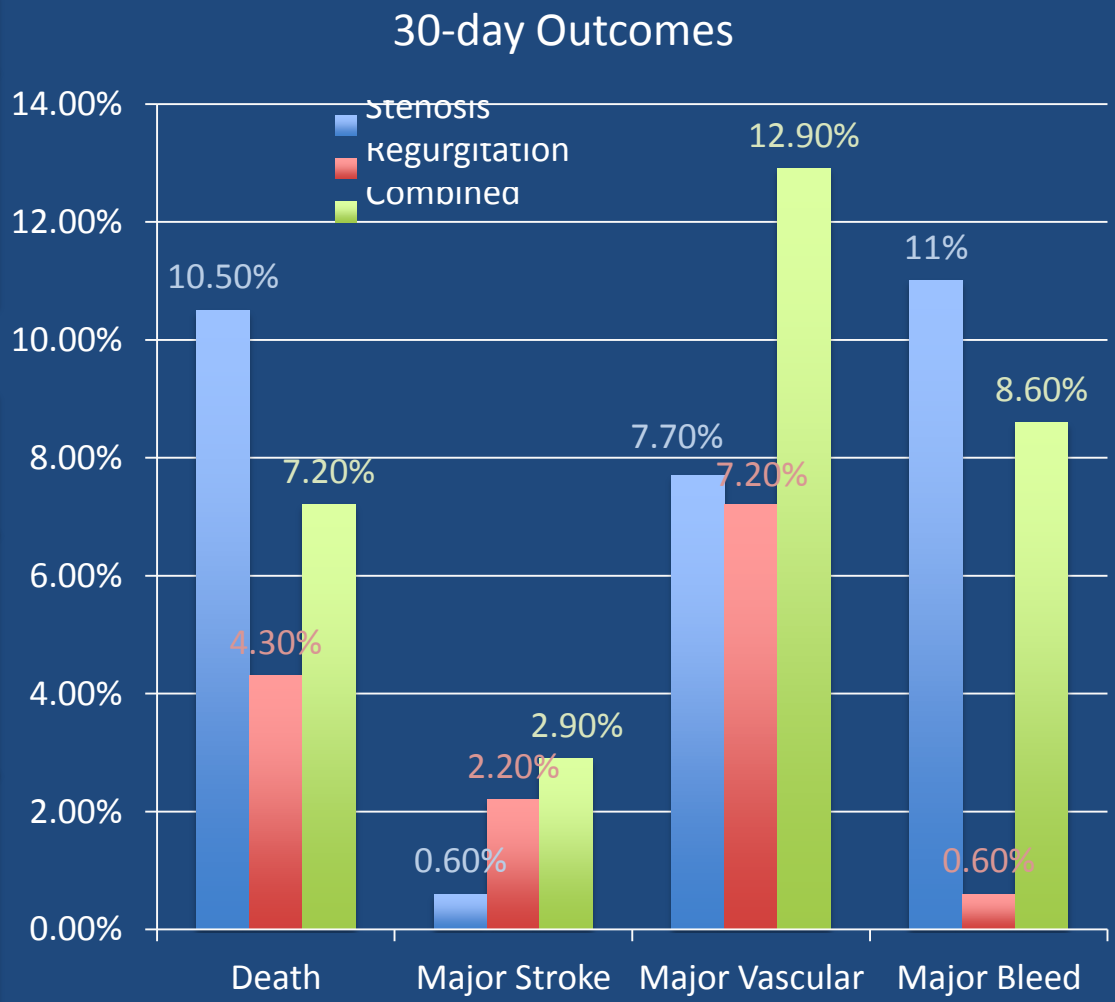
Methods and Results—The Global Valve-in-Valve Registry included 202 patients with degenerated bioprosthetic valves (aged 77.7 ± 10.4 years; 52.5% men) from 38 cardiac centers. Bioprosthesis mode of failure was stenosis ($n=85$; 42%), regurgitation ($n=68$; 34%), or combined stenosis and regurgitation ($n=49$; 24%). Implanted devices included CoreValve ($n=124$) and Edwards SAPIEN ($n=78$). Procedural success was achieved in 93.1% of cases. Adverse procedural outcomes included initial device malposition in 15.3% of cases and ostial coronary obstruction in 3.5%. After the procedure, valve maximum/mean gradients were $28.4 \pm 14.1/15.9 \pm 8.6$ mm Hg, and 95% of patients had $\leq +1$ degree of aortic regurgitation. At 30-day follow-up, all-cause mortality was 8.4%, and 84.1% of patients were at New York Heart Association functional class I/II. One-year follow-up was obtained in 87 patients, with 85.8% survival of treated patients.

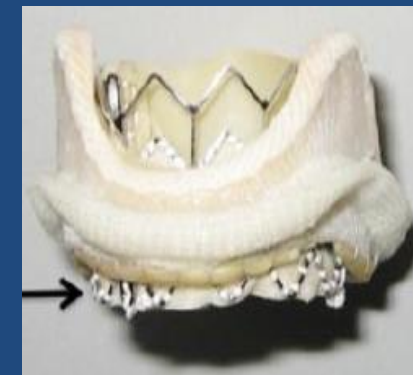
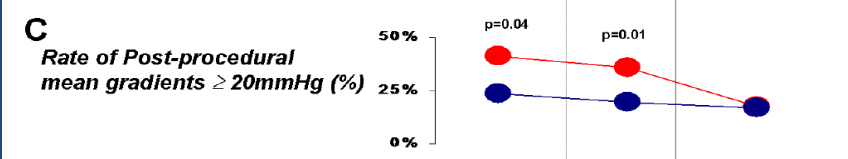
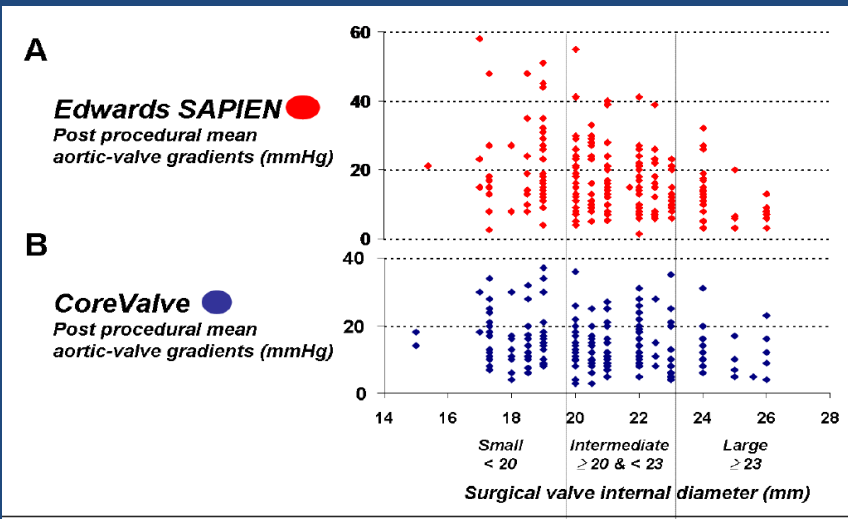
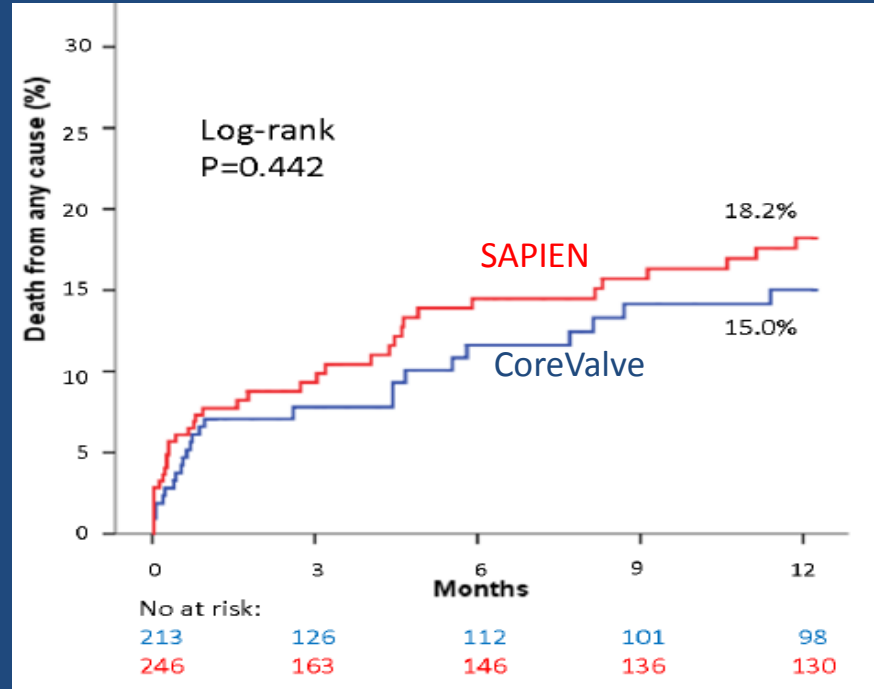
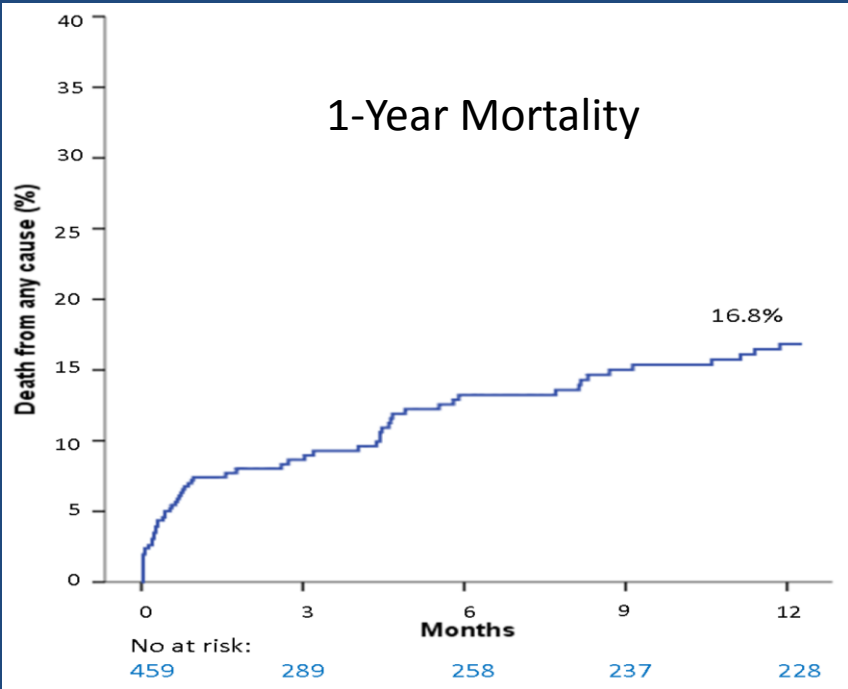
Conclusions—The valve-in-valve procedure is clinically effective in the vast majority of patients with degenerated bioprosthetic valves. Safety and efficacy concerns include device malposition, ostial coronary obstruction, and high gradients after the procedure. (*Circulation*. 2012;126:2335-2344.)

Key Words: bioprosthesis ■ transcatheter aortic valve implantation ■ valve-in-valve

Global ViV Registry Aortic ViV

Total Valve-in-Valve	681
Aortic Valve-in-valve	459
Stenosis	181
Regurgitation	139
Combined	139
Age	77 years
Logistic EuroSCORE	32
STS Score	12
Post TAVR Mean AV gradient	
Stenosis	18.4 mmHg
Regurgitation	12.0 mmHg
Combined	16.0 mmHg
Post TAVR AR \geq 2+	p = 0.04
Stenosis	2.8%
Regurgitation	9.4%
Combined	5.0%

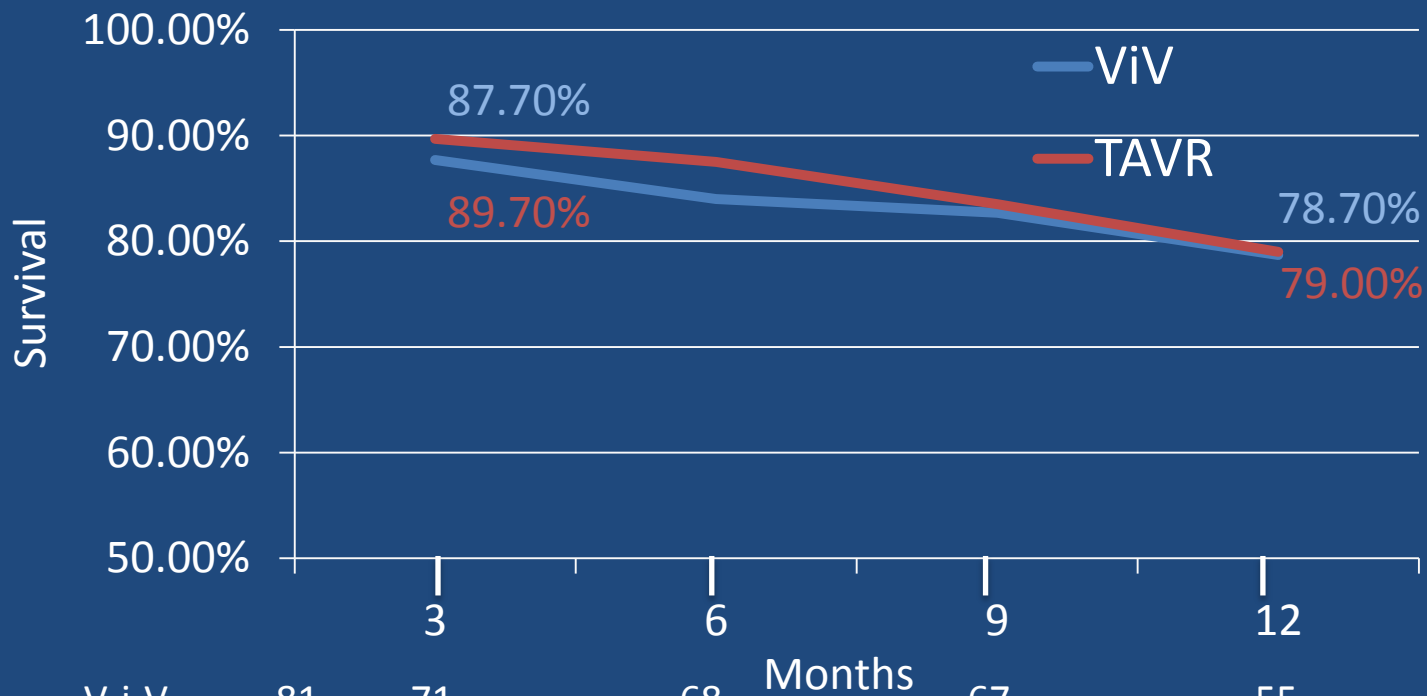




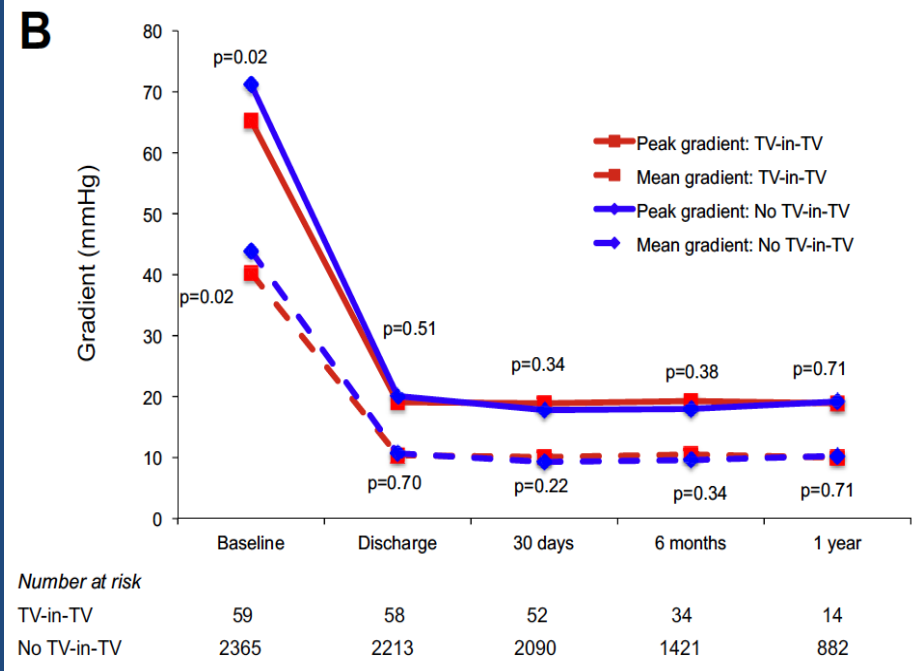
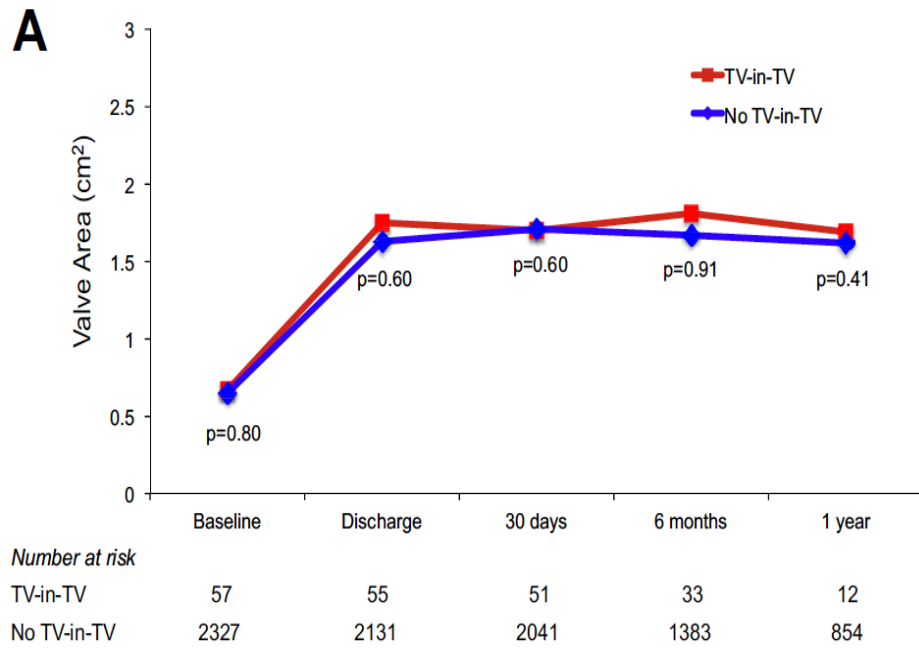
Dvir D for the Global ViV Registry Investigators.
TVT 2013

SOURCE & SOURCE XT ViV Registry

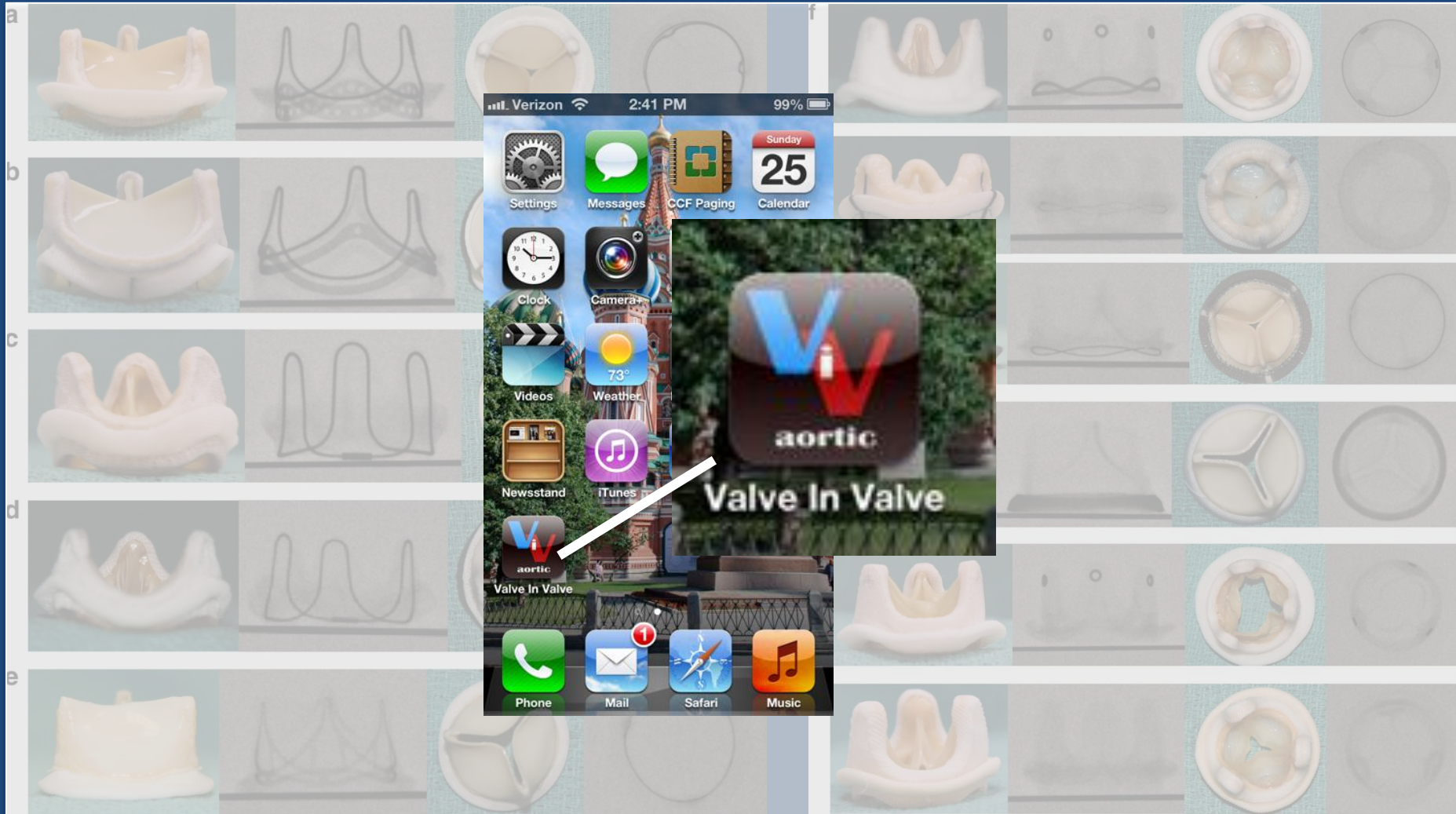
	SOURCE ViV N = 22	SOURCE TAVR N = 2285	SOURCE XT ViV N = 59	SOURCE XT TAVR N = 2629
Age, yrs	77.7	81.2	78.5	81.5
STS, %	7.0	12.7	7.4	7.9
EuroSCORE	32.6	25.9	28.4	20.3



PARTNER: Valve-in-SAPIEN Valve



Aortic Valve-in-Valve Implantation



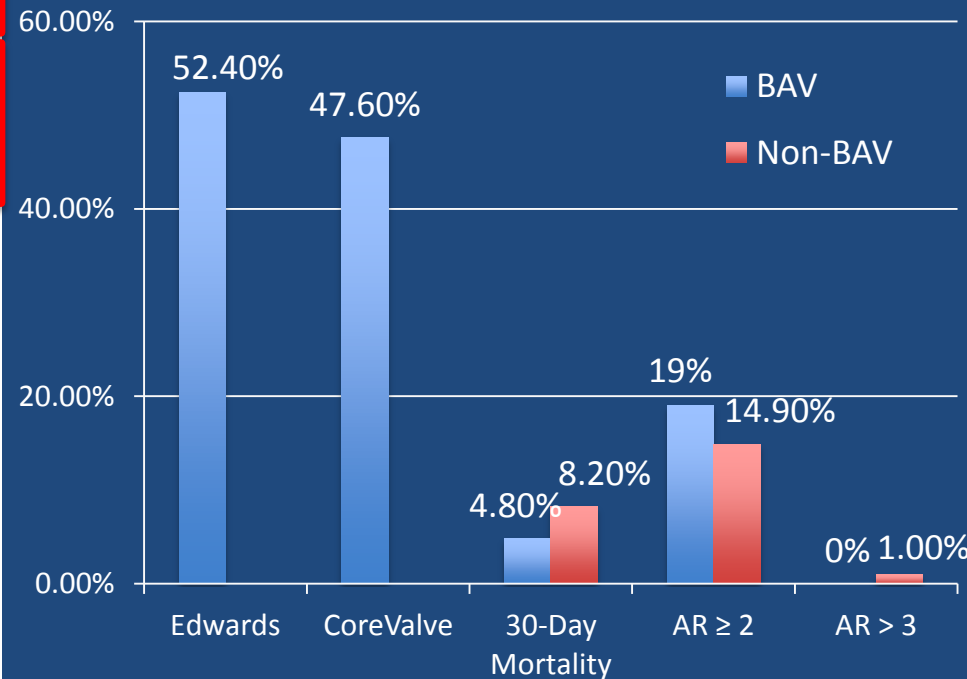
Emerging Indications

- Intermediate Risk Patients
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- **Bicuspid aortic stenosis**
- Pure aortic regurgitation

Transcatheter Aortic Valve Implantation for Patients With Severe Bicuspid Aortic Valve Stenosis

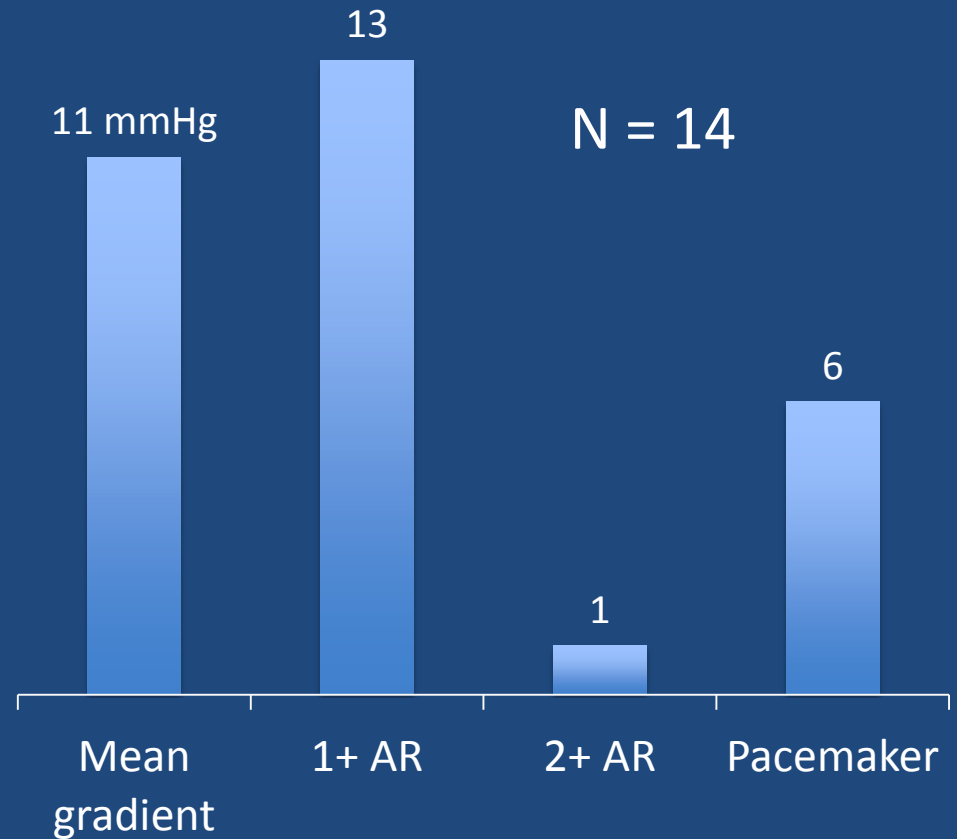
Kentaro Hayashida, MD, PhD, FESC; Erik Bouvier, MD; Thierry Lefèvre, MD, FSCAI, FESC; Bernard Chevalier, MD, FSCAI, FESC; Thomas Hovasse, MD; Mauro Romano, MD; Philippe Garot, MD, FESC; Yusuke Watanabe, MD; Arnaud Farge, MD; Patrick Donzeau-Gouge, MD; Bertrand Cormier, MD; Marie-Claude Morice, MD, FESC

	Total	BAV	Non-BAV	P Value
Patients	229	21	208	
Age, years	83.1±6.6	82.0±7.0	83.2±6.5	0.29
Aortic annulus size (TEE-measured), mm	22.6±2.0	23.4±2.7	22.5±1.9	0.11
Mean aortic annulus size (CT-measured), mm	23.8±2.0	24.7±3.0	23.7±1.9	0.07
Short-axis annulus size (CT-measured), mm	22.0±2.0	22.7±2.8	21.9±1.9	0.09
Long-axis annulus size (CT-measured), mm	26.5±2.5	27.4±3.1	26.4±2.5	0.06
Long/short Diam-CT ratio	1.21±0.08	1.21±0.07	1.21±0.08	0.53
Circumference, mm	75.6±6.8	77.5±9.5	74.3±6.4	0.11
Aortic valve calcification degree, %	28.7±11.4	32.2±10.1	28.4±11.9	0.39
Length of raphe (CT), mm	—	12.7±2.7	—	—
Aortic regurgitation (0–4)	0.84±0.70	0.95±0.74	0.83±0.70	0.98
Mitral regurgitation (0–4)	0.81±0.69	0.74±0.87	0.82±0.67	0.72
Ascending aorta size, mm	36.1±4.3	38.3±3.4	35.8±4.3	0.01



CoreValve Implantation for Bicuspid AS

Patients	15
Age	80 years
Logistic EuroSCORE	17
STS Score	8
Aortic Annulus (mean)	25mm
Ascending aorta (mean)	37mm



Emerging Indications

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- Pure aortic regurgitation

Transcatheter Aortic Valve Implantation for Pure Severe Native Aortic Valve Regurgitation

JACC 2013;61:1577-84

David A. Roy, MD,* Ulrich Schaefer, MD, PhD,† Victor Guetta, MD,‡ David Hildick-Smith, MD,§

Age, yrs	75.3 ± 8.8
Logistic EuroSCORE	26.9 ± 17.9
STS score	10.2 ± 5.3
Ascending aortic diameter, mm†	35.9 ± 8.8
Sinus of Valsalva dimension, mm†	32.8 ± 4.9
LVEDD, mm	59.4 ± 13.7
LVESD, mm	41.7 ± 14.4
LV ejection fraction, %	45.5 ± 12.9
Aortic regurgitation grade (echocardiography)	
II	0
III	24 (55.8)
IV	19 (44.2)
Aortic regurgitation grade (angiography)	
II	1 (2.3)
III	22 (51.2)
IV	20 (46.6)

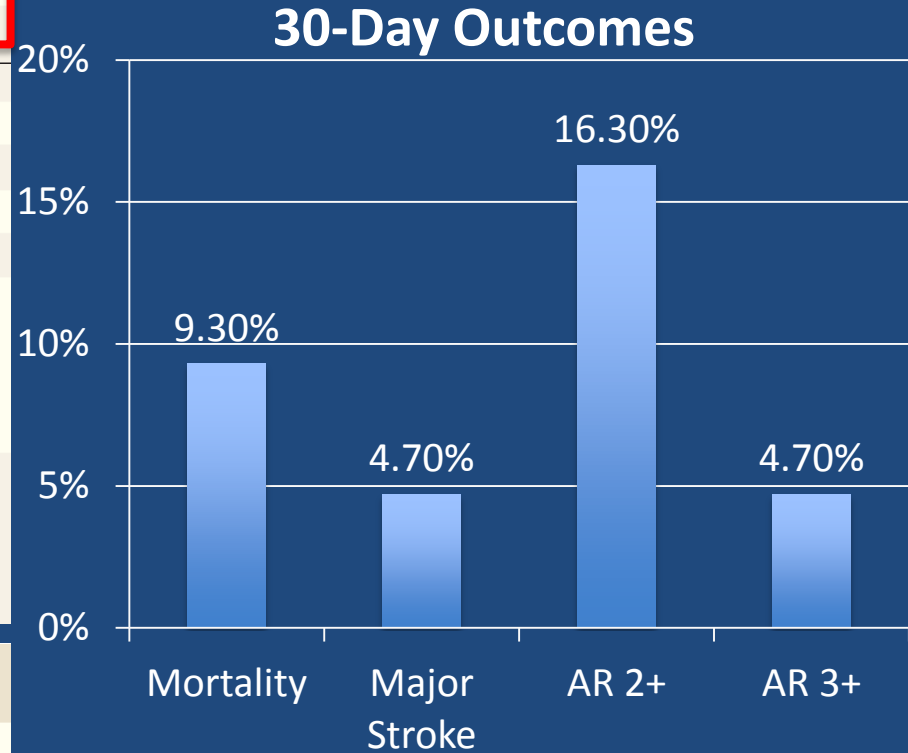


Table 2 Mechanism of Aortic Regurgitation

Degenerative	27 (62.8)
Post-endocarditis	6 (14.0)
Aortic aneurysm	4 (9.3)
Aortic valve cusp restriction due to rheumatoid vasculitis, Takayasu's arteritis, unknown	3 (7.0)
Post-radiotherapy	2 (4.7)
Chronic dissection	1 (2.3)

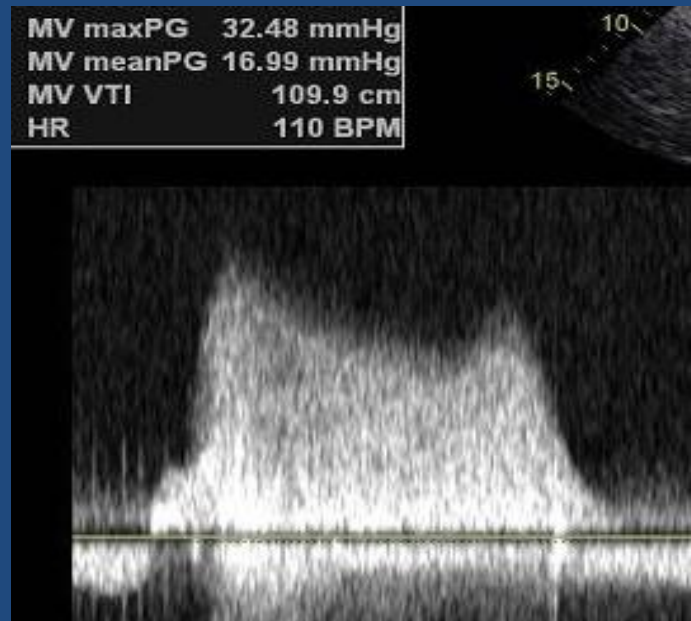
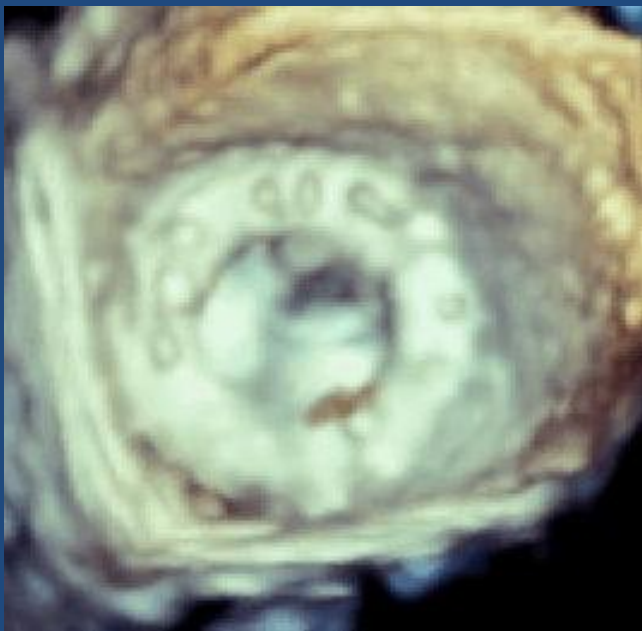
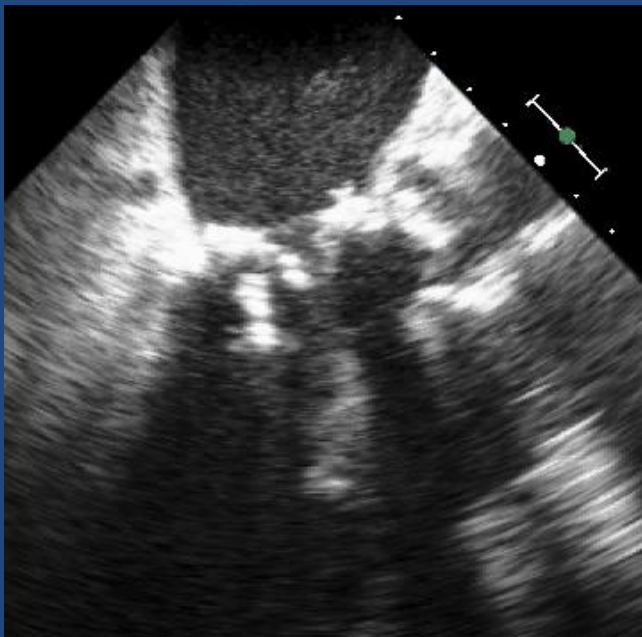
Conclusions

- TAVR is an established treatment for patients who are inoperable or at high-risk for surgical AVR
- Registry & propensity-matched data of TAVR for intermediate risk patients is promising
- Randomized trials enrolling intermediate risk patients are underway and eagerly anticipated
- Valve-in-valve implantation is promising
 - 1-year outcomes similar to native TAVR
 - Importance of prosthetic valve size on post-ViV gradients
 - Mitral ViV has more challenges, but may be an important treatment
- TAVR for bicuspid AS should be approached cautiously
- Treatment of pure native AR may be reasonable

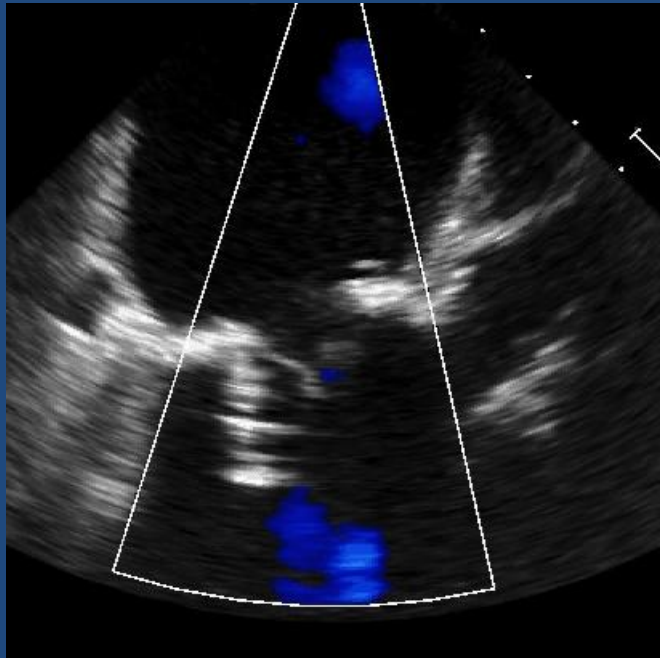
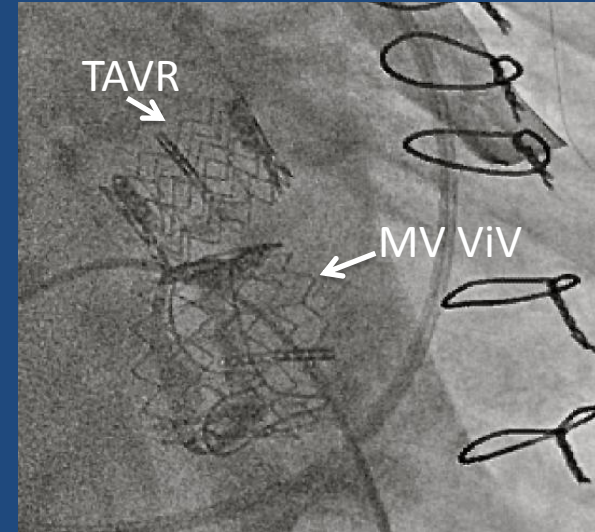
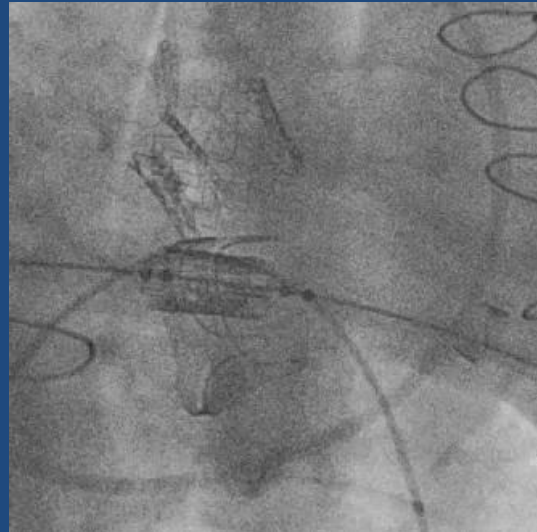
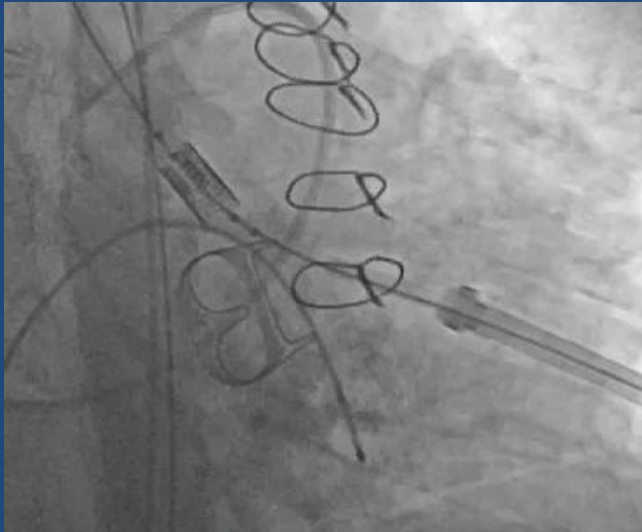
Thank You

 Cleveland Clinic
Sydell & Arnold Miller Family Pavilion

Patient with Native AS and Bioprosthetic MS

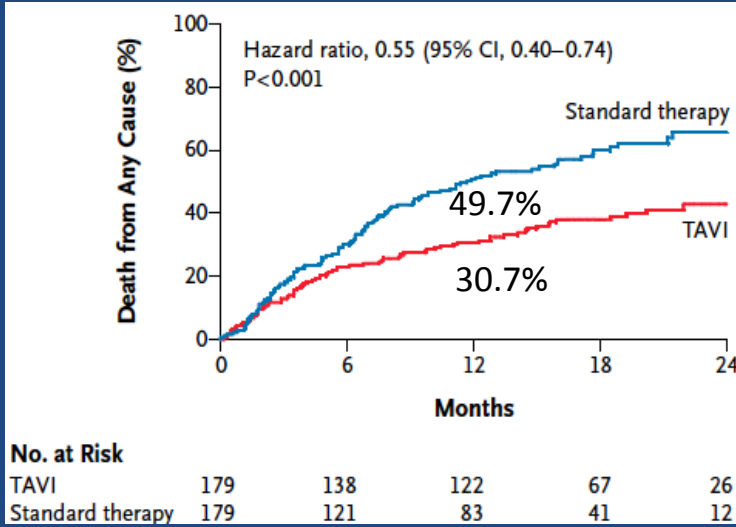


TA-TAVR + Mitral Valve-in-Valve Implantation

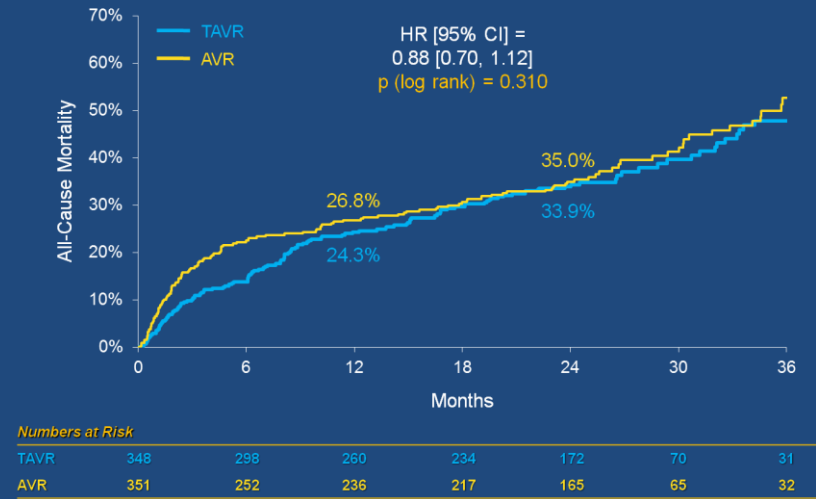


TAVR: Inoperable and High Risk

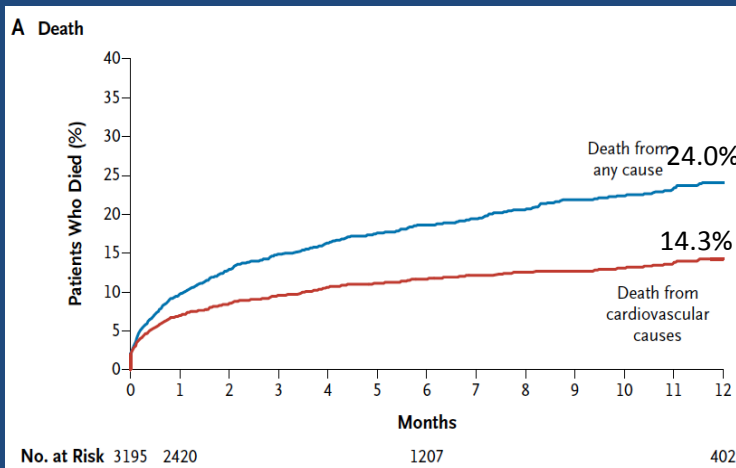
PARTNER IB – Inoperable Cohort



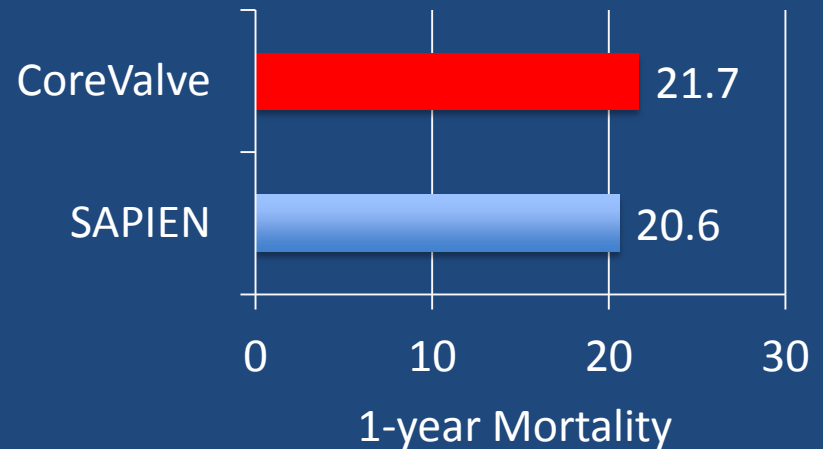
PARTNER IA – High Risk Cohort



FRANCE-2 – High Risk Patients



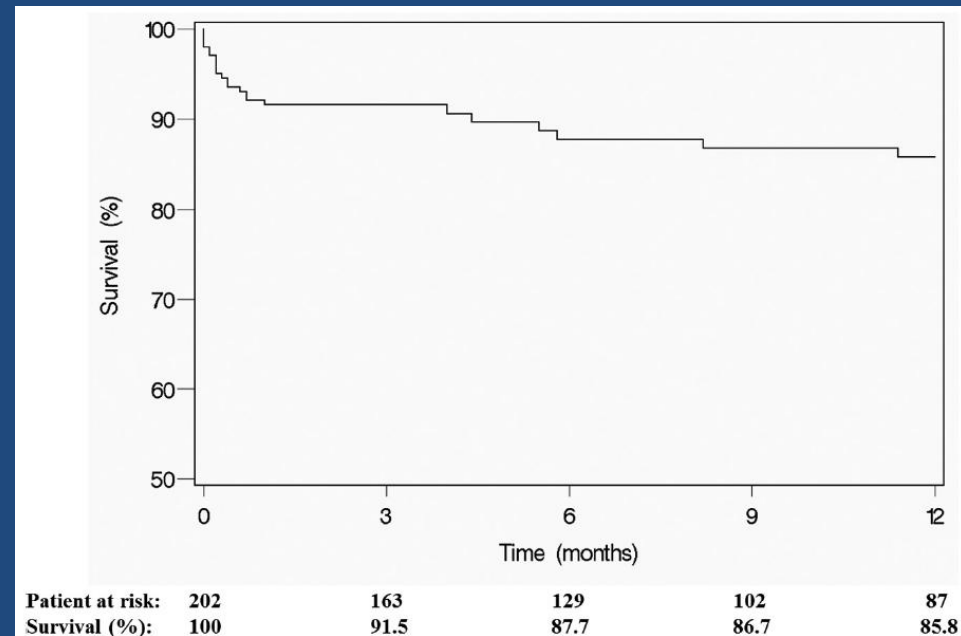
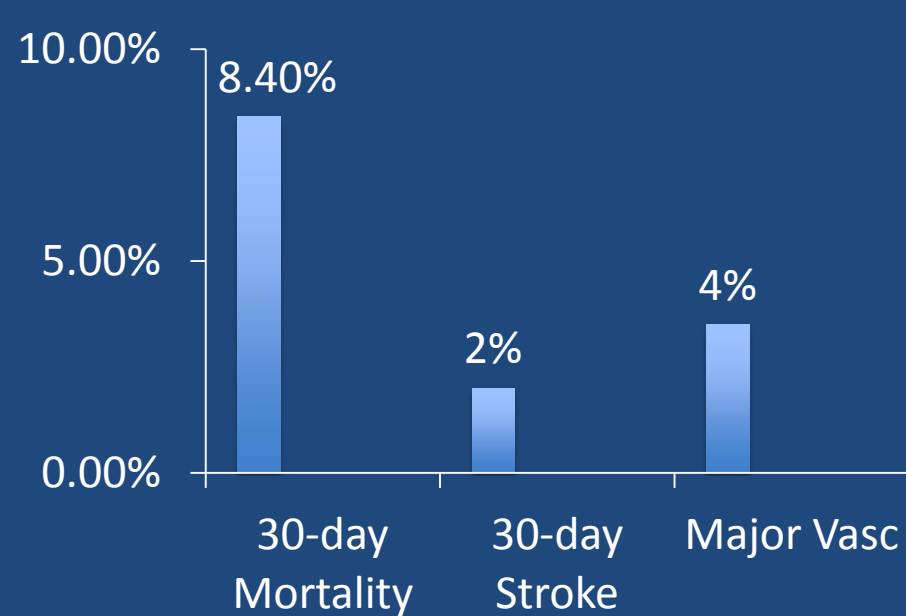
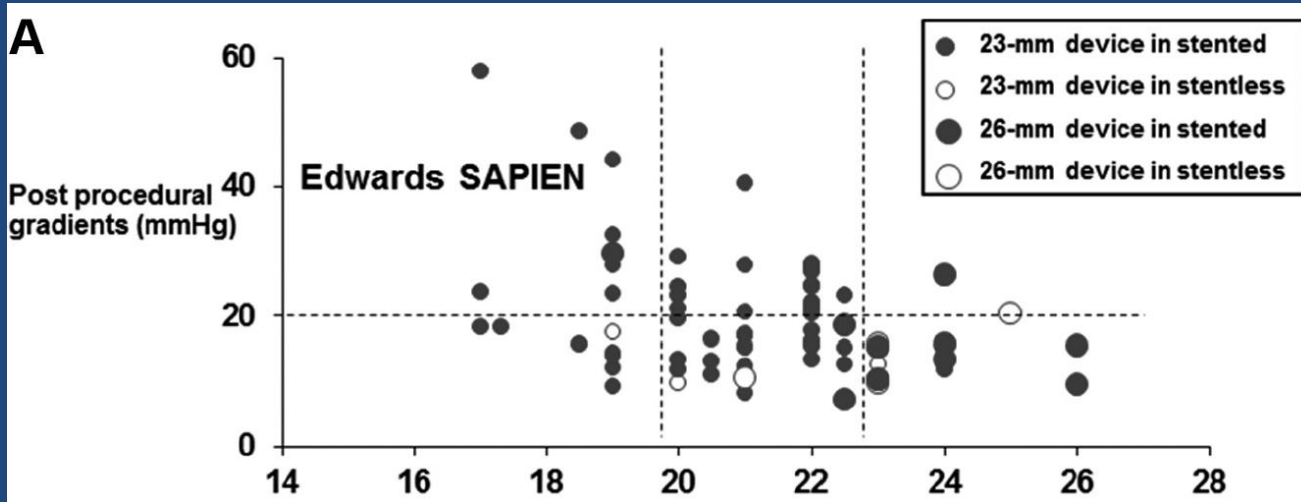
UK Registry – High Risk Patients



Global Valve-in-Valve Registry

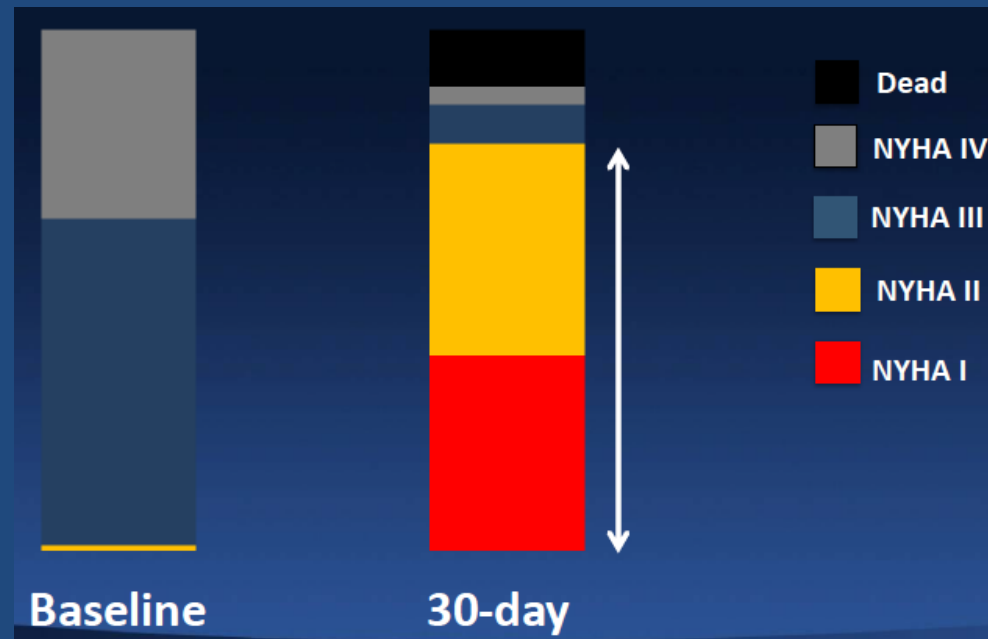
	All (n=202)	CoreValve (n=124)	Edwards SAPIEN (n=78)	<i>P</i> *
Patient characteristics				
Age, y	77.7±10.4	77.4±11	78.3±9.4	0.53
Men, n (%)	106 (52.5)	65 (52.4)	41 (52.6)	1.0
Log EuroSCORE	31.1±16.4	31±16.6	31.2±16.1	0.92
STS score	11.8±9.9	12.8±11	10.2±7.5	0.07
Diabetes mellitus, n (%)	59 (29.2)	43 (34.7)	16 (20.5)	0.03
Peripheral vascular disease, n (%)	41(20.3)	22 (17.7)	19 (24.4)	0.26
Chronic renal failure, n (%)†	94 (46.5)	52 (41.9)	42 (53.8)	0.10
Previous stroke, n (%)	25 (12.4)	16 (12.9)	9 (11.5)	0.77
Time since last SAVR, y‡	9 (6, 13)	10 (6, 14)	8 (5, 13)	0.33
Mechanism of failure, n (%)				0.25
Stenosis	85 (42.1)	50 (40.3)	35 (44.9)	
Regurgitation	68 (33.7)	47 (37.9)	21 (26.9)	
Combined	49 (24.3)	27 (21.8)	22 (28.2)	

Global Valve-in-Valve Registry



Global ViV Registry Mitral ViV

Mitral or Tricuspid Valve-in-Valve	134
Age	75 years
Logistic EuroSCORE	30
STS Score	16.3
Mean MV gradient	6.4 mmHg
MR \geq 2+	4.4%



Transcatheter Aortic Valve Implantation for Pure Severe Native Aortic Valve Regurgitation

JACC 2013;61:1577-84

David A. Roy, MD,* Ulrich Schaefer, MD, PhD,† Victor Guetta, MD,‡ David Hildick-Smith, MD,§

Age, yrs	75.3 ± 8.8
Logistic EuroSCORE	26.9 ± 17.9
STS score	10.2 ± 5.3
Ascending aortic diameter, mm†	35.9 ± 8.8
Sinus of Valsalva dimension, mm†	32.8 ± 4.9
LVEDD, mm	59.4 ± 13.7
LVESD, mm	41.7 ± 14.4
LV ejection fraction, %	45.5 ± 12.9
Aortic regurgitation grade (echocardiography)	
II	0
III	24 (55.8)
IV	19 (44.2)
Aortic regurgitation grade (angiography)	
II	1 (2.3)
III	22 (51.2)
IV	20 (46.6)

Access	
Transfemoral	35 (81.4)
Subclavian	4 (9.3)
Direct aortic	3 (7.0)
Carotid	1 (2.3)
Implantation of prosthesis	42 (97.7)
Annulus size, mm	24.0 ± 2.3
Prosthesis size, mm	
29	22 (51.2)
26	14 (32.6)
31	7 (16.3)
Valve post-dilation	4 (9.3)
Second valve required	8 (18.6)
Post-procedure AR grade	
I or lower	34 (79.1)
II	7 (16.3)
III	2 (4.7)
New permanent pacemaker	7 (16.3)
Mortality	
30-day all-cause	4 (9.3%)
30-day cardiovascular	1 (2.3%)
12 month all-cause	6/28 (21.4)
12-month cardiovascular	3/28 (10.7)
Major stroke (30 days)	2 (4.7)

Table 2 Mechanism of Aortic Regurgitation

Degenerative	27 (62.8)
Post-endocarditis	6 (14.0)
Aortic aneurysm	4 (9.3)
Aortic valve cusp restriction due to rheumatoid vasculitis, Takayasu's arteritis, unknown	3 (7.0)
Post-radiotherapy	2 (4.7)
Chronic dissection	1 (2.3)