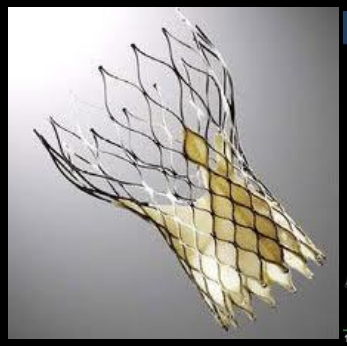
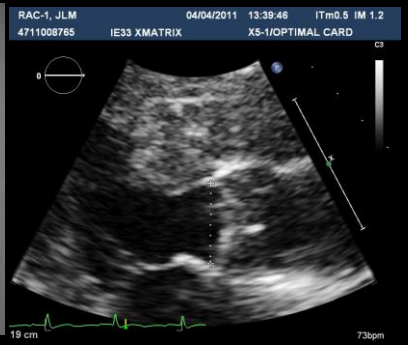
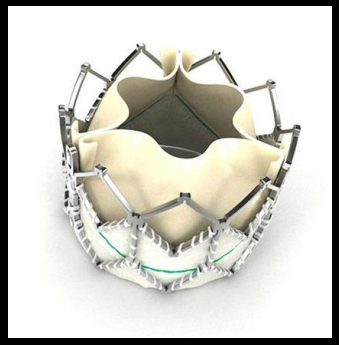
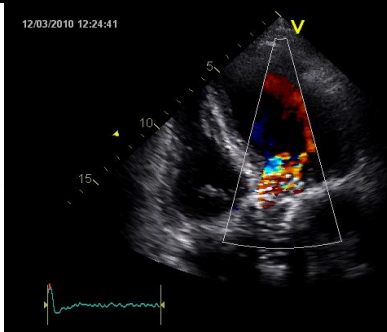
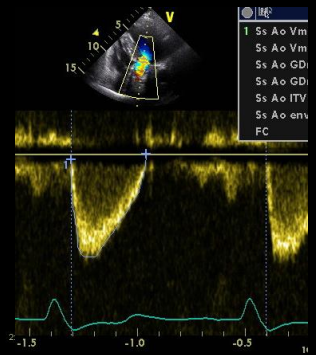
Even mild para-valvular AR impacts mortality after TAVI



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My disclosures

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Abbott Vascular, Astrazeneca, Bristol-Myers Squibb, Daiichi-Sankyo, Edwards Lifesciences, GE Healthcare, Ipsen Pharma, Medtronic, MSD, Saint-Jude Medical, Sanofi-Aventis, Servier, Siemens, Toshiba.

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Transcatheter aortic valves: A rapidly evolving technology

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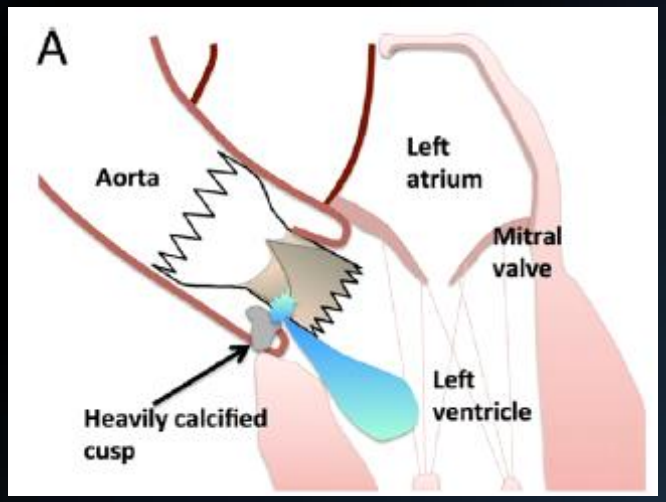
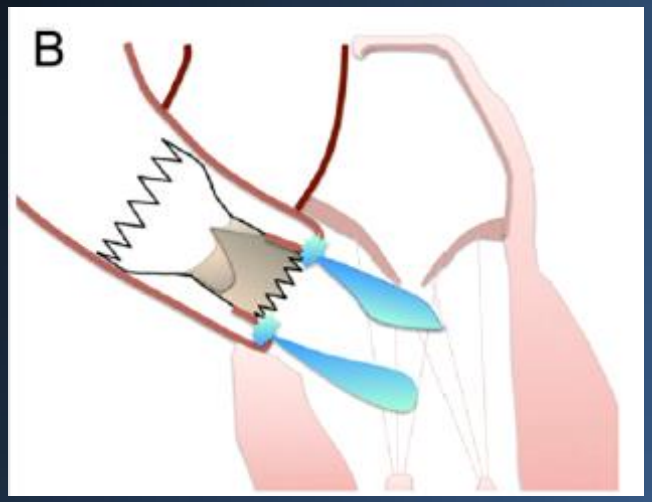
Mechanisms of paravalvular leaks after TAVI

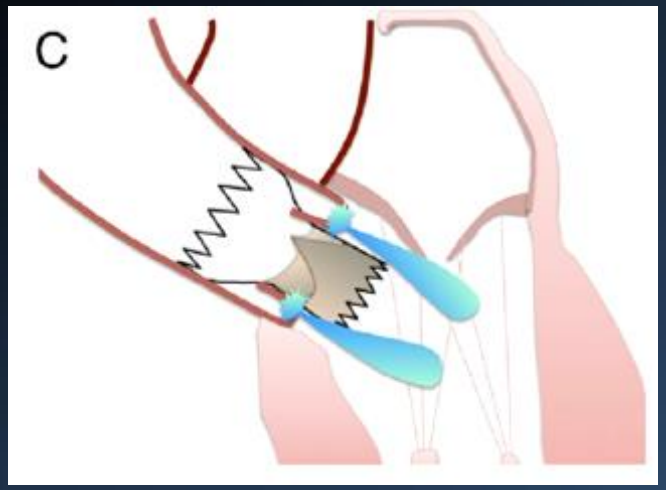
Sinning et al. *J Am Coll Cardiol.* 2012; 59: 1134-41

Heavily calcified valve

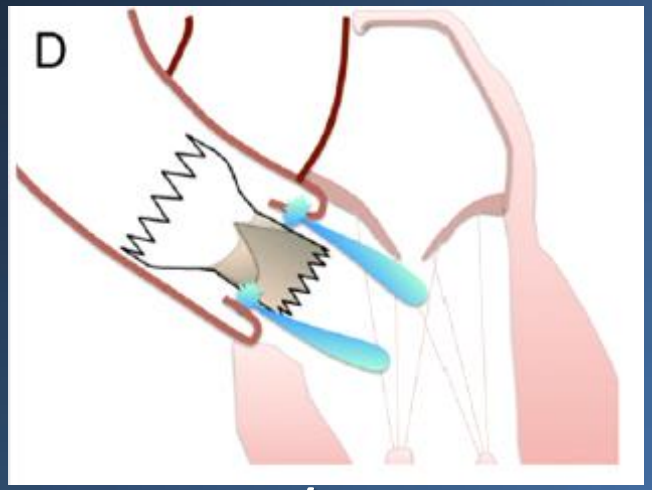


Malposition : too high



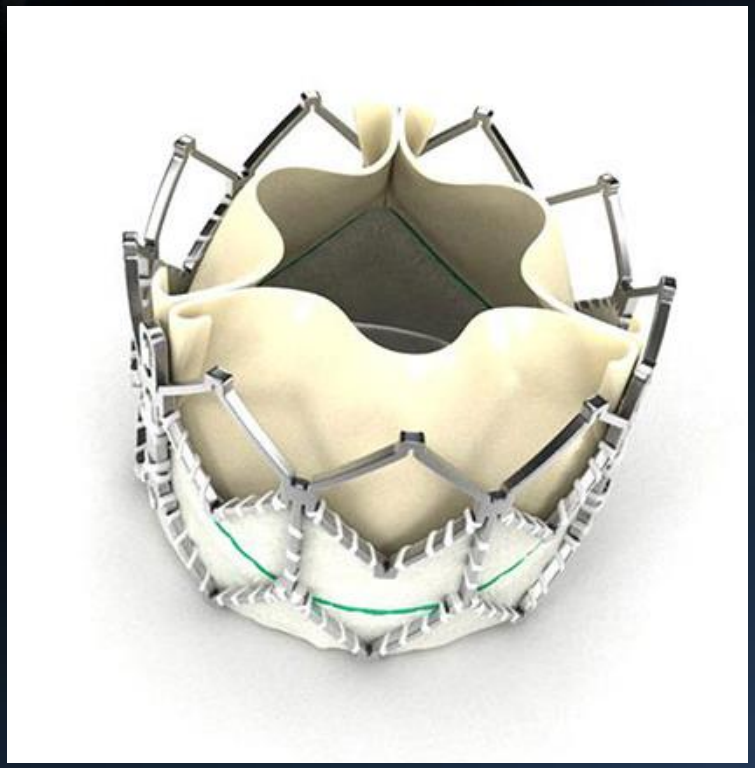


Malposition : too deep

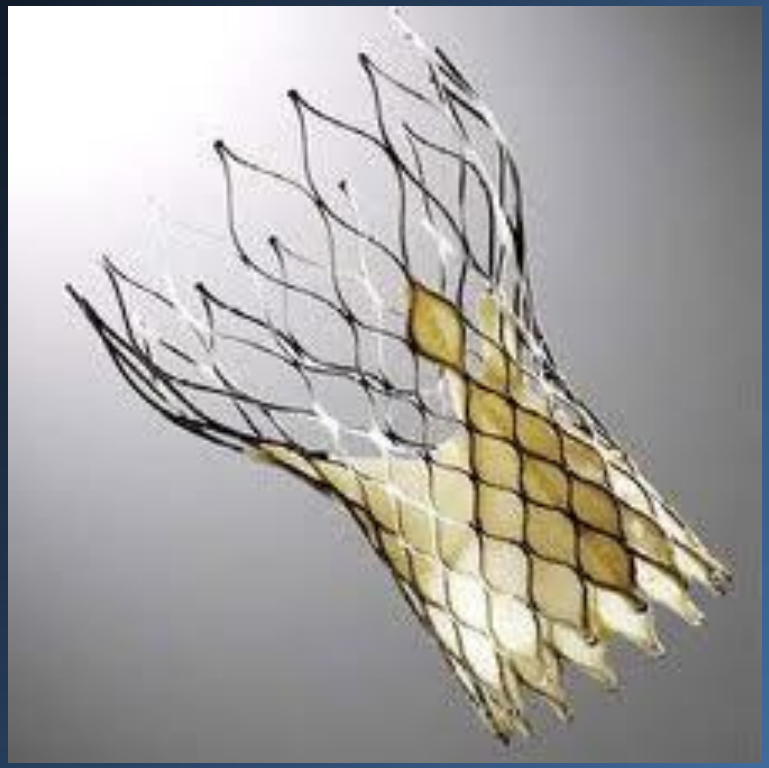


Large ring/ sizing errror

Currently available transcatheter valves: Soon to become "vintage"

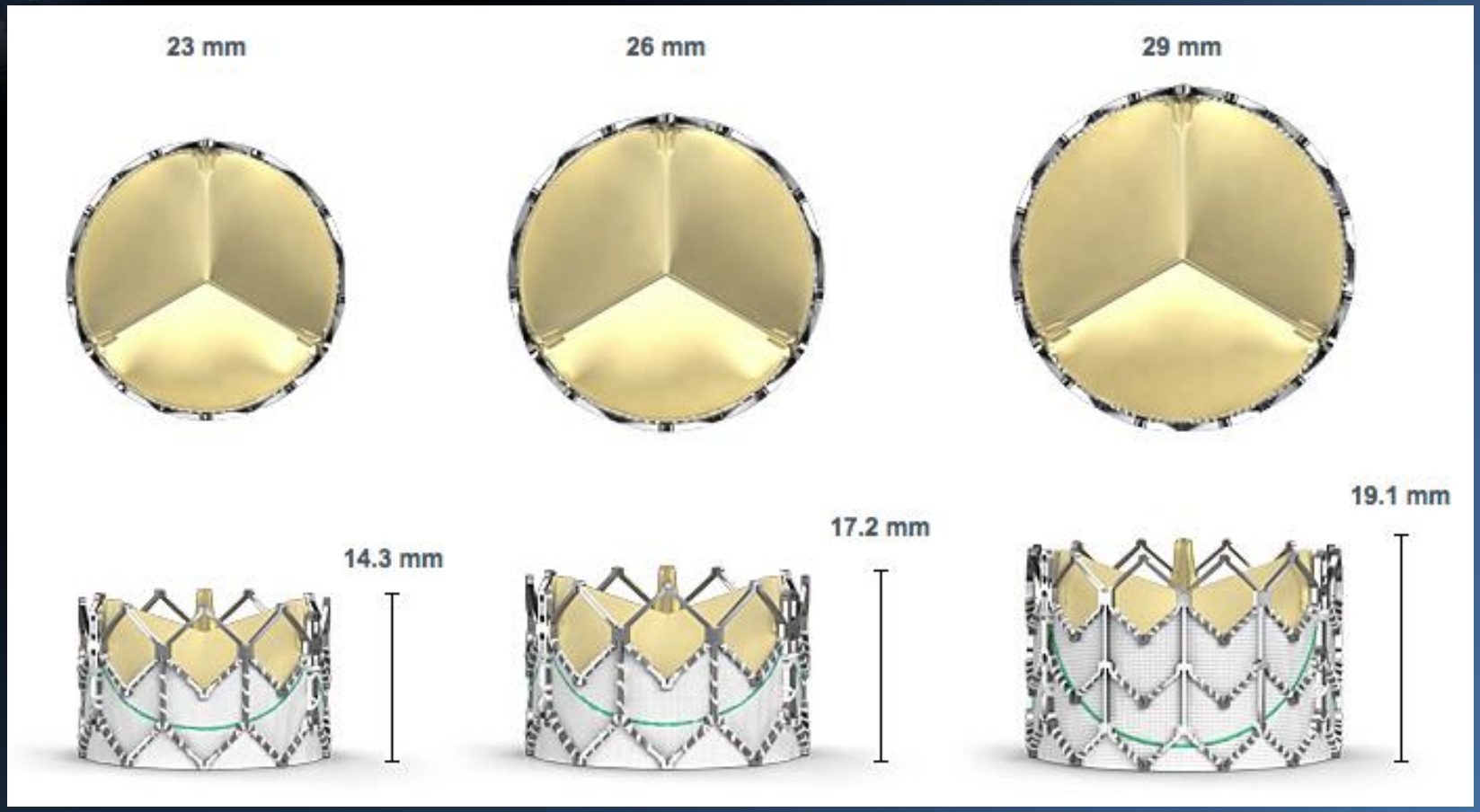


Edwards SAPIEN XT ®



Medtronic CoreValve ®

Edwards XT Transcatheter heart valve

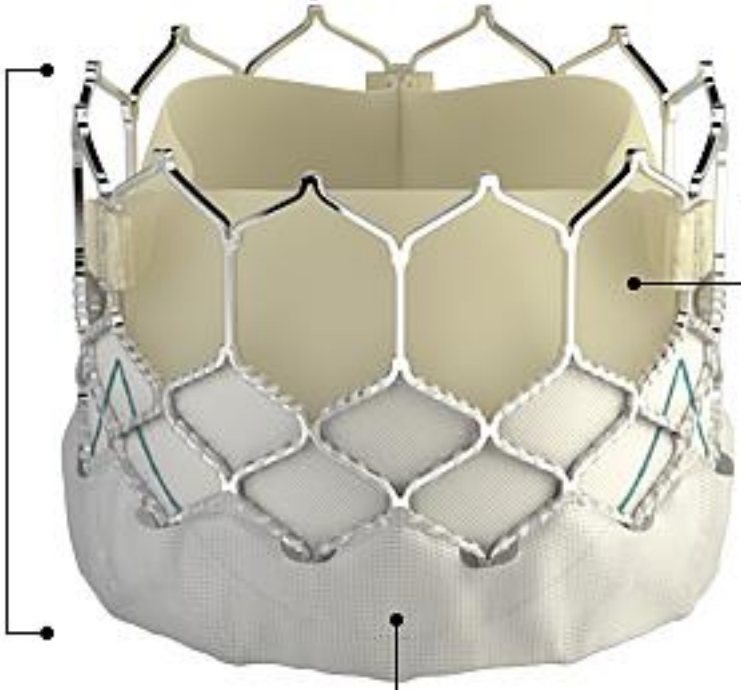


16F (18-22 mm)	18F (22-24 mm)	20F (25-27 mm)

Next generation: Edwards SAPIEN 3 Transcatheter Heart Valve

Frame design

- Enhanced frame geometry for ultra-low delivery profile
- High radial strength for circularity and optimal hemodynamics



Low frame height

- Respects the cardiac anatomy

Bovine pericardial tissue

- Leaflet shape optimized for hemodynamics and durability
- Carpentier-Edwards ThermaFix* process intended to reduce the risk of calcification

Outer skirt

- Designed to minimize paravalvular leak

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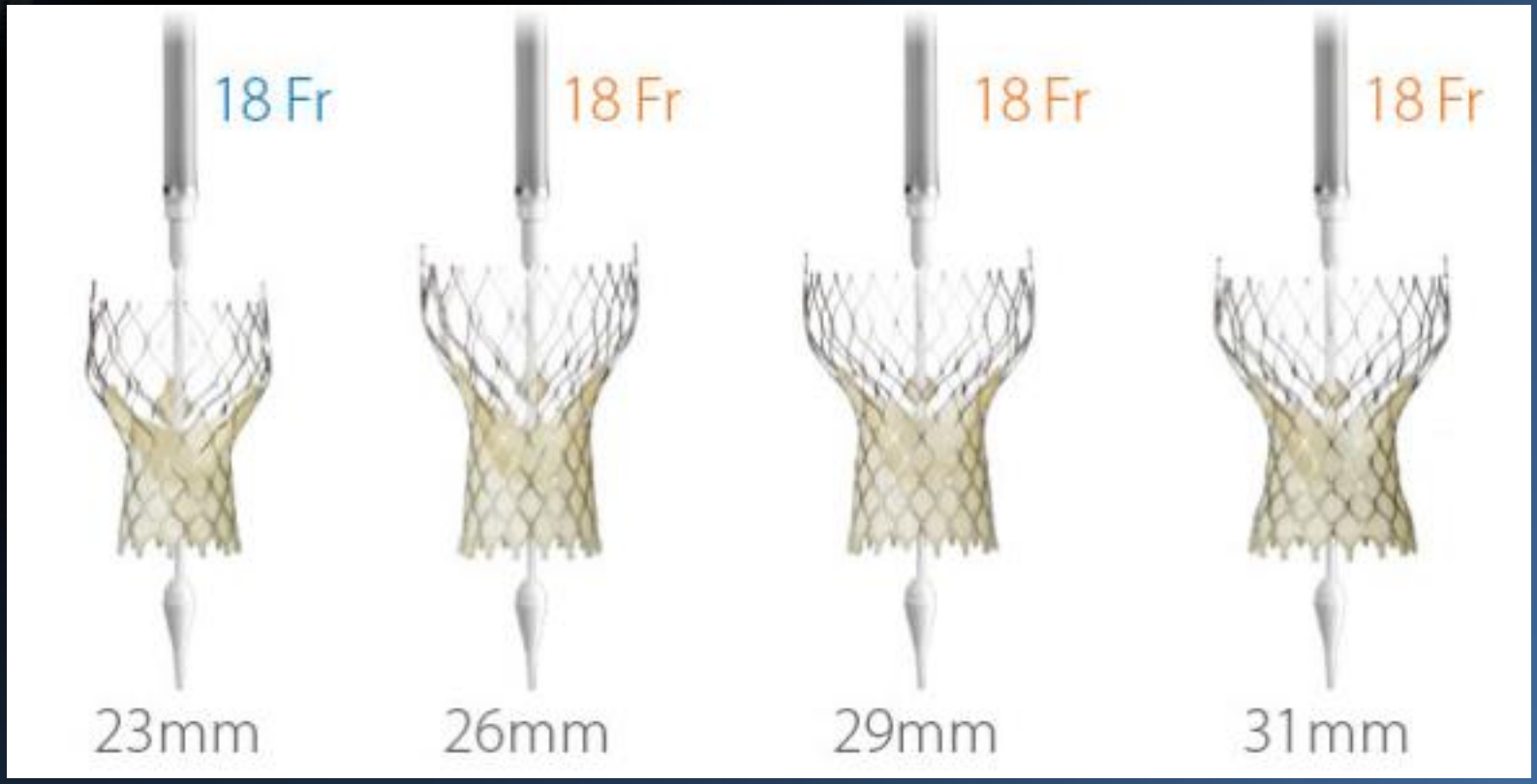
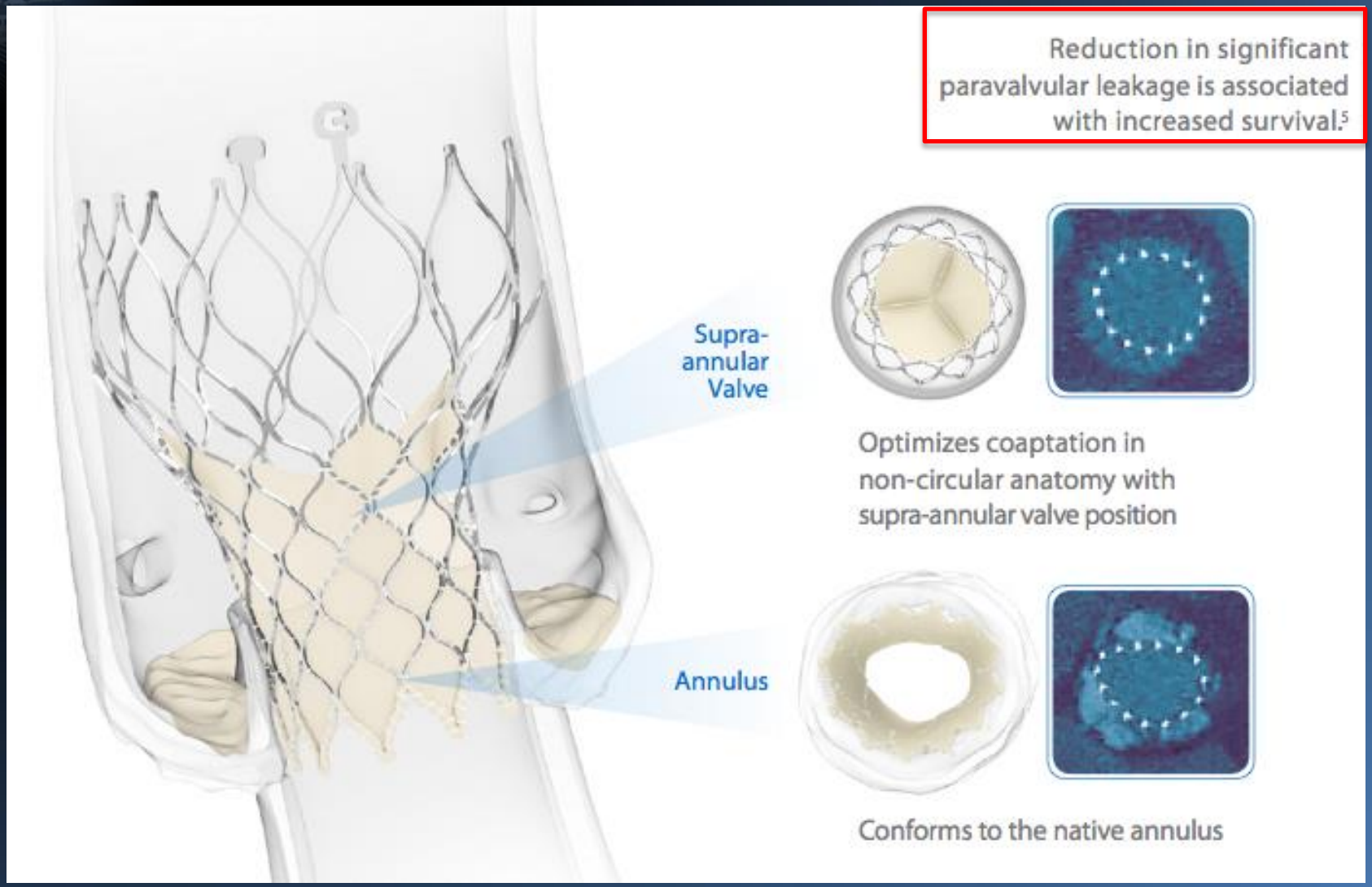
Medtronic CoreValve®
Transcatheter heart valve



18-20 mm	20-23 mm	24-27 mm	27-29 mm

Next generation: Medtronic Evolut™ Transcatheter Heart Valve



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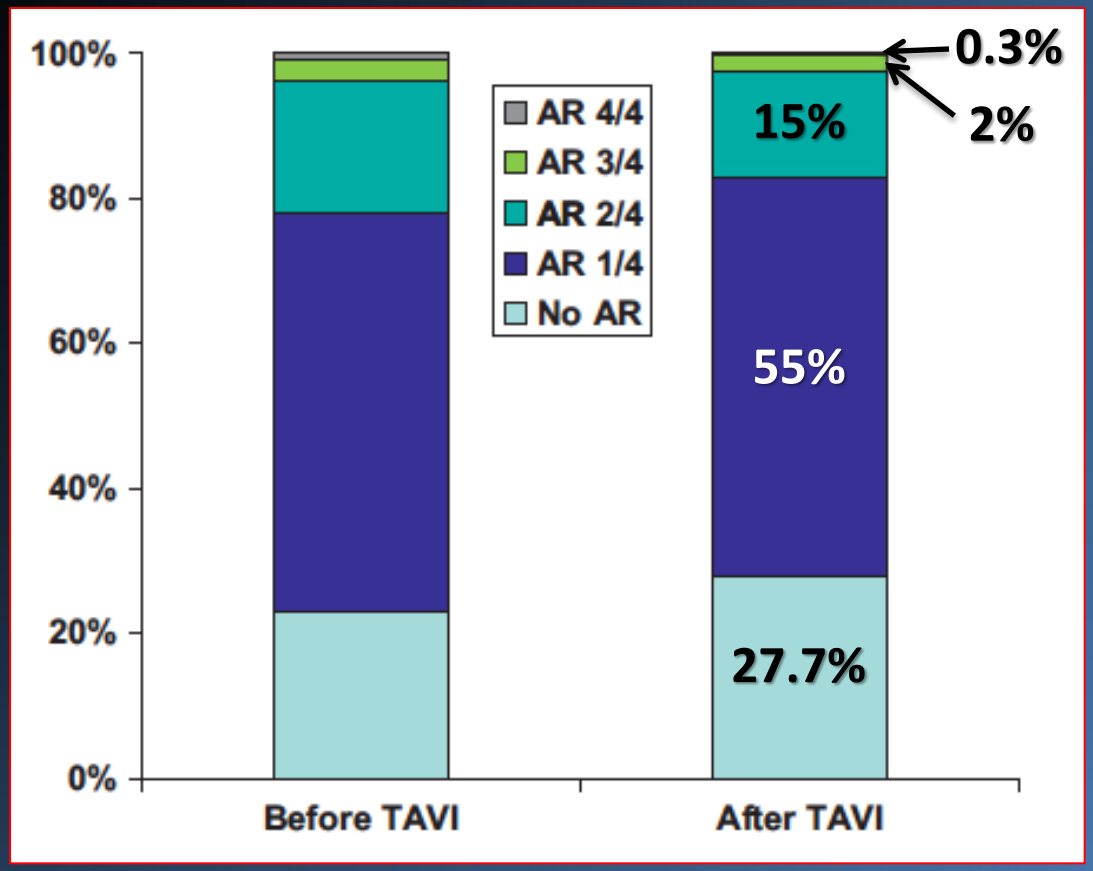
Negative impact of (even mild) paravalvular leaks: The evidence

Para-valvular leaks after TAVI: Incidence and impact on early outcome

Data from 690 patients treated with TAVI / Prospective multicentre German TAVI registry (year 2009)

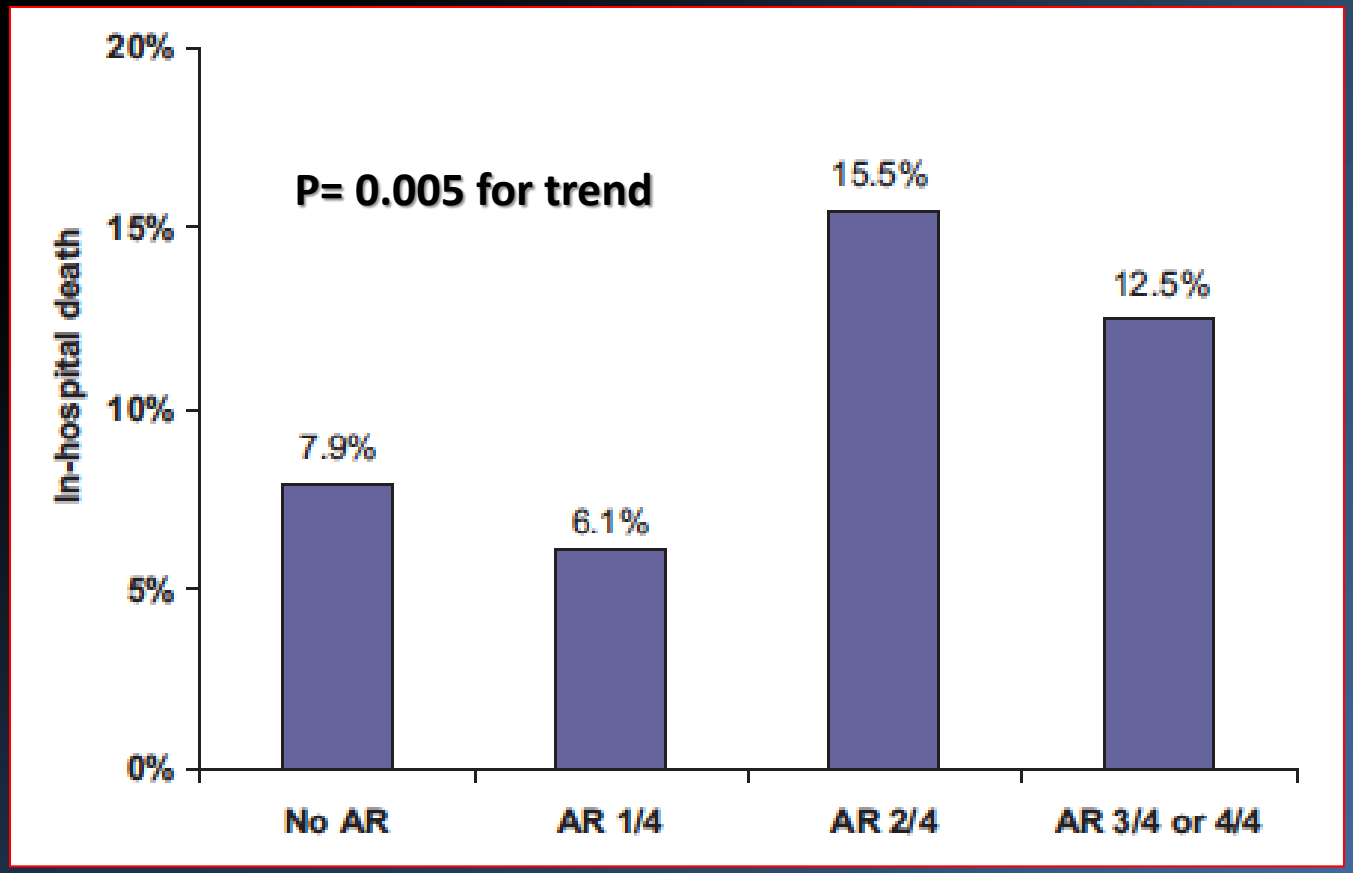
- Age: 81±6 years
- Female gender: 56%
- EuroSCORE: 20±13%
- Medtronic CoreValve: 84%
- Edwards SAPIEN: 16%
- Transfemoral: 92%
- AR assessed by angio +++ after device deployment and removal of catheter/ guidewire



Abdel-Wahab et al. *Circulation*. 2011; 97: 899-906

Para-valvular leaks after TAVI: Incidence and impact on early outcome

Post-procedural AR≥ 2/4 is a strong independent predictor of in-hospital death (adjusted OR: 2.43, 95% CI 1.22 to 4.85)



Abdel-Wahab et al. *Circulation.* 2011; 97: 899-906

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Predictors of early and late mortality after TAVI (Italian registry)

June 2007-December 2009: 663 patients implanted at 14 Italian centers (self-expanding 18-F CoreValve prosthesis)

Age: 81±7 years; Female gender : 56%; EuroSCORE: 23±13%; Transfemoral: 90%; 30-day mortality: 5,4%

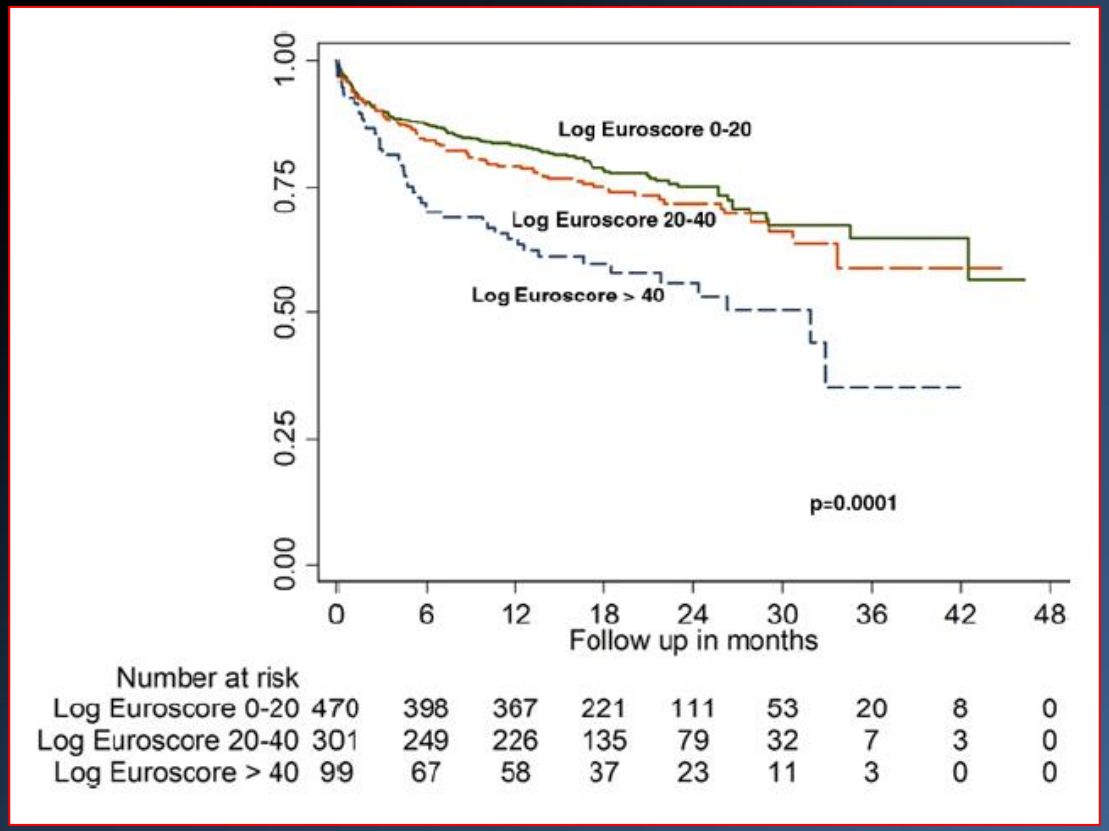
	Odds Ratio	95% LCL	95% UCL	*P* Value
Early mortality				
Conversion to open heart surgery	38.68	2.86	522.59	0.006
Cardiac tamponade	10.97	1.59	75.61	0.02
Major access site complications	8.47	1.67	42.82	0.01
Left ventricular ejection fraction <40%	3.51	1.62	7.62	0.002
Prior balloon aortic valvuloplasty	2.87	1.24	6.65	0.01
Diabetes mellitus	2.66	1.26	5.65	0.01
	Hazard Ratio	**95% LCL**	**95% UCL**	***P* Value**
Late mortality				
Prior stroke	5.468	1.47	20.39	0.01
Post-procedural paravalvular leak ≥2+	3.785	1.57	9.10	0.003
Prior acute pulmonary edema	2.696	1.09	6.68	0.03
Chronic kidney disease	2.532	1.01	6.35	0.048

LCL indicates lower confidence limit; UCL indicates upper confidence limit.

Tamburino et al. *Circulation*. 2011; 123: 299-308

Long-term outcome after TAVI : the UK-TAVI Registry

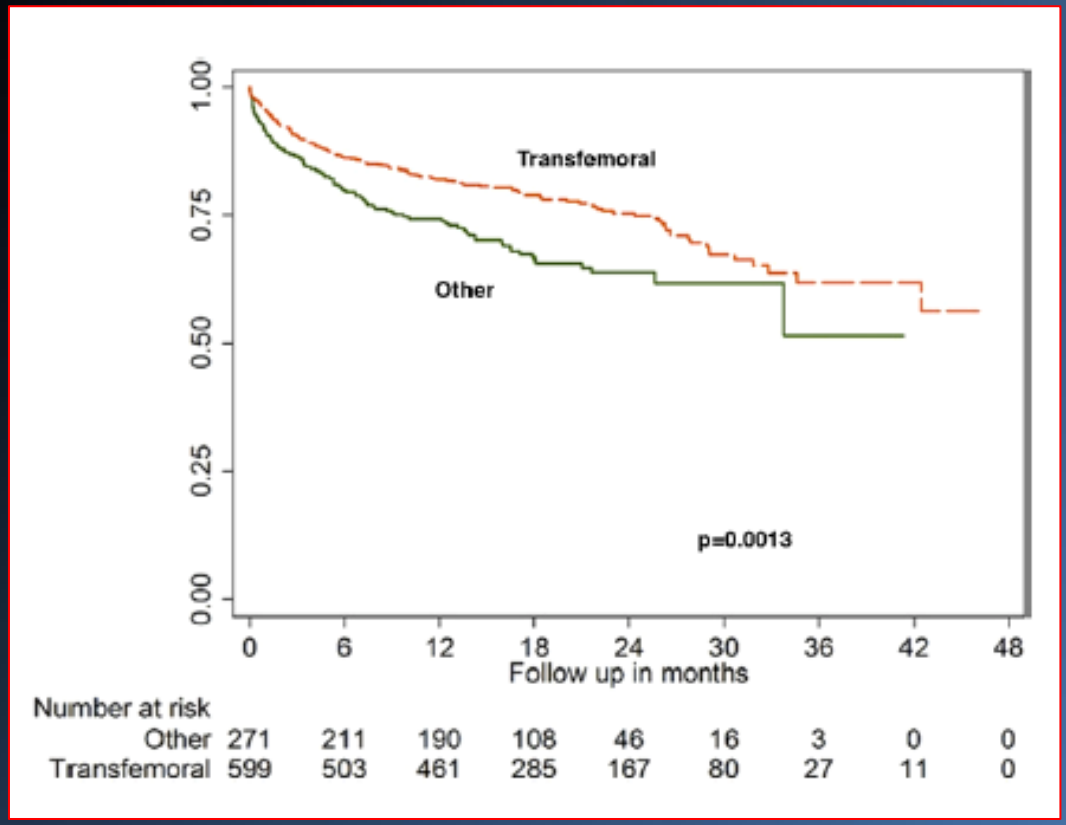
- Prospective registry: 870 patients from 25 centers from England and Wales
- Age: 82±7 years, 52% males, median EuroSCORE: 19% (12-28%)
- Complete/ valid data : 98.5% (30-D outcomes); 100% (mortality tracking)



Moat et al. *J Am Coll Cardiol.* 2011; 58: 2130-8

Long-term outcome after TAVI : the UK-TAVI Registry

- Edwards/ CoreValve: 410/452
- Transfemoral: N= 599
- Transapical/ Subclavian: N= 271
- 30-day mortality: 7%
- Stroke: 4.1%
- Myocardial infarction: 1.3%



Predictors of 1-year mortality: AR> 2/4: HR: 1.7 (1.1-2.5, p=0.016);
LVEF< 50%: HR: 1.5 (1.03-2.16, p=0.03) and COPD: HR: 1.4 (1.00-1.98, p=0.05)

Moat et al. *J Am Coll Cardiol.* 2011; 58: 2130-8

PARTNER-A / High-risk patients : TAVI versus surgical AVR

Mortality at 30 days: 3% (TAVI) vs. 7% (surgery), p= 0,07.
Overestimated by both STS: 12±4 (x2) and EuroSCORE: 29±16% (x4)

Clinical outcome at 1 year	TAVI (n= 348)	Surgical AVR (n= 351)	P value
Death from any cause, n (%)	84 (24)	89 (27)	0,44
Cardiovascular death, n (%)	47 (14)	40 (13)	0,63
Death/ Repeat Hosp., n (%)	120 (35)	119 (36)	0,73
Stroke or TIA, n (%)	27 (8)	13 (4)	0,04
Major stroke, n (%)	17 (5)	8 (2)	0,07
Death/ major stroke, n (%)	92 (27)	93 (28)	0,68

Smith et al. *N Engl J Med.* 2011; 364: 2187-98

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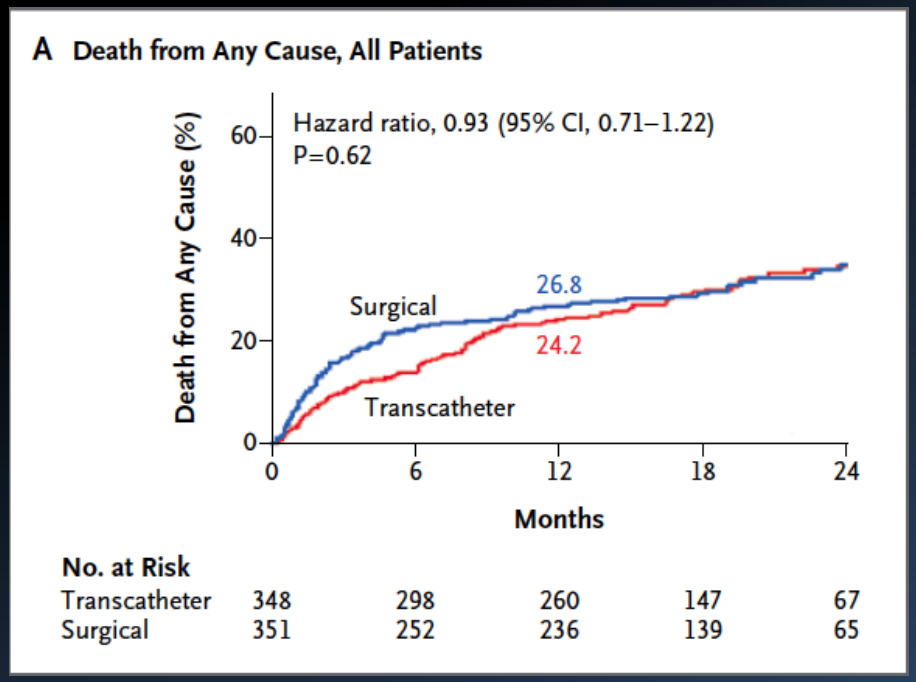
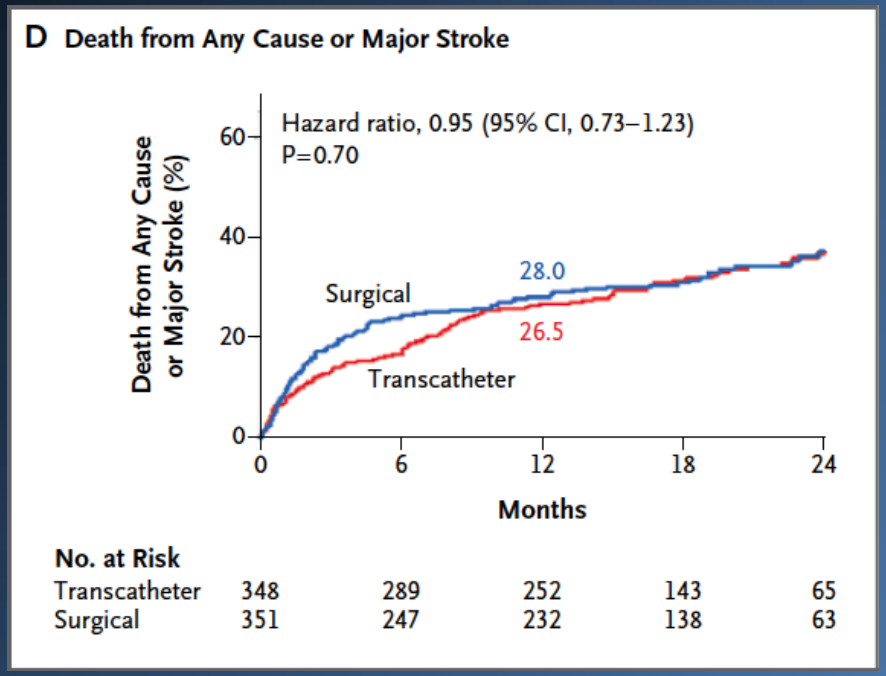
High-risk patients: no difference in 1-year outcome after TAVI or surgical AVR

TAVI: At what price?

The approximate doubling in the rate of neurologic events (including major strokes) after TAVI as compared with surgery remains a concern.





Smith et al. *N Engl J Med.* 2011; 364: 2187-98

Lazar HL. *N Engl J Med.* 2011; 364: 1667-8

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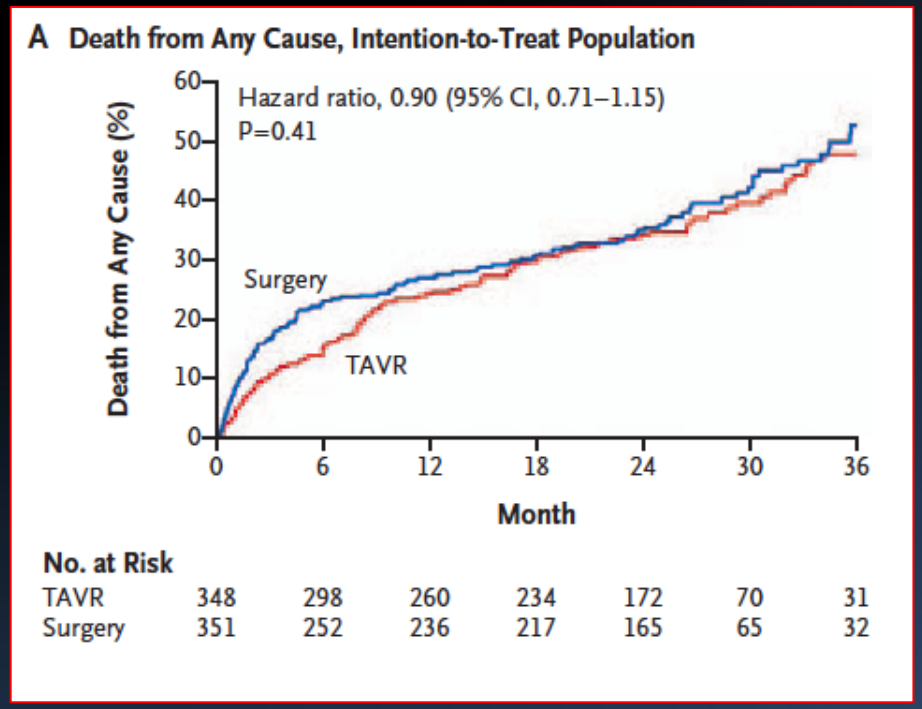
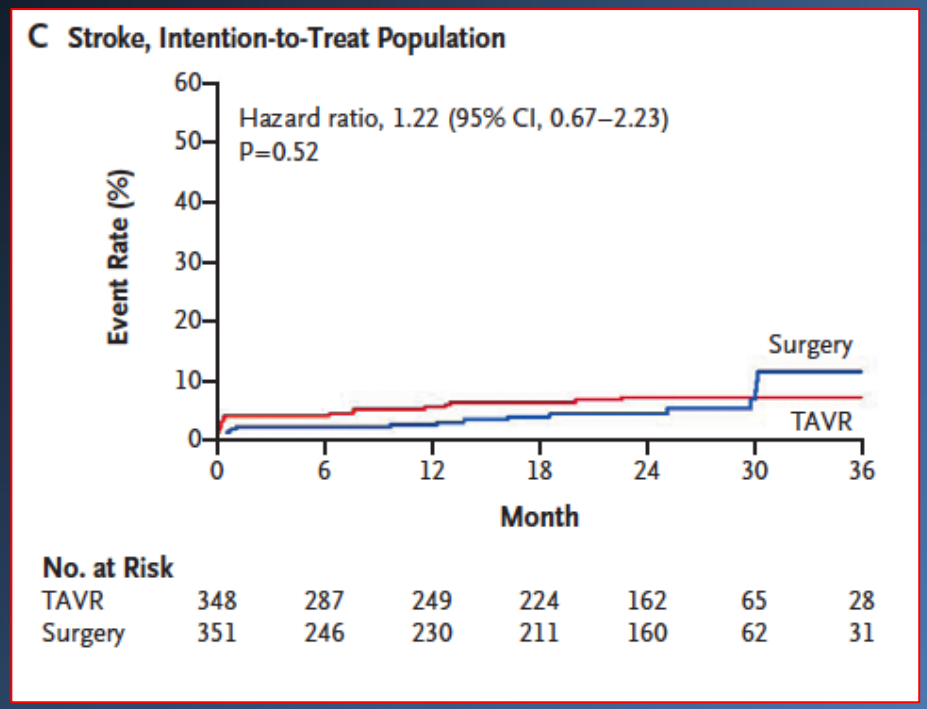
Two-year outcomes after TAVI or surgical aortic valve replacement (PARTNER-A)

- After 2 years, the rates of death from any cause were similar between groups: 34% for TAVI versus 35% for surgery (P = 0.78).
- The frequency of all strokes after 2 years did not differ significantly between the groups (hazard ratio, 1.22; 95% CI, 0.67 to 2.23; p = 0.52).





Kodali et al. *N Engl J Med.* 2012; 366: 1686-95

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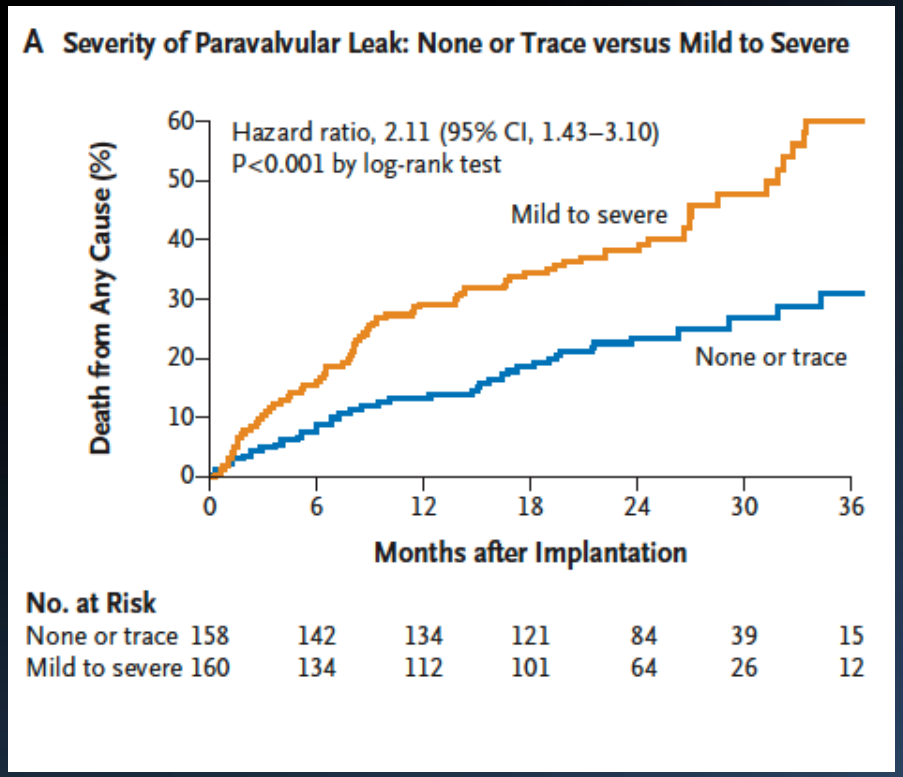
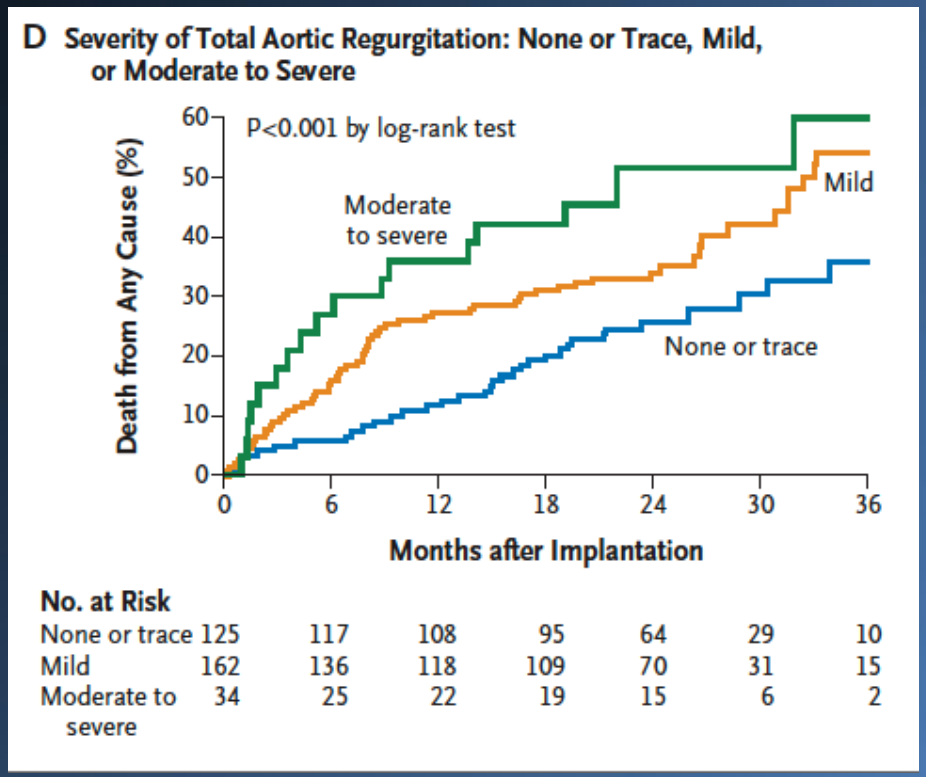
Two-year outcomes after TAVI or surgical aortic valve replacement (PARTNER-A)

- Para-valvular AR was more frequent after TAVI (P<0.001)
- Even mild para-valvular AR was associated with increased late mortality (P<0.001)





Kodali et al. *N Engl J Med.* 2012; 366: 1686-95

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More evidence: The meta analysis

Meta Analysis: Incidence, predictors and outcome of aortic regurgitation after TAVI

- 45 studies, 12 926 patients
- Edwards SAPIEN: n= 7 279
- Medtronic CoreValve: n=5 261
- Pooled estimate for moderate/severe AR = 11.7% (95% CI: 9.6 to 14.1).
- Moderate/severe AR was more common with the CoreValve: 16.0% vs. 9.1%, p 0.005.

Table 1 Selected Studies on the Incidence of AR Post-TAVR

First Author (Ref. #)	Center	Year	n	Approach	Valve	Follow-Up
Rodés-Cabau et al. (3)	Canada (multicenter)	March 2010	339	TF/TA	ES	1 yr
Tamburino et al. (4)	Italy (multicenter)	January 2011	663	TF/SC	MC	1 yr
Moat et al. (5)	UK (multicenter)	November 2011	870	TF/TA	ES/MC	2 yrs
Kodali et al. (10)	USA	March 2012	348	TF/TA	ES	2 yrs
Lemos et al. (14)	Sao Paulo, Brazil	May 2012	79		MC	1 yr
Sinning et al. (15)	Bonn, Germany	March 2012	146	TF/SC	MC	1 yr
Fraccaro et al. (16)	Italy (multicenter)	April 2012	384	TF/SC/TA	ES/MC	1 yr
Bagur et al. (Online Ref. 1)	Quebec, Canada	February 2011	100	TA	ES	6 months
Gurvitch et al. (Online Ref. 2)	Vancouver, Canada	May 2011	310	TF/TA	ES	30 days
Lefevre et al. (Online Ref. 3)	International multicenter	January 2011	130	TF/TA	ES	1 yr
Eltchaninoff et al. (Online Ref. 4)	France (multicenter)	September 2010	244	TF/TA	ES/MC	30 days
Attias et al. (Online Ref. 5)	France (multicenter)	April 2010	83	TF	ES/MC	1 yr
Tchetche et al. (Online Ref. 6)	Toulouse, France	January 2010	45	TF	ES/MC	30 days
Hayashida et al. (Online Ref. 7)	Massy, France	February 2012	260	TF/TA/SC	ES/MC	1 yr
Abdel-Wahab et al. (Online Ref. 8)	Germany (multicenter)	March 2011	690	TF/TA/SC/AA	ES/MC	30 days
Unbehaun et al. (Online Ref. 9)	Berlin, Germany	January 2012	358	TA	ES	2 yrs
Conradi et al. (Online Ref. 10)	Hamburg, Germany	January 2012	82	TF/TA	ES	30 days
Lange et al. (Online Ref. 11)	Munich, Germany	January 2012	415	TF/TA/SC/AA	ES/MC	6 months
Leber et al. (Online Ref. 12)	Munich, Germany	December 2011	68	TF	MC	1 yr
Chorianopoulos et al. (Online Ref. 13)	Heidelberg, Germany	April 2012	70	TF	MC	1 yr
Grube et al. (Online Ref. 14)	Siegburg, Germany	December 2008	136	TF/SC/IL	MC	1 yr
Grube et al. (Online Ref. 15)	International multicenter	July 2011	60	TF	MC	30 days
Walther et al. (Online Ref. 16)	Germany (multicenter)	February 2012	299	TA	ES	3 yrs
Stohr et al. (Online Ref. 17)	Aachen, Germany	December 2011	175	TF/TA	MC/ES	30 days
Sherif et al. (Online Ref. 18)	Germany (multicenter)	November 2010	56	TF	MC	30 days
Puls et al. (Online Ref. 19)	Göttingen, Germany	February 2012	180	TF/TA	ES/MC	1 yr
Gotzmann et al. (Online Ref. 20)	Bochum, Germany	August 2011	145	TF/SC	MC	6 months
Amabile et al. (Online Ref. 21)	France and USA	March 2012	126	TF/TA	ES/MC	1 yr
Buchanan et al. (Online Ref. 22)	Milan, Italy	September 2011	305	TF/TA/AX/AA	ES/MC	30 days
D'Onofrio et al. (Online Ref. 23)	Italy (multicenter)	August 2011	504	TA	ES	2 yrs
Ewe et al. (Online Ref. 24)	International multicenter	October 2011	104	TF/TA	ES	30 days
Makkar et al. (Online Ref. 25)	USA	March 2012	179	TF	ES	2 yrs
Munoz-Garcia et al. (Online Ref. 26)	Málaga, Spain	April 2011	141	TF/SC	MC	6 months
Goncalves et al. (Online Ref. 27)	Madrid, Spain	May 2011	74	TF/TA	MC/ES	6 months
Wenaweser et al. (Online Ref. 28)	Bern, Switzerland	November 2011	257	TF/TA/SC	ES/MC	2.5 yrs
Dworakowski et al. (Online Ref. 29)	London, UK	August 2010	151	TF/TA	ES	30 days
Jabbour et al. (Online Ref. 30)	London, UK	November 2011	87	TF	ES/MC	—
Piazza et al. (Online Ref. 31)	International multicenter	August 2008	646	TF	MC	30 days
Buellesfeld et al. (Online Ref. 32)	International multicenter	April 2011	126	TF/SC	MC	2 yrs
Thomas et al. (Online Ref. 33)	International multicenter	April 2010	1,038	TF/TA	ES	1 yr
van der Boon et al. (Online Ref. 34)	Rotterdam, Netherlands	January 2012	230	TF/SC	MC	30 days
Stahli et al. (Online Ref. 36)	Bern, Switzerland	August 2011	130	TF/TA	ES/MC	1 yr
Kodali et al. (Online Ref. 36)	USA	March 2011	55	TF	ES	1 yr
Gilard et al. (Online Ref. 37)	France	May 2012	3,195	TF/SC/TA/TC/AA	ES/MC	1 yr
Wendler et al. (Online Ref. 38)	International multicenter	April 2012	120	TA	ES	1 yr

Athappan et al. *J Am Coll Cardiol.* 2013; 61:1585–95

Meta Analysis: Incidence, predictors and outcome of aortic regurgitation after TAVI

Study name	Hazard ratio	Lower limit	Upper limit	Z-Value	p-Value
Lemos•	4.900	1.367	17.570	2.439	0.015
Hayashida	1.970	1.187	3.271	2.621	0.009
Amabile	1.500	0.329	6.829	0.524	0.600
Sinning	3.890	2.020	7.491	4.063	0.000
Tamburino	3.785	1.572	9.112	2.969	0.003
Fraccaro	2.190	1.023	4.686	2.020	0.043
Kodali	2.110	1.433	3.107	3.783	0.000
Moat	1.490	1.002	2.215	1.971	0.049
Gilard	2.490	1.909	3.248	6.728	0.000
All (N=4791)	2.273	1.840	2.808	7.609	0.000

Statistics for each study

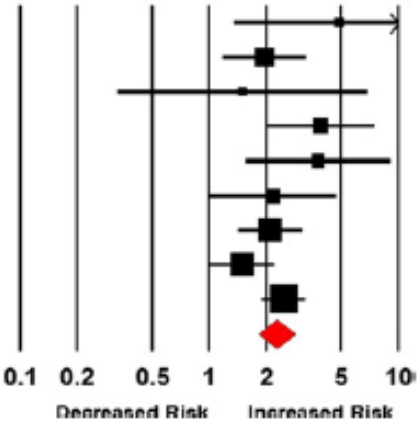

Figure 4 Forest Plot Showing the HRs of Moderate or Severe AR on Overall Mortality

- Moderate/severe AR increased mortality at 30 days: odds ratio: 2.95; 95% CI: 1.73 to 5.02.
- Moderate/severe AR increased mortality at 1 year: odds ratio: 2.27; 95% CI: 1.84 to 2.81.

Athappan et al. *J Am Coll Cardiol.* 2013; 61:1585–95

Meta Analysis: Incidence, predictors and outcome of aortic regurgitation after TAVI

- Mild AR was also associated with an increased hazard ratio for mortality of 1.829 (95% CI: 1.005 to 3.329)

Study name	Hazard ratio	Lower limit	Upper limit	Z-Value	p-Value
Lemos	10.080	1.229	82.673	2.152	0.031
Sinning	2.342	1.066	5.145	2.119	0.034
Kodali	2.110	1.433	3.107	3.782	0.000
Fraccaro	2.064	0.968	4.400	1.876	0.061
Tamburino	0.780	0.499	1.218	-1.092	0.275
All (N=1620)	1.829	1.005	3.329	1.975	0.048

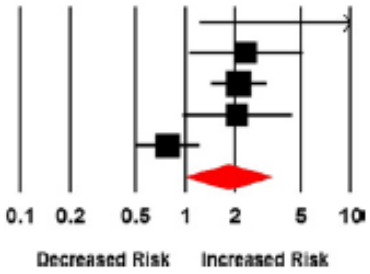

Figure 5 Forest Plot Showing the HRs of Mild AR on Overall Mortality

25 studies reported on predictors of AR post TAVI:

1. Implantation depth
2. valve undersizing
3. Agatston calcium score (r= 0.47, p= 0.001) were identified as predictors.

Athappan et al. *J Am Coll Cardiol.* 2013; 61:1585–95

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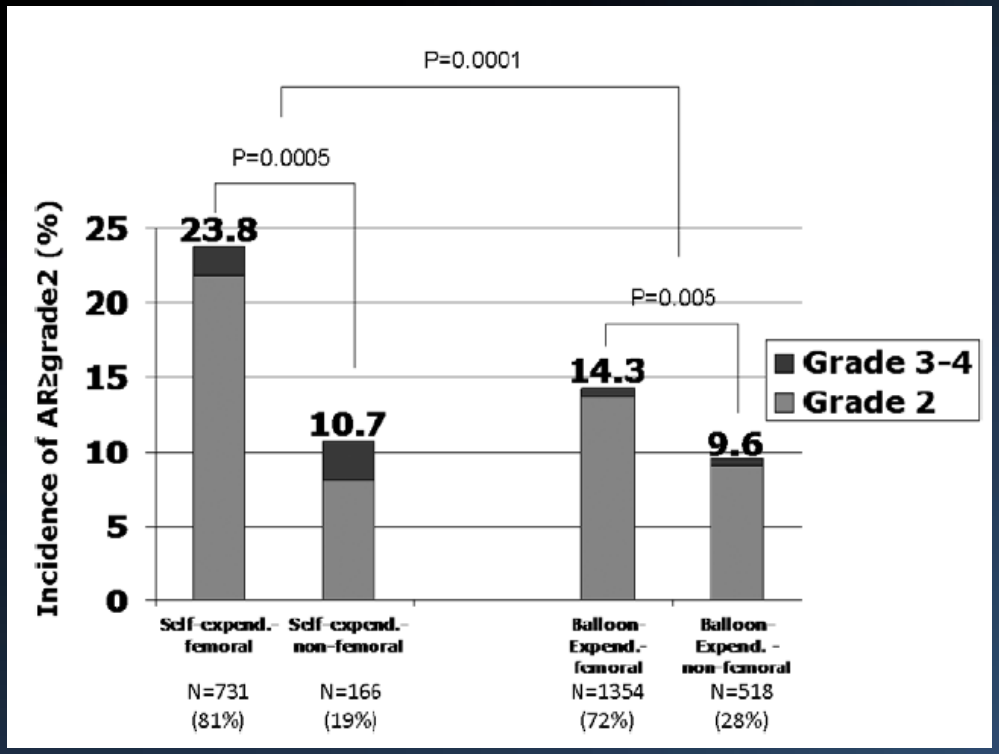
More evidence (2): The largest registry (to date)

Incidence, predictors and outcome of aortic regurgitation after TAVI: FRANCE 2 Registry

- TAVI performed in 3 195 consecutive patients at 34 hospitals in France
- Balloon-expandable (BE) devices in 68% (n=1 872), self-expandable (SE) in 32% (n= 897).
- Delivery was femoral (75%) or non femoral (25%).
- Post implant TTE in 2 769 (92%) patients, Median FU= 306 days (Q1–Q3=178–490).



- Based on TTE, post implant AR ≥grade 2 was present in 16%
- Post implant AR was more frequent with SE (22%) than with BE (13%, *P*=0.0001).

Van Belle et al. *Circulation*. 2014;129:1415-27

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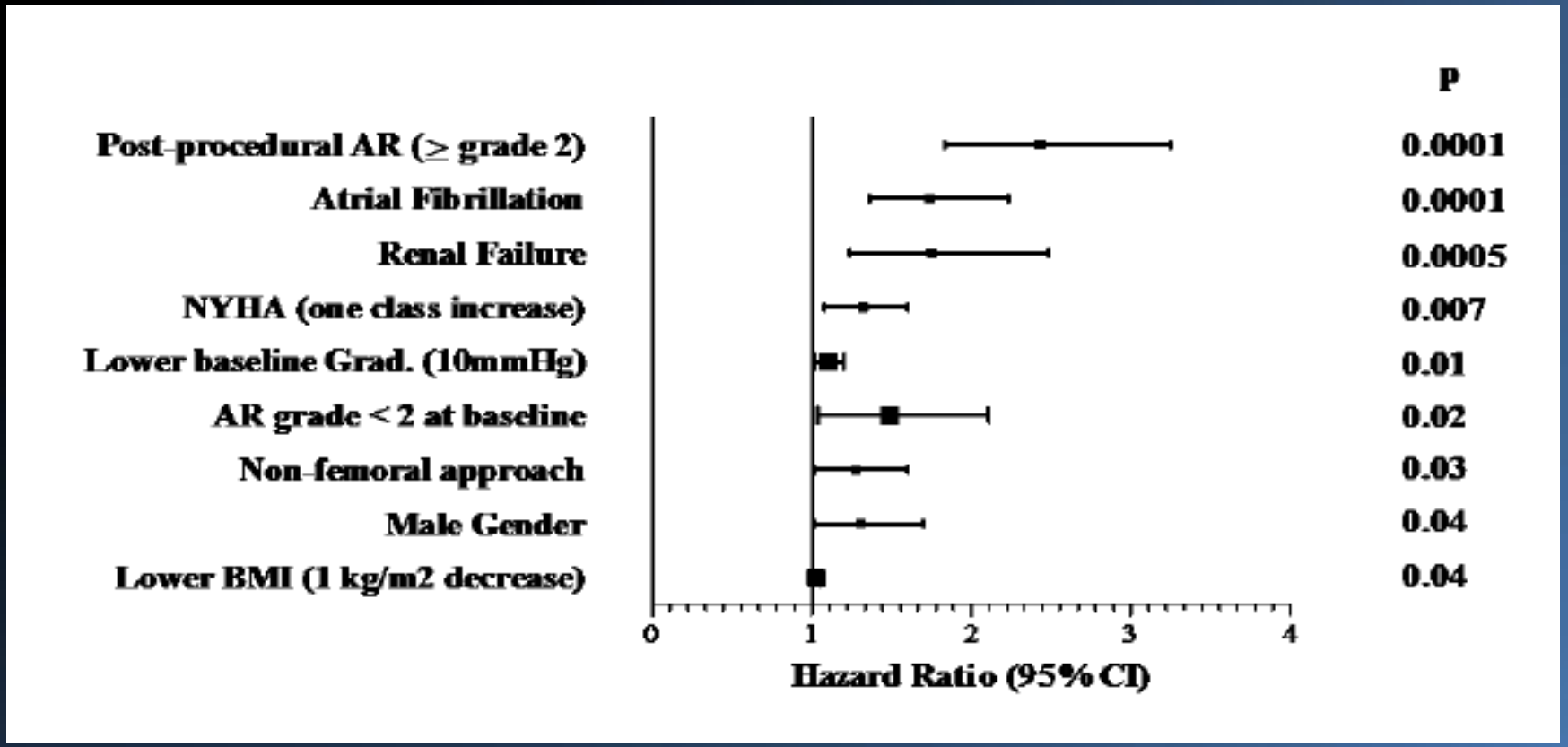
Incidence, predictors and outcome of aortic regurgitation after TAVI: FRANCE2 Registry

A post procedural AR≥ grade 2 was a strong independent predictor of 1-year mortality for BE (HR=2.50; *P*=0.0001) and SE-TAVI (HR=2.11; *P*=0.0001)



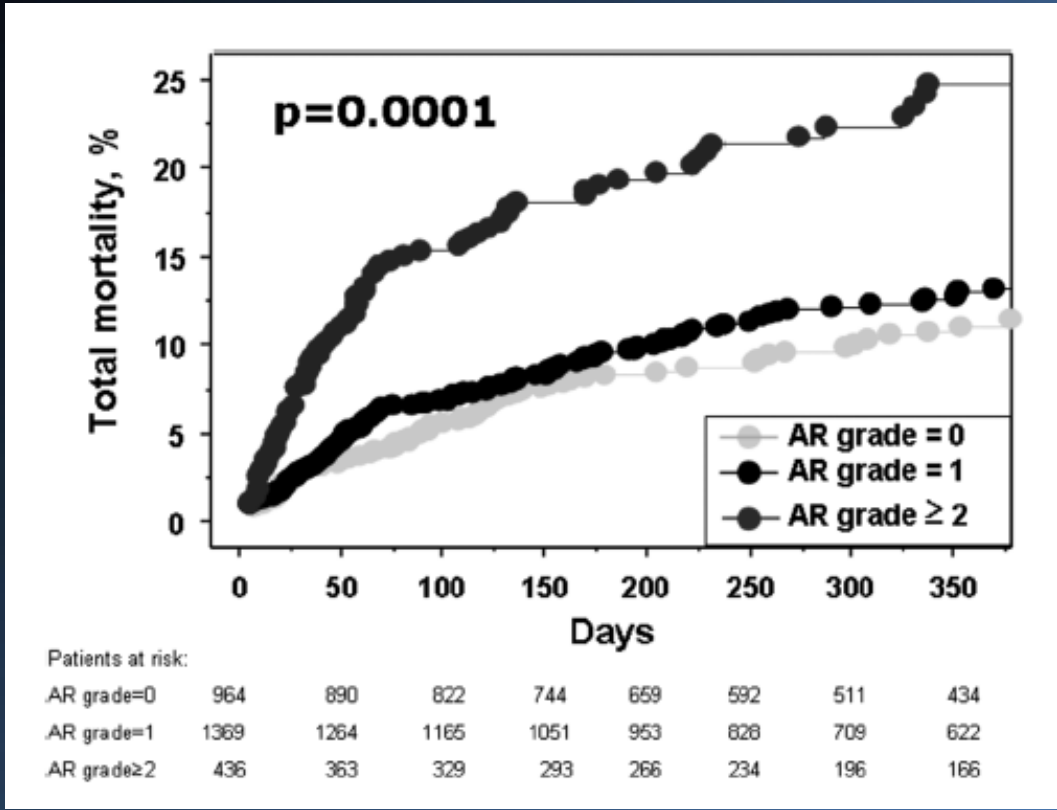
Van Belle et al. *Circulation*. 2014;129:1415-27

Incidence, predictors and outcome of aortic regurgitation after TAVI: FRANCE2 Registry

Post procedural AR≥ grade 2 was well tolerated in patients with an AR grade ≥2 at baseline (1-year mortality=7%)

Post procedural AR≥ grade 2 was associated with a high mortality in other subgroups:

- Renal failure (43%)
- AR<grade 2 at baseline (31%)
- Low transaortic gradient (35%)
- Non femoral delivery (45%).



Van Belle et al. *Circulation*. 2014;129:1415-27

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More evidence (3): The illustrative case

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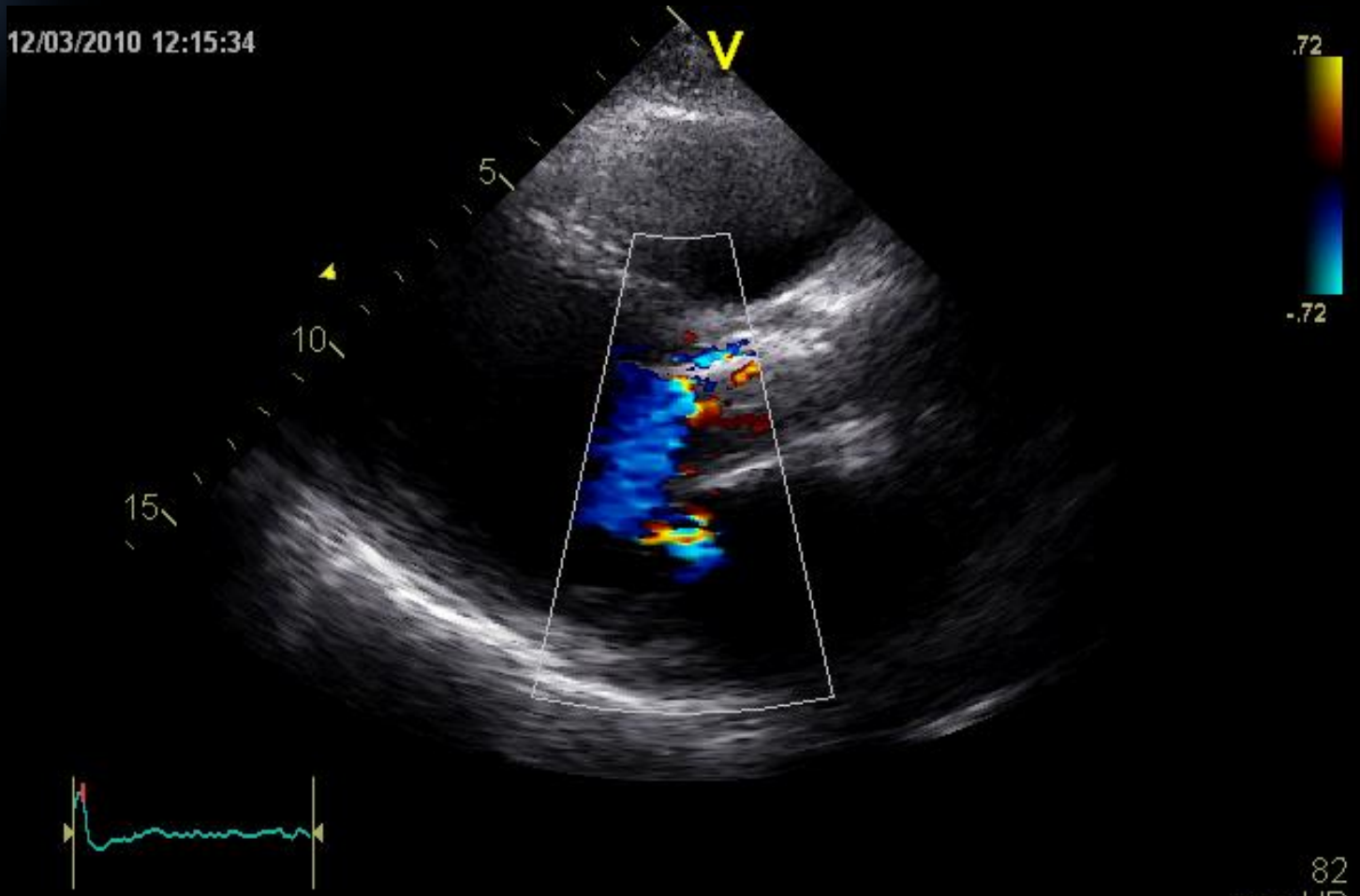
Self-expandable transcatheter valve: anterior para-valvular leak



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What is mild aortic regurgitation? VARC II recommendations

Table 4 VARC II Recommendations for Evaluation of Aortic and/or Paravalvular Regurgitation After TAVR

	Mild	Moderate	Severe
Semiquantitative parameters			
Diastolic flow reversal in the descending aorta—pulsed wave	Absent or brief early diastolic	Intermediate	Prominent, holodiastolic
Circumferential extent of prosthetic valve paravalvular regurgitation (%)*	<10	10–29	≥30
Quantitative parameters†			
Regurgitant volume (ml/beat)	<30	30–59	≥60
Regurgitant fraction (%)	<30	30–49	≥50
Effective regurgitant orifice area (cm^2)	0.10	0.10–0.29	≥0.30

*Not well validated and may overestimate severity compared with quantitative Doppler. †For LVOT >2.5 cm, significant stenosis criteria is <0.20. Adapted with permission from Kappetein et al. (66).
VARC = Valve Academic Research Consortium; other abbreviations as in Table 1.

Généreux et al. *J Am Coll Cardiol.* 2013; 61: 1125–36

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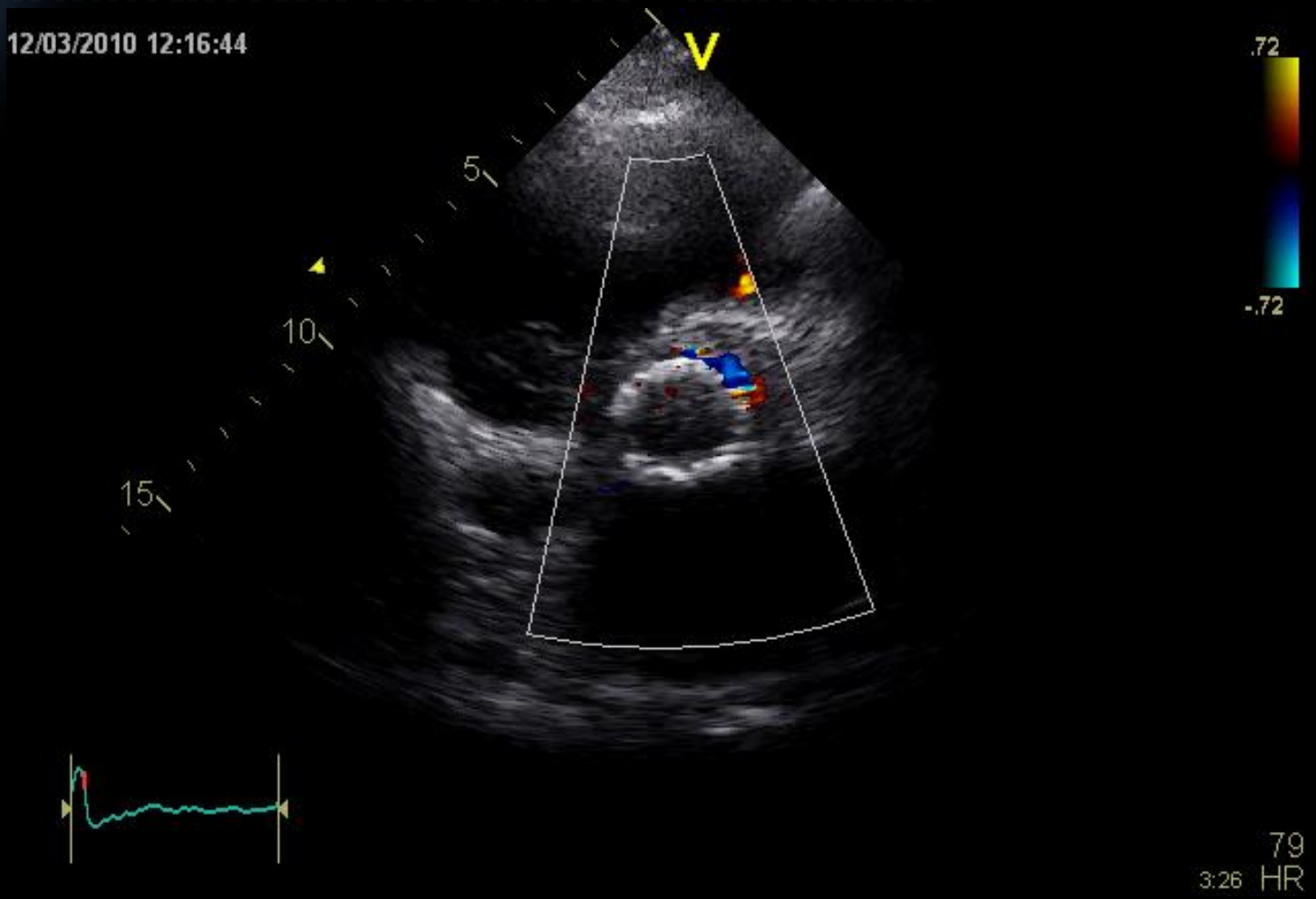
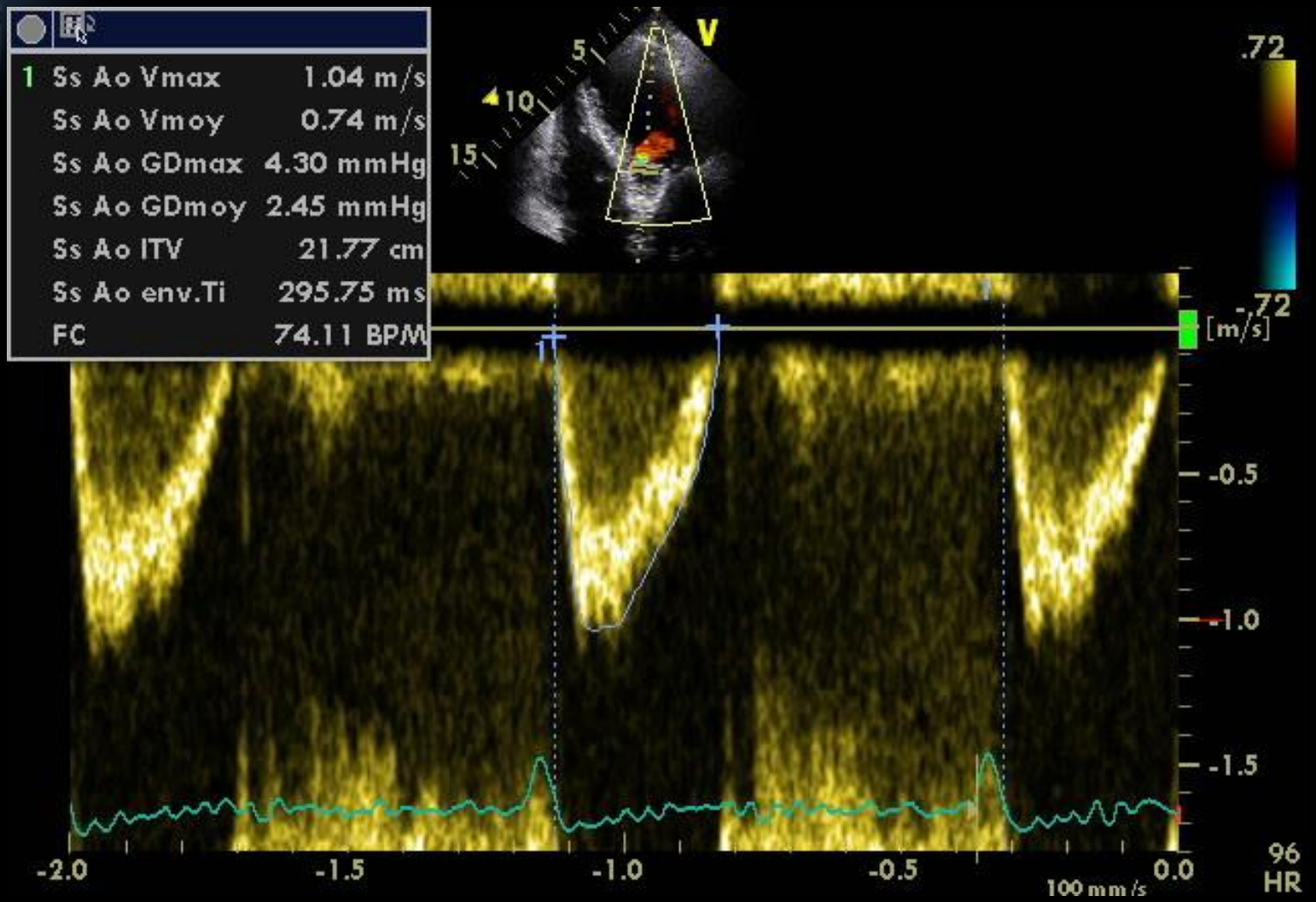
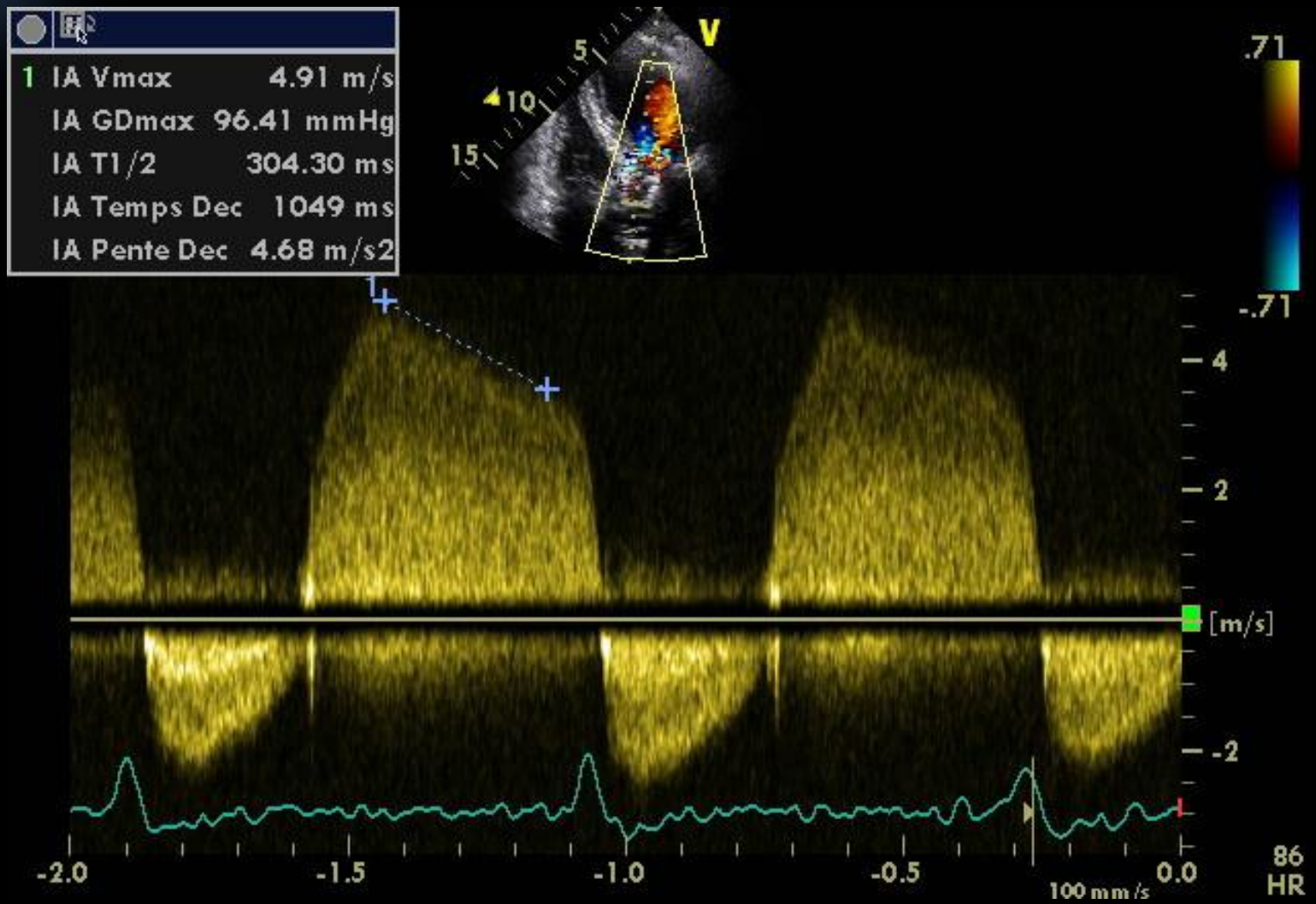
Mild anterior para-valvular leak according to VARC criteria



Cardiac output = 7,5 l/min



Pressure half time is short (300 ms): AR is poorly tolerated



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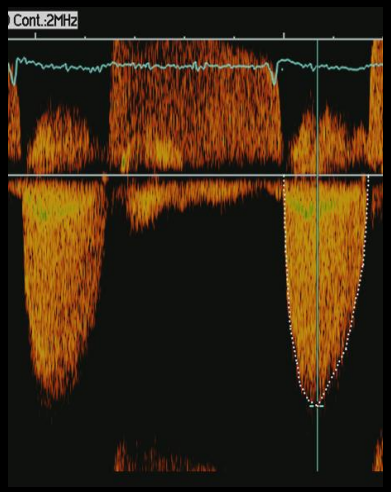
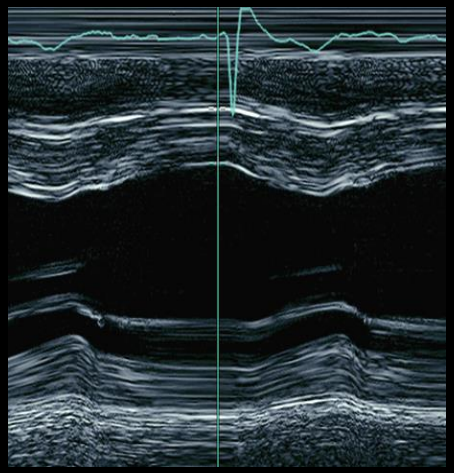
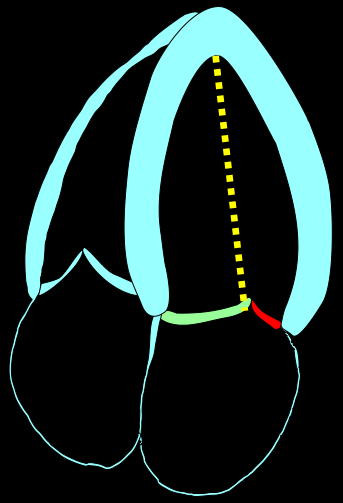
Even mild (acute) AR is poorly tolerated by a small hypertrophied LV

$$\sigma c = (1.35\ P \times LVIDs/2\ Th)\ (1- \{LVIDs^2/L^2\})$$







$P = 4\ (Vmax)^2$ + Systolic AP

LVIDs/ wall thickness (Th)

L = LV systolic length (A4C)

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More evidence (4): The second largest registry

Clinical impact of paravalvular leaks after TAVI: Insights from the PARTNER trials

A total of 2 515 patients underwent TAVI as part of the randomized trial (n=496), RCA registry (n=40), or the NRCA registry (n=1979). 2 434 patients included in this analysis.

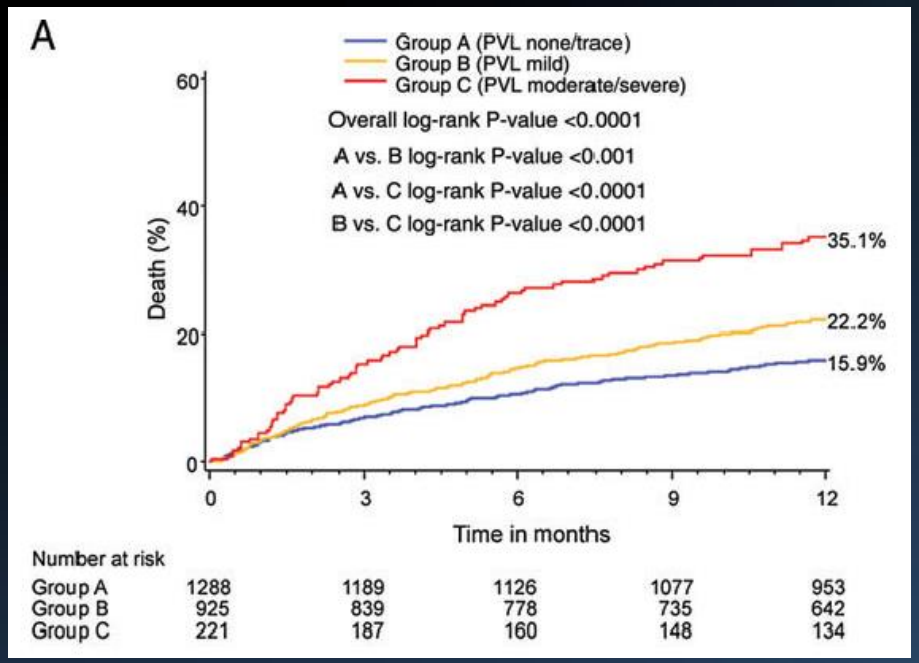
Table I Baseline clinical parameters of patients by severity of paravalvular regurgitation

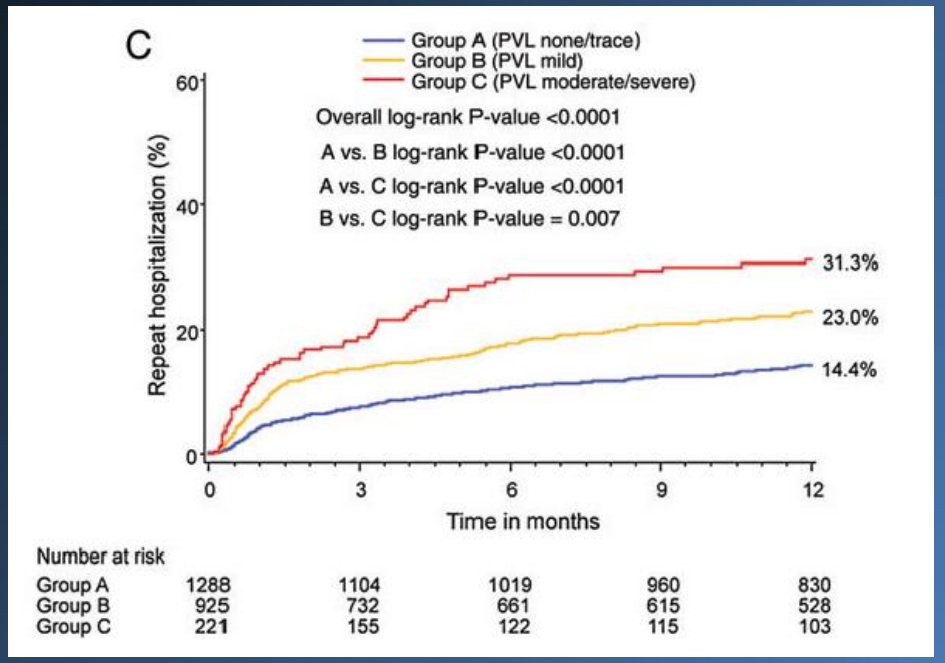
Baseline parameters	Severity of paravalvular regurgitation			*P*-value (all groups)
	None/trace (*n* = 1288)	Mild (*n* = 925)	Moderate/severe (*n* = 221)	
Age	84.17 ± 7.05	84.71 ± 7.22	85.04 ± 7.52	0.10
Male, %	44.3	59.8	70.6	<0.0001
Body surface area	1.78 ± 0.24	1.83 ± 0.25	1.82 ± 0.24	<0.0001
Body mass index	27.17 ± 6.45	26.53 ± 6.09	25.12 ± 5.52	<0.0001
Logistic EuroSCORE	25.74 ± 16.06	26.42 ± 16.24	29.79 ± 17.05	0.004
STS score	11.56 ± 4.32	11.31 ± 3.85	11.10 ± 3.50	0.17
Diabetes, %	37.6	37.8	30.9	0.14
Carotid disease, %	27.1	26.4	17.1	<0.01
Prior coronary artery bypass grafting, %	43.3	41.5	44.5	0.60
Prior balloon aortic Valvuloplasty, %	24.1	23.0	19.6	0.34
Renal disease (Cr ≥ 2), %	14.8	18.3	18.6	0.059
Major arrhythmia, %	46.9	54.7	60.0	<0.0001
Permanent pacemaker, %	20.1	22.4	26.4	0.08
Smoking, %	47.8	50.9	44.5	0.15
Chronic obstructive pulmonary disease, %	43.9	45.6	40.3	0.33
Pulmonary hypertension, %	37.6	38.6	48.0	0.02

Kodali et al. *Eur Heart J*. 2014; doi:10.1093/eurheartj/ehu384

Clinical impact of paravalvular leaks after TAVI: Insights from the PARTNER trials

- At 1 year, there was increased all-cause mortality with worsening PVR: 16% (none/ trace) vs. 22% (mild) vs. 35% (moderate/ severe), P= 0.0001.
- A multivariable analysis indicated that moderate/severe PVR (HR: 2.18, 95% CI: 1.57–3.02, P = 0.0001) or even mild PVR (HR: 1.37, 95% CI: 1.14–1.90, P = 0.012) were associated with higher late mortality.





Kodali et al. *Eur Heart J.* 2014; doi:10.1093/eurheartj/ehu384

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CLINICAL RESEARCH
Valvular heart disease

Paravalvular Regurgitation after Transcatheter Aortic Valve Replacement with the Edwards Sapien Valve in the PARTNER trial: characterizing patients and impact on outcomes

Susheel Kodali[1]*, Philippe Pibarot[2], Pamela S. Douglas[3], Mathew Williams[1], Ke Xu[4], Vinod Thourani[5], Charanjit S. Rihal[6], Alan Zajarias[7], Darshan Doshi[1], Michael Davidson[8], E. Murat Tuzcu[9], William Stewart[9], Neil J. Weissman[10], Lars Svensson[9], Kevin Greason[6], Hersh Maniar[7], Michael Mack[11], Saif Anwaruddin[12], Martin B. Leon[1], and Rebecca T. Hahn[1]

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Conclusions

- The negative impact of moderate/ severe paravalvular leaks after TAVI is widely recognized with a pooled 30-day OR for mortality of 2.95 (95% CI: 1.73 to 5.02) and a 1-year HR of 2.27 (95% CI: 1.84 to 2.89)
- Most studies (including the 2 largest registries to date) demonstrate that even mild AR has a negative impact on long-term outcome.
- In a meta analysis, mild AR was associated with a significant increase in mortality at 1-year: HR of 1.9 (95% CI: 1.09 to 3.45)
- Philippe Pibarot is the second author of one major paper supporting the negative impact of mild AR

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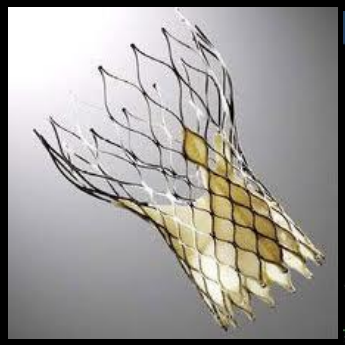

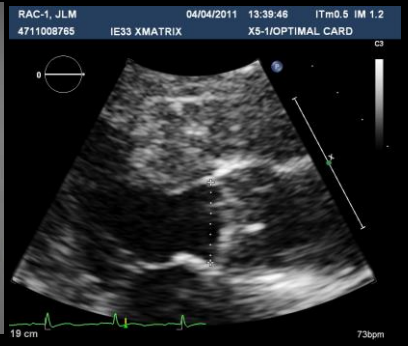

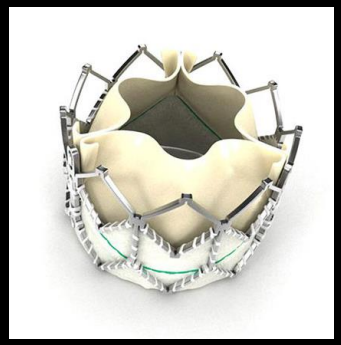

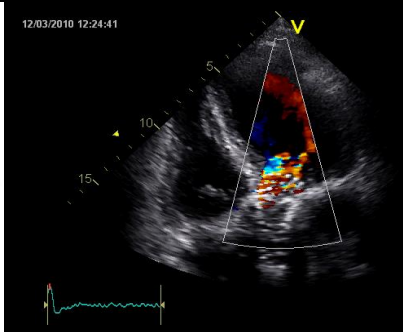

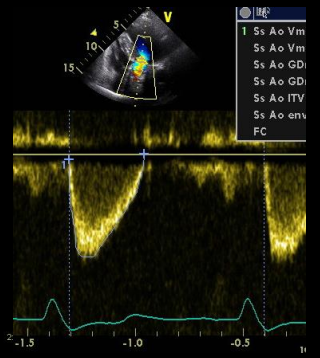

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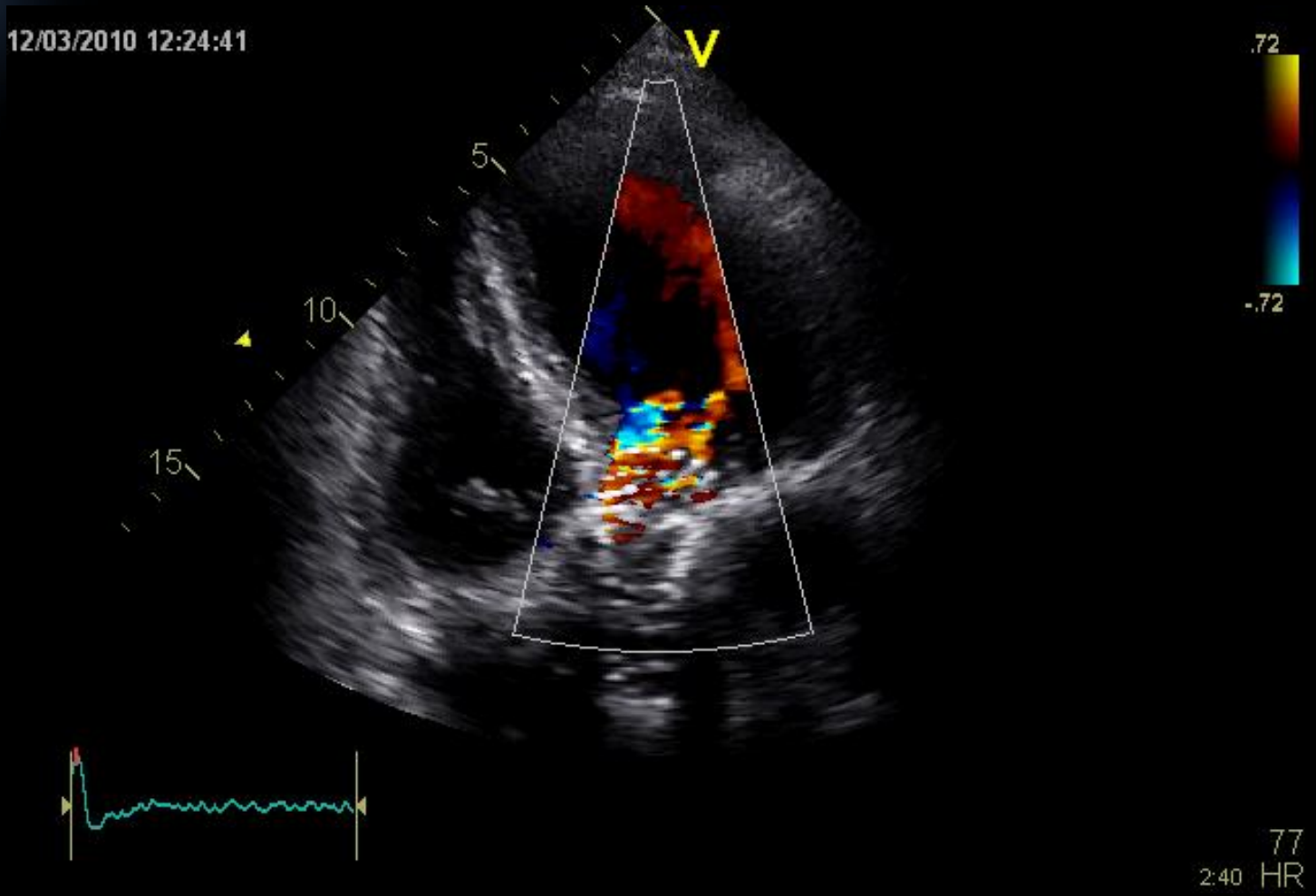
Small/ hypertrophied LV + ACUTE para-valvular leak = poor tolerance



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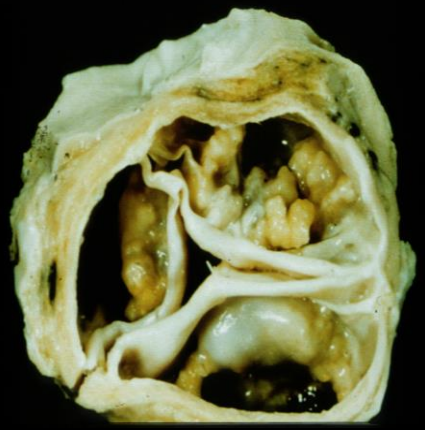
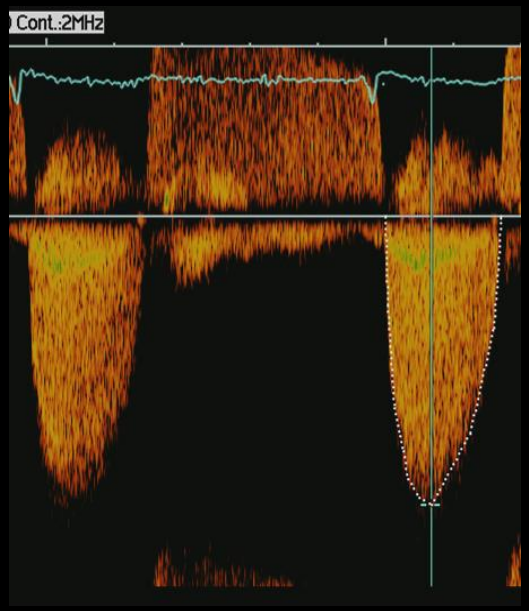
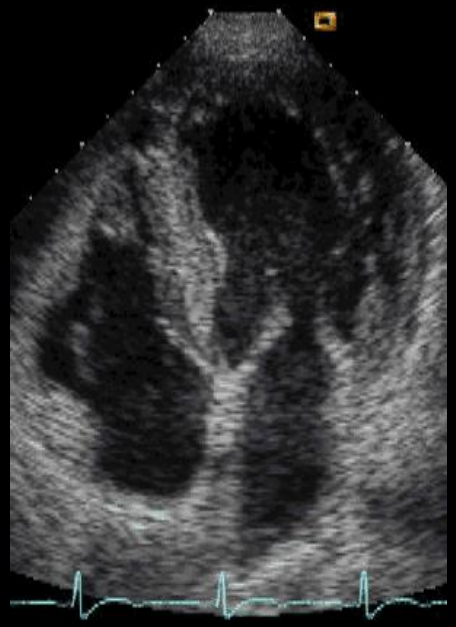
LV Adaptation to progressive AS: Concentric hypertrophy (small cavity)







Progressive AV narrowing

Transaortic pressure gradient

Concentric hypertrophy