Minimizing complications: Paravalvular leak

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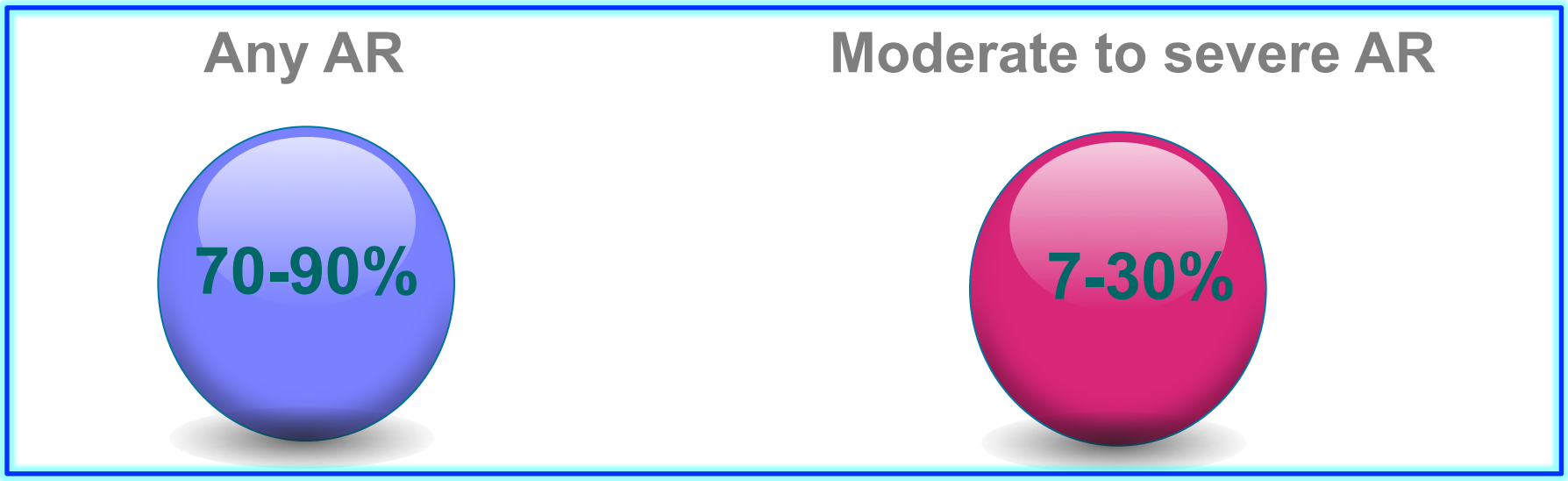
Paravalvular regurgitation: an integrated approach

- Introduction
- AR mechanism and predictors
- Evaluation and follow-up
- Upcoming improvements
- Conclusion

Paravalvular regurgitation: an integrated approach

- **Paravalvular AR is common after TAVI**
- **Moderate or severe paravalvular AR is more common after TAVR than after surgical replacement**



Kodali et al. N Engl J Med. 2012; Leon et al. N Engl J Med 2010 ; Gilard M et al. N Engl J Med. 2012

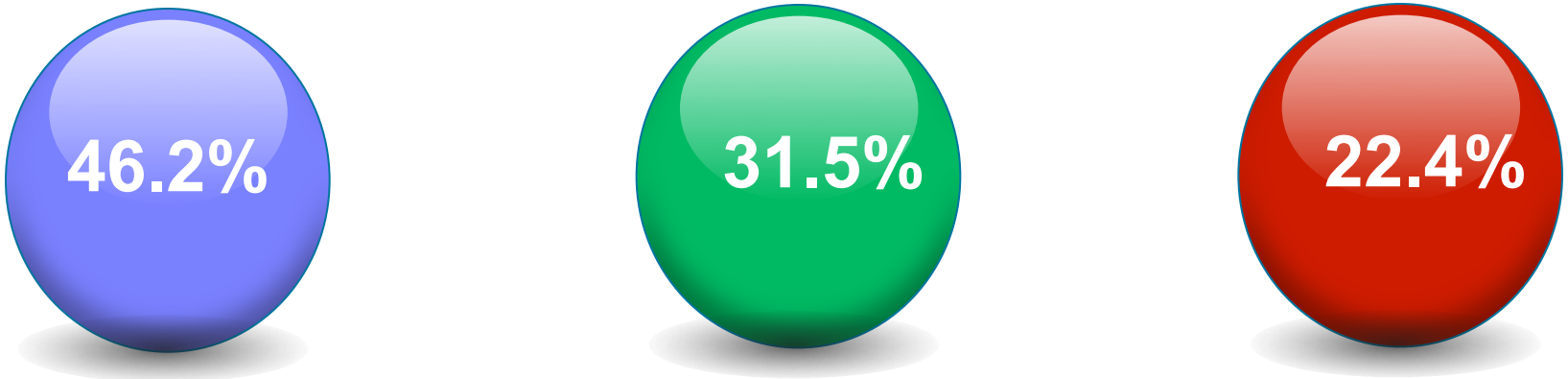
Zahn R et al. Heart J 2011; Webb JG, et al. Circulation 2009; Abdel-Wahab M, et al. Heart 2011

Paravalvular regurgitation: an integrated approach

The NEW ENGLAND JOURNAL of MEDICINE

Partner trial

AR Evolution at 2 years follow-up



Unchanged **Improved** **Worse**

Kodali et al. N Engl J Med. 2012

Long-Term Outcomes After Transcatheter Aortic Valve Implantation in High-Risk Patients With Severe Aortic Stenosis

The U.K. TAVI (United Kingdom Transcatheter Aortic Valve Implantation) Registry

Mortality

Predictors of Mortality at 1 Year

870 patients

Variables	Multivariate Model	p Value
Edwards SAPIEN		
Medtronic CoreValve		
Route, other		
Route, transfemoral	0.73 (0.52–1.04)	0.08
AR moderate/severe	1.66 (1.10–2.51)	0.016
Major vascular complication		
Permanent pacemaker		
Male		
Age, yrs		
AV gradient		
LVEF ≥50%	1.00	
LVEF 30%–49%	1.49 (1.03–2.16)	0.03
LVEF <30%	1.65 (0.98–2.79)	0.06
NYHA functional class I/II		
NYHA functional class III/IV		
Coronary disease	1.23 (0.88–1.73)	0.23
Any previous cardiac surgery		
PVD		
Diabetes mellitus		
COPD	1.41 (1.00–1.98)	0.05
Creatinine >200 mmol/l	1.55 (0.90–2.68)	0.11

AR 1.66 (1.10–2.51)

Similar results at one year follow-up from the French registry Italian registry

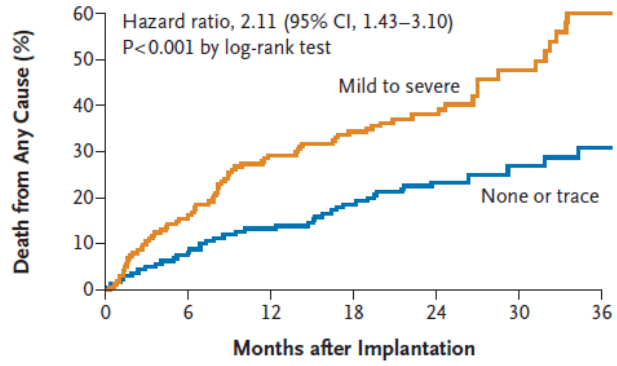
Tamburino, C. *et al Circulation* 2011
Eltchaninoff, H. *Eur. Heart J.* 2011

Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement

The NEW ENGLAND JOURNAL of MEDICINE

Partner trial

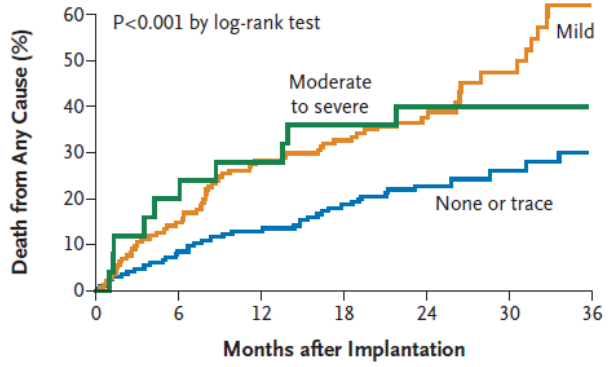
A Severity of Paravalvular Leak: None or Trace versus Mild to Severe



No. at Risk

None or trace	158	142	134	121	84	39	15
Mild to severe	160	134	112	101	64	26	12

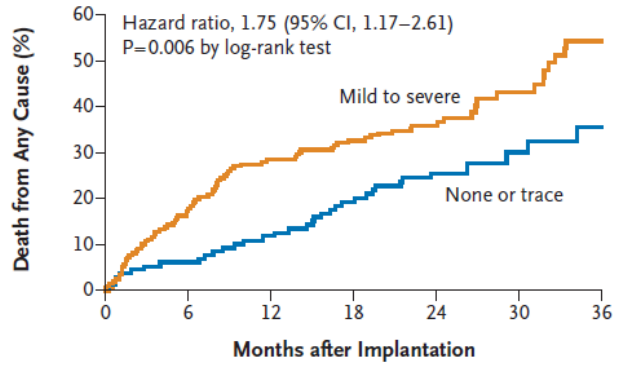
B Severity of Paravalvular Leak: None or Trace, Mild, or Moderate to Severe



No. at Risk

None or trace	158	142	134	121	84	39	15
Mild	136	115	95	86	51	21	10
Moderate to severe	24	19	17	15	13	5	2

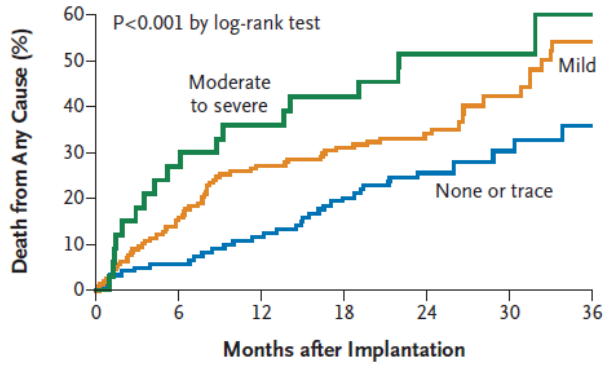
C Severity of Total Aortic Regurgitation: None or Trace versus Mild to Severe



No. at Risk

None or trace	125	117	108	95	64	29	10
Mild to severe	196	161	140	128	85	37	17

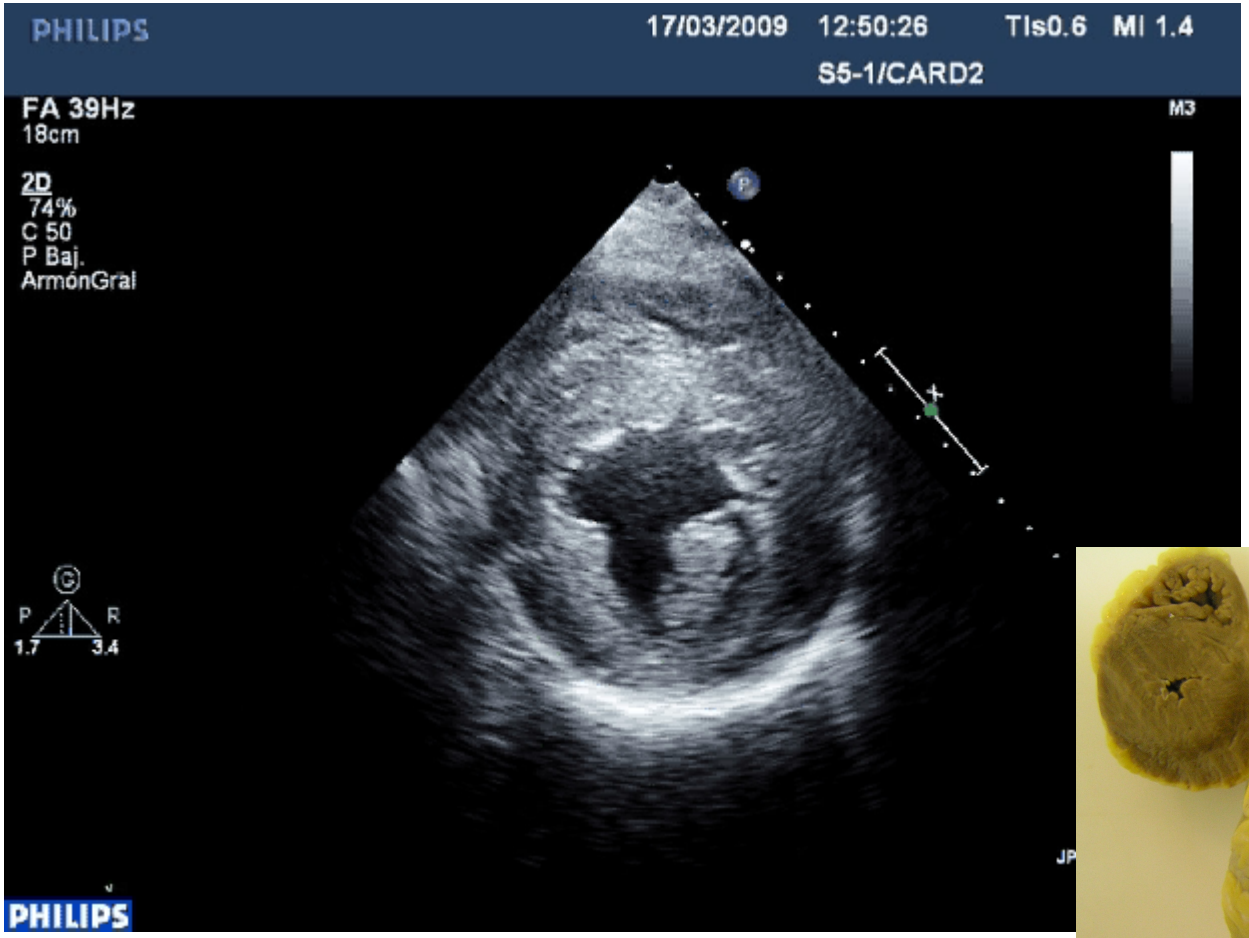
D Severity of Total Aortic Regurgitation: None or Trace, Mild, or Moderate to Severe



No. at Risk

None or trace	125	117	108	95	64	29	10
Mild	162	136	118	109	70	31	15
Moderate to severe	34	25	22	19	15	6	2

Paravalvular regurgitation: The LVH response¡

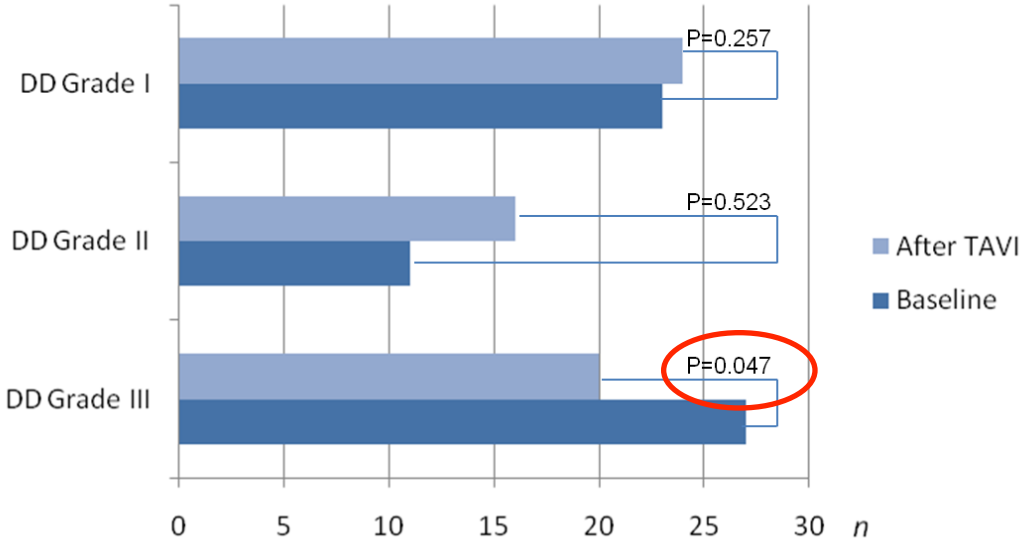


European Journal of Echocardiography

Acute left ventricle diastolic function improvement after transcatheter aortic valve implantation

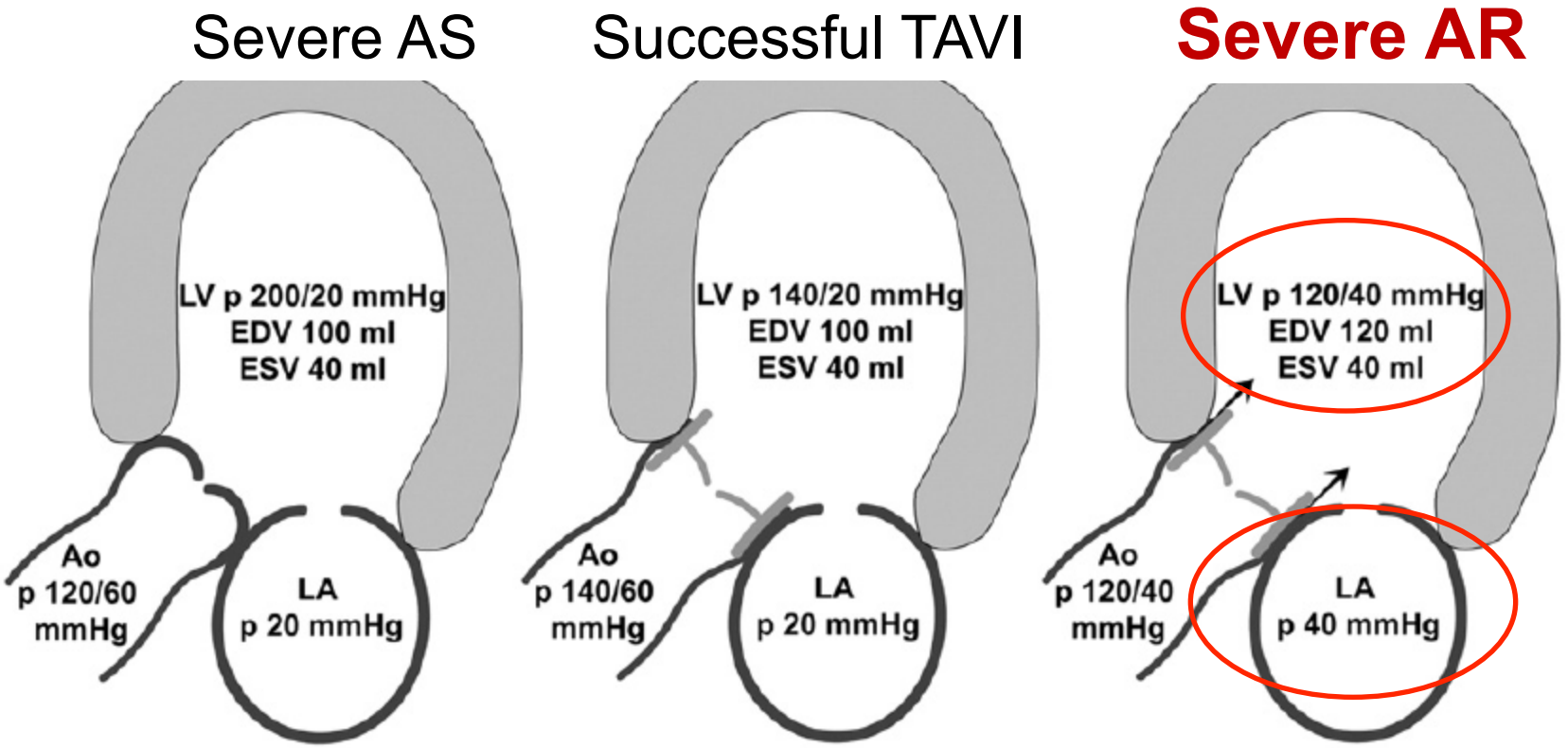
Alexandra Gonçalves[1,2], Pedro Marcos-Alberca[1], Carlos Almeria[1], Gisela Feltes[1], Enrique Rodríguez[1], Rosa Ana Hernández-Antolín[1], Eulogio Garcia[1], Luis Maroto[1], Cristina Fernandez Perez[3], José C. Silva Cardoso[2], Carlos Macaya[1], and José Luis Zamorano[1]*

- 61 patients with preserved LV systolic function submitted to successful TAVI.
- Parameters of diastolic function were evaluated before and minutes after TAVI.



This is the first study describing LV diastolic performance during TAVI.
Immediate improvement in diastolic function parameters was described.

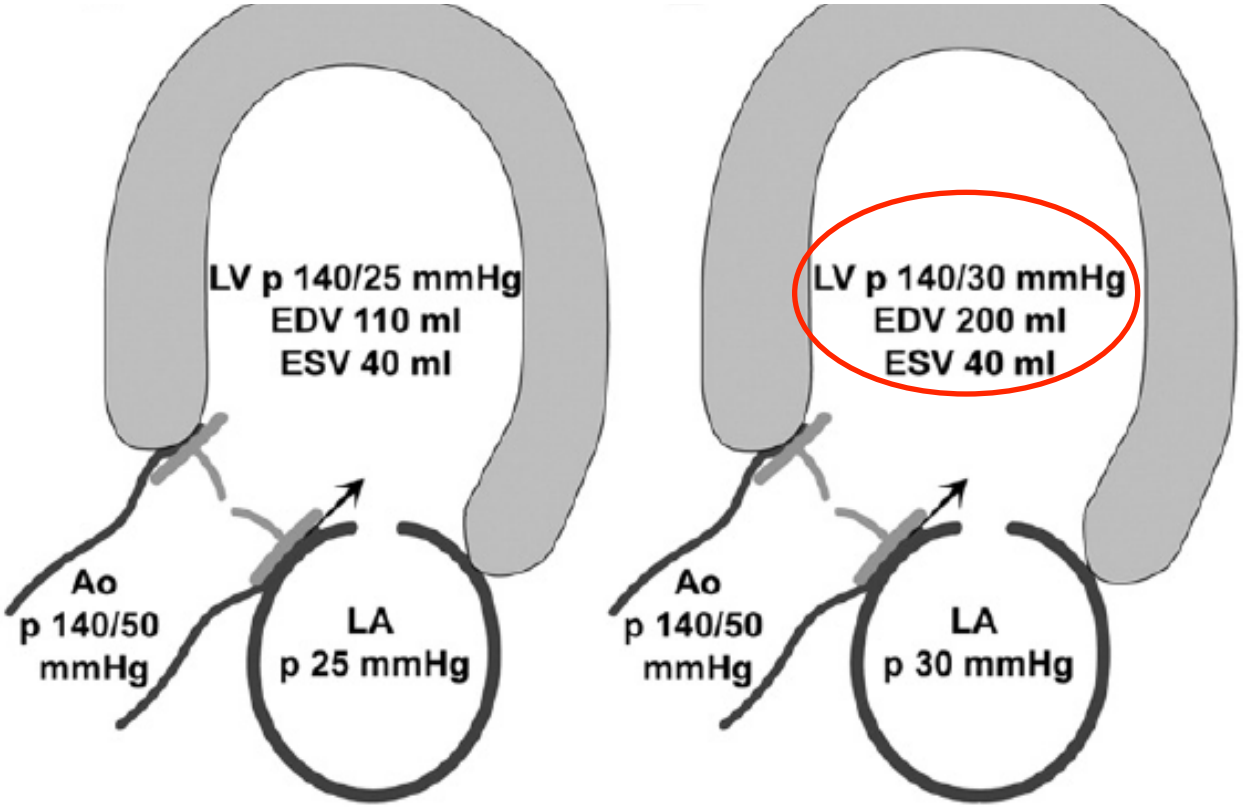
Paravalvular regurgitation: an integrated approach



M Gotzmann et al. Am Heart J 2012;163:903-11

Paravalvular regurgitation: an integrated approach

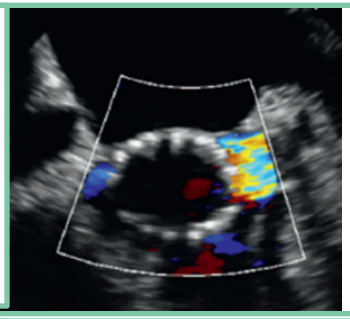
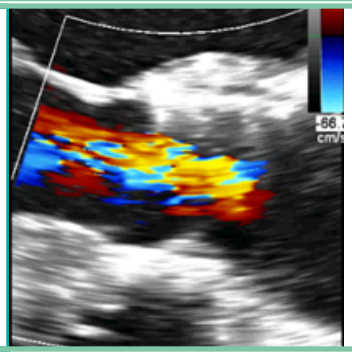
Chronic AR



M Gotzmann et al. Am Heart J 2012;163:903-11

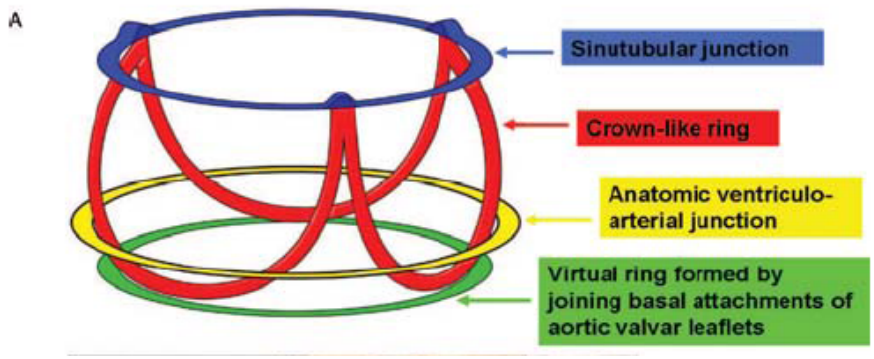
Paravalvular regurgitation: an integrated approach

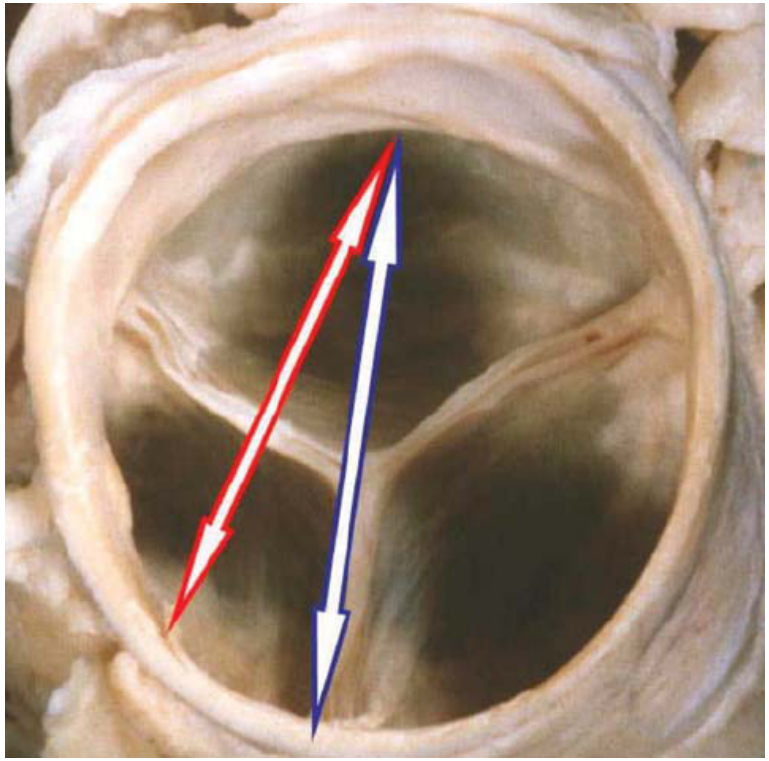
Causes of AR after TAVI

ParaVal v AR		Prosthesis malposition/ under-expansion/ undersizing
Central AR		Incomplete expansion of prosthesis Restricted cusp motion

Paravalvular regurgitation: an integrated approach

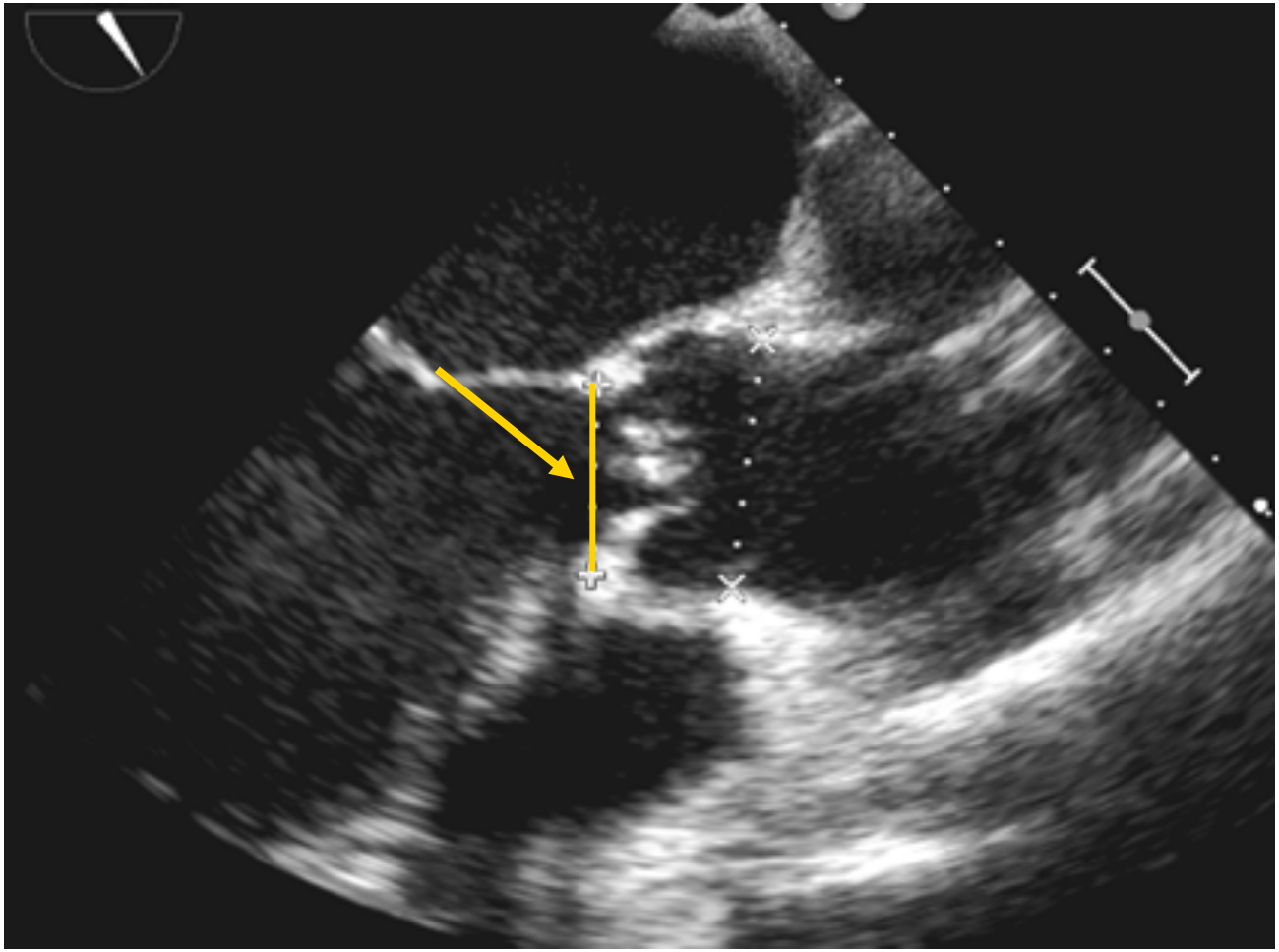
Circulation
Cardiovascular Interventions
Journal of the American Heart Association



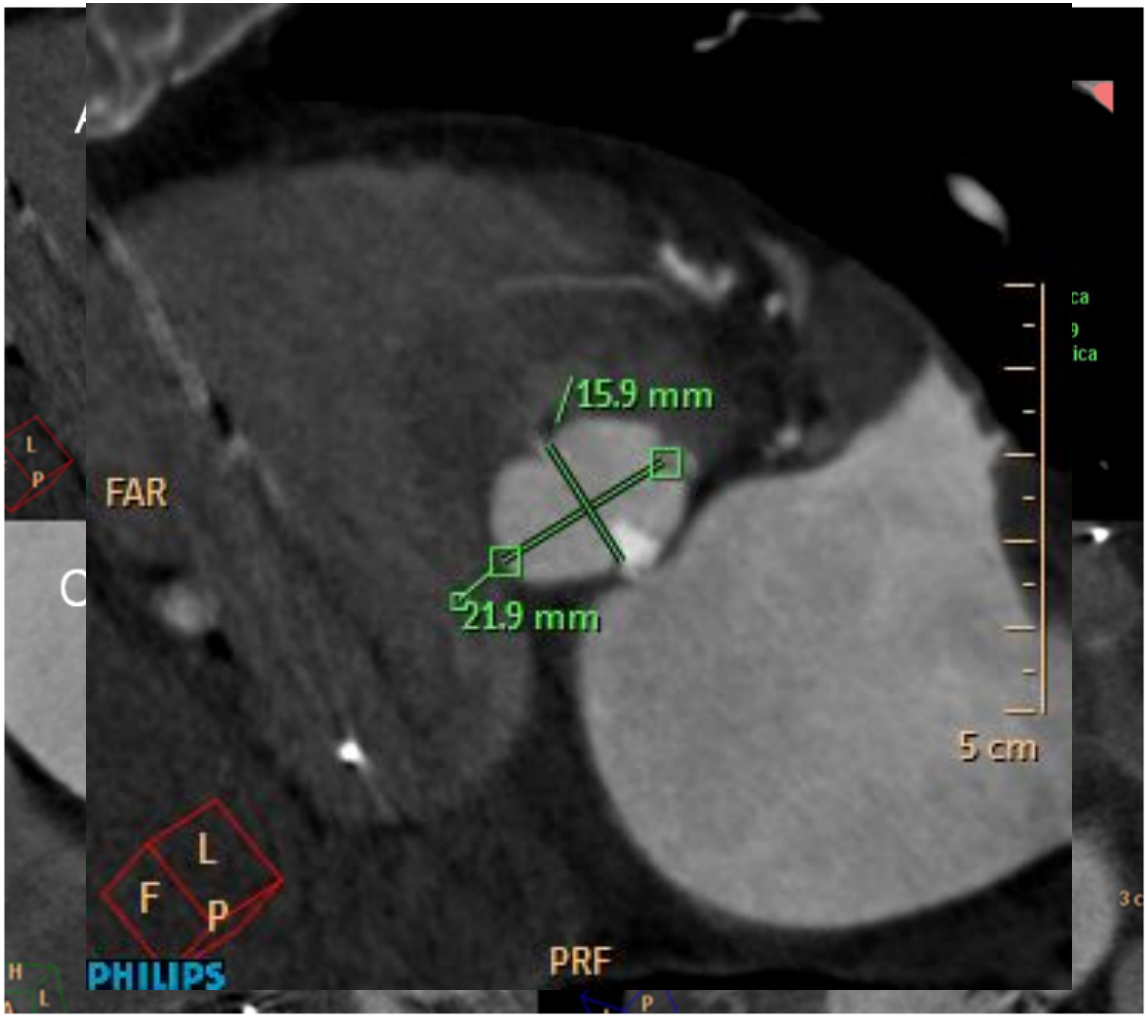


Piazza N et al. *Circ Cardiovasc Interv 2008*

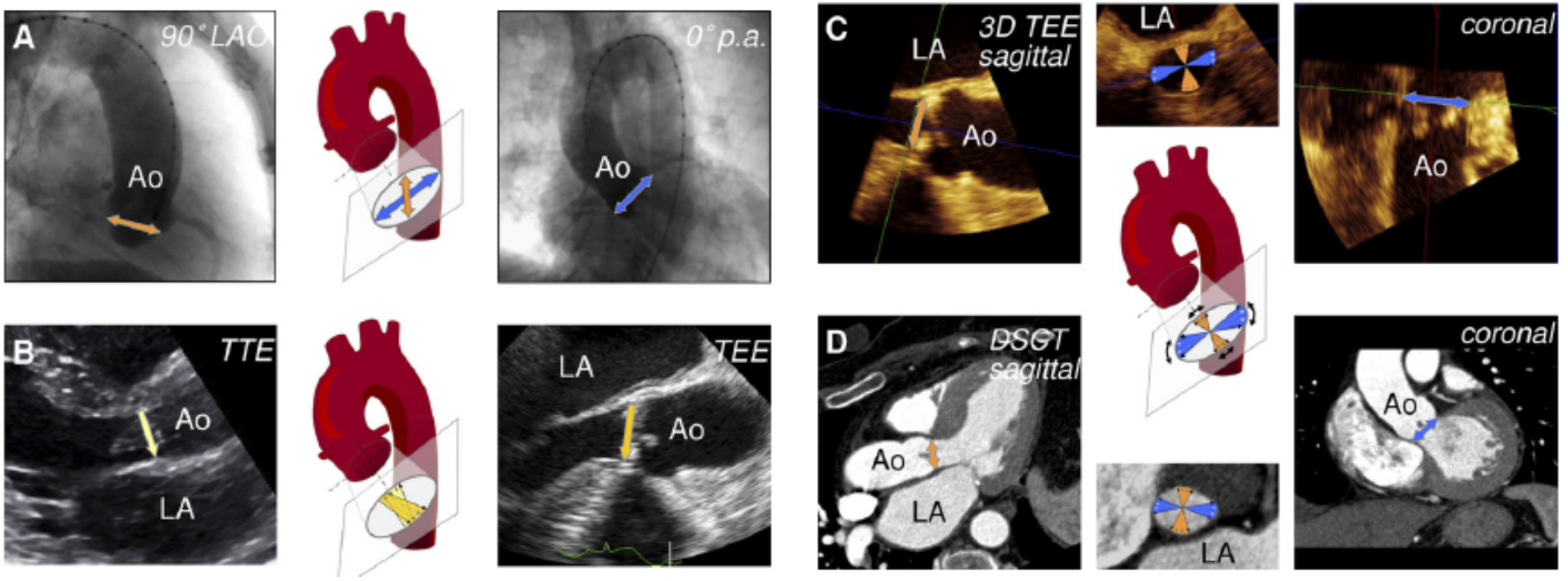
Paravalvular regurgitation: an integrated approach



Paravalvular regurgitation: an integrated approach



Paravalvular regurgitation: an integrated approach



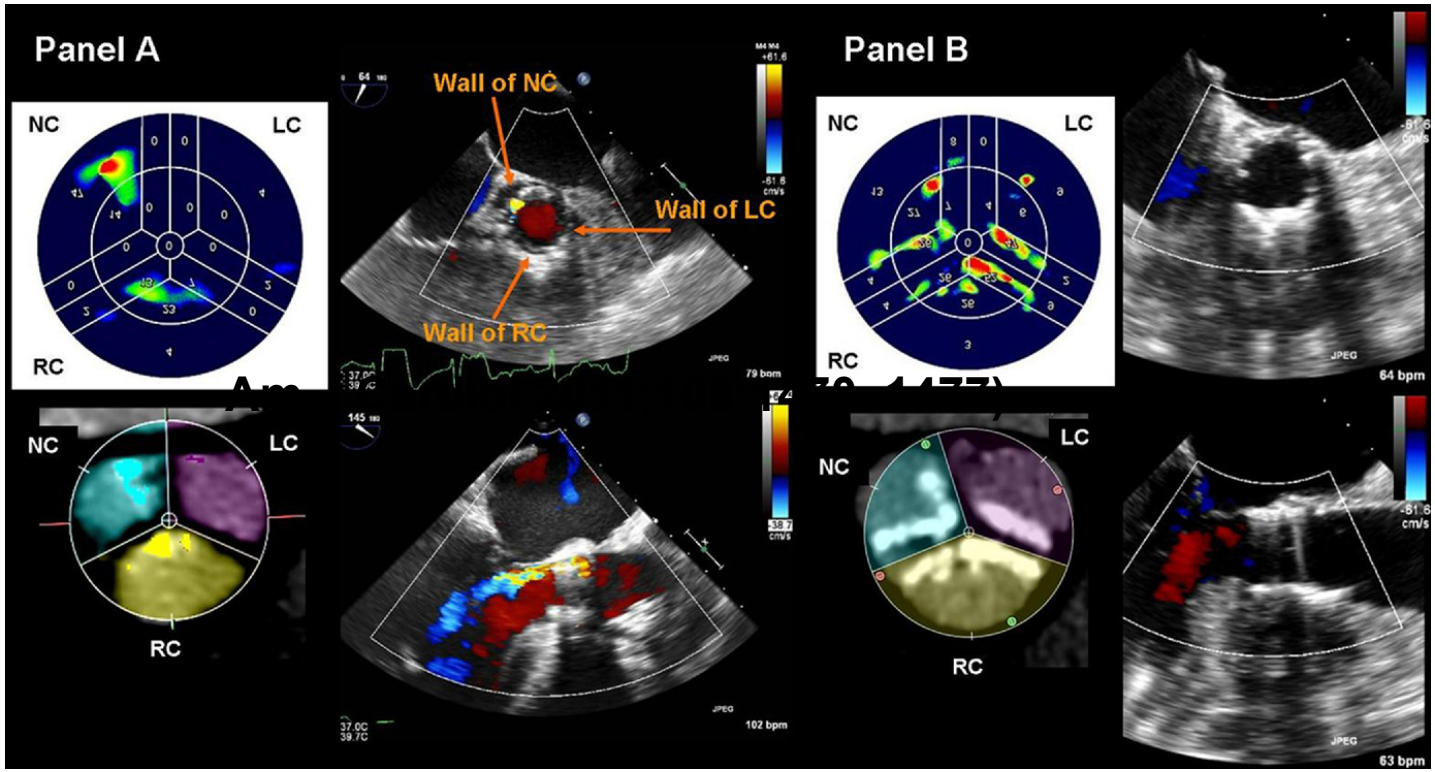
3D imaging techniques should be used to evaluate aortic annulus diameters

2D imaging techniques, providing only a sagittal view, underestimate them.

3D TEE provides measurements of aortic annulus diameters similar to those obtained by DSCT.

Heart 2011;97:1578e1584

Paravalvular regurgitation: an integrated approach



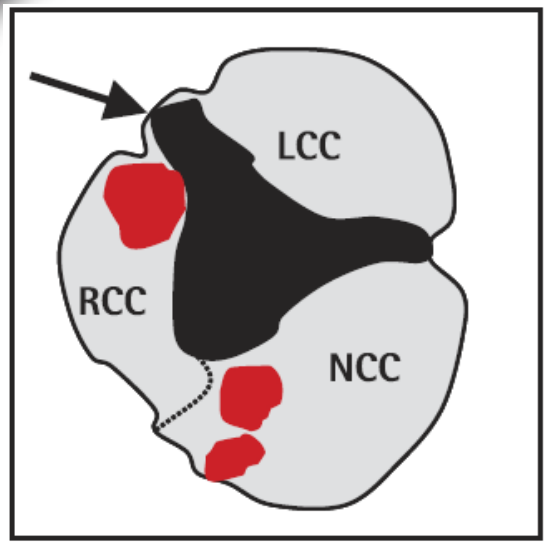
Calcium at the valvular commissure was better than calcium at the valvular edge in predicting paravavular AR originating from the corresponding commissure.

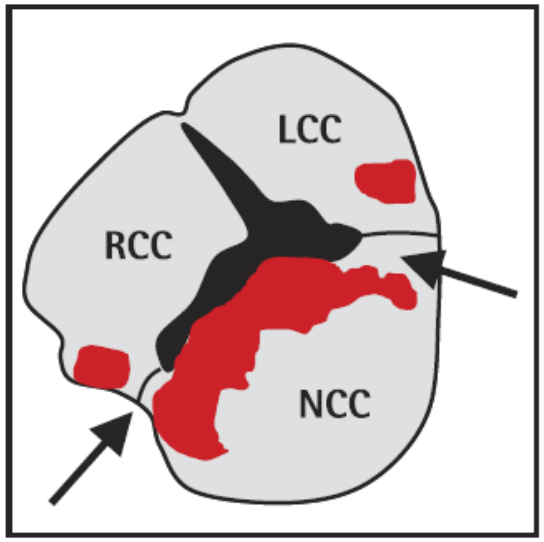
Ewe SH et al. Am J Cardiol 2011;108:1470–1477

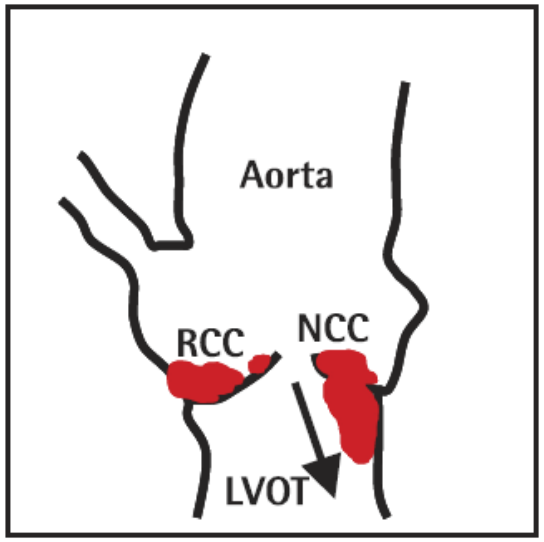
Paravalvular regurgitation: an integrated approach

Transapical Aortic Valve Implantation

Incidence and Predictors of Paravalvular Leakage and Transvalvular Regurgitation in a Series of 358 Patients

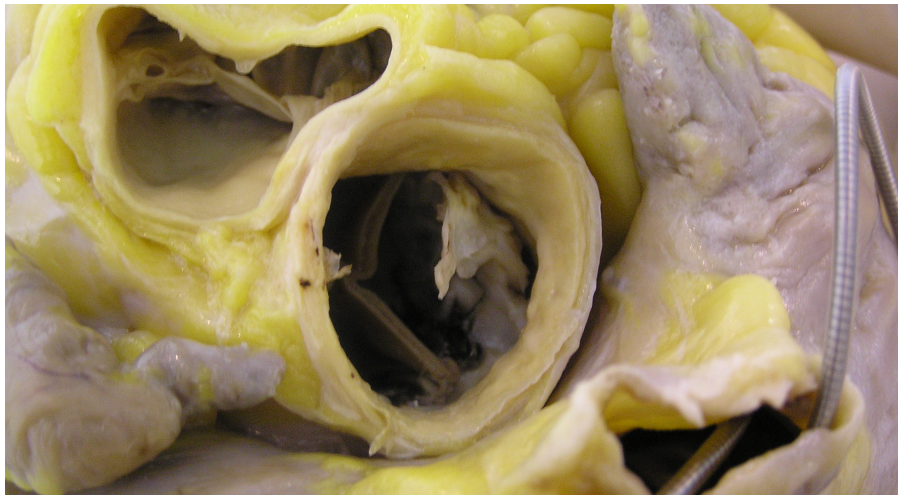


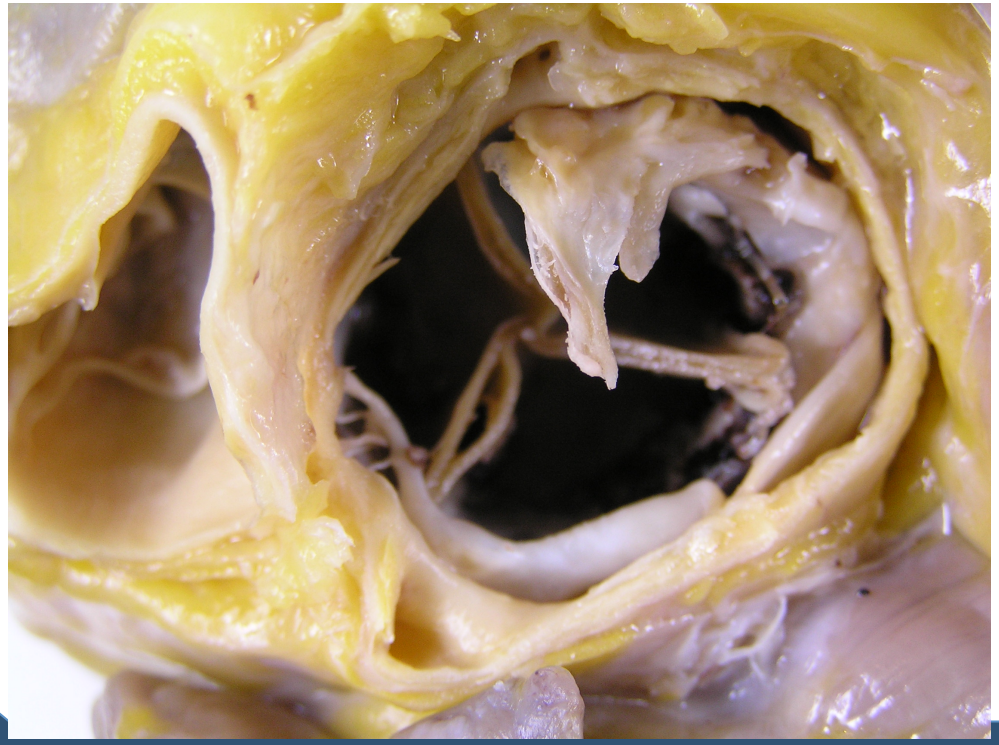


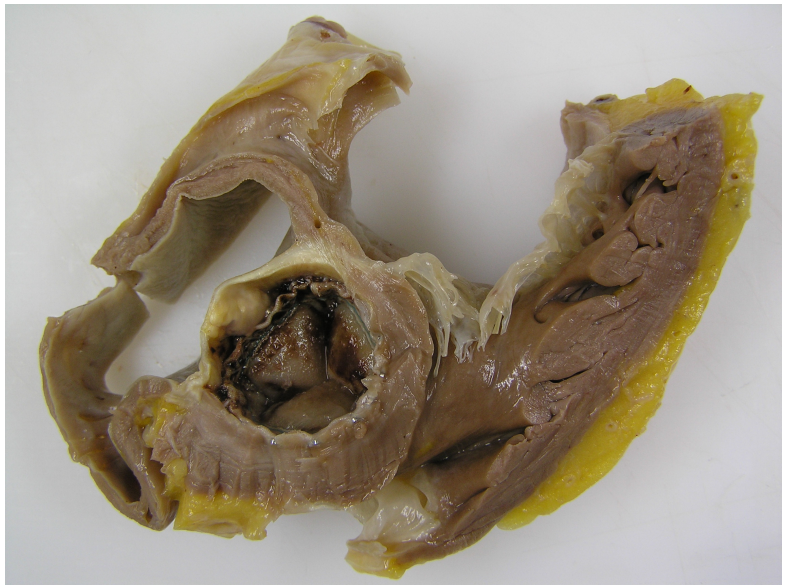


Asymmetric cusp calcification	5.65	0.44–3.03	0.009*
Device landing zone calcification	4.90	0.79–2.39	0.001*
Oval-shaped annulus	9.16	0.68–3.75	0.005*

Unbehaun, A, et al. J Am Coll Cardiol 2012







• Evaluation of success and complications

Echocardiography: guidance during valve implantation

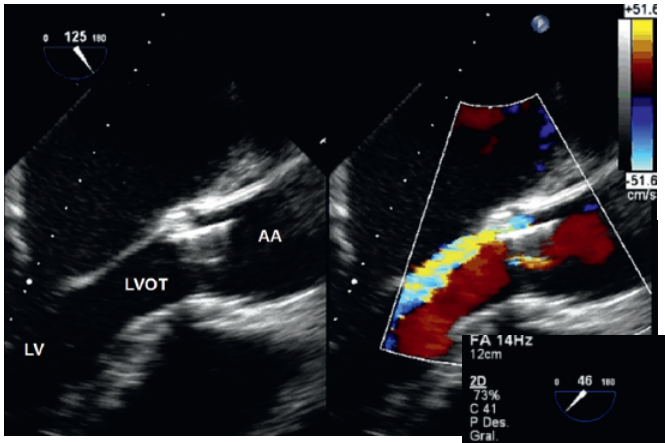
EuroIntervention

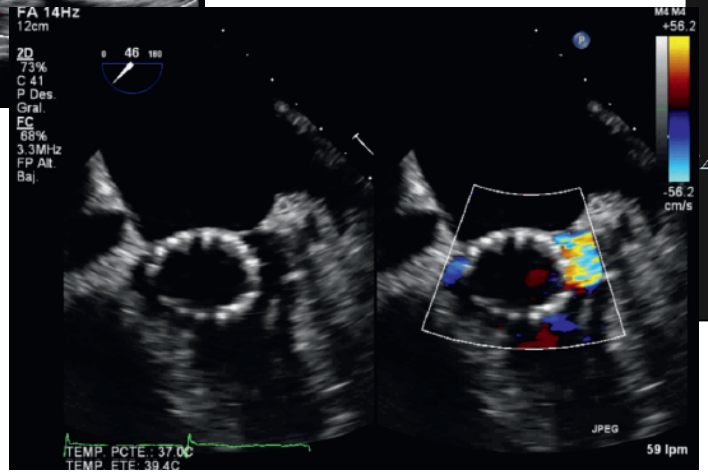
Alexandra Gonçalves, MD; Pedro Marcos-Alberca, MD, PhD; José Luis Zamorano*, MD, PhD, FESC

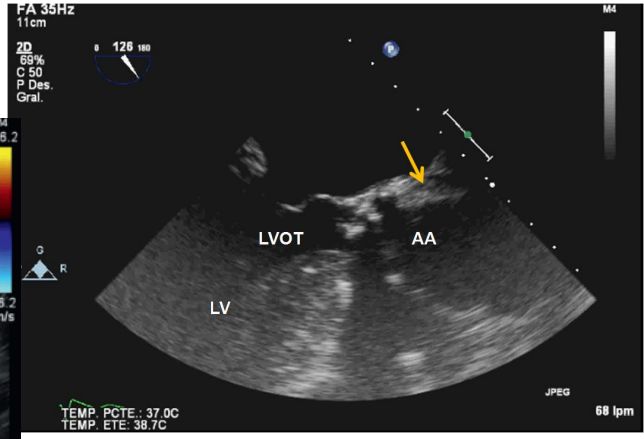
Cardiovascular Institute, Hospital Clínico San Carlos, Madrid, Spain

Abstract

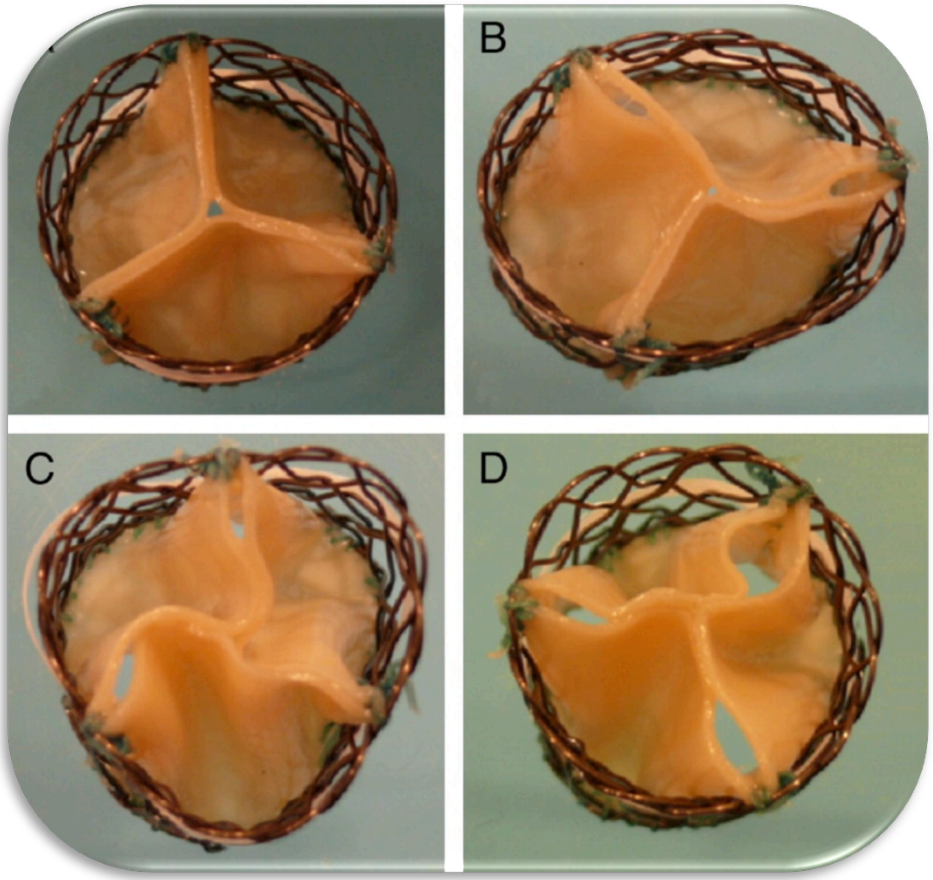
Transcatheter aortic valve implantation (TAVI) by percutaneous or transapical aproach has emerged as an effective and less-invasive treatment for patients with severe symptomatic aortic valve stenosis and high surgical risk. Echocardiography is a fundamental tool in patients' selection for TAVI, for guiding the intervention as well as evaluating the position, deployment and function of the prosthesis. This review describes the role of echocardiography during the intervention, in procedure guidance and in the assessment of complications.



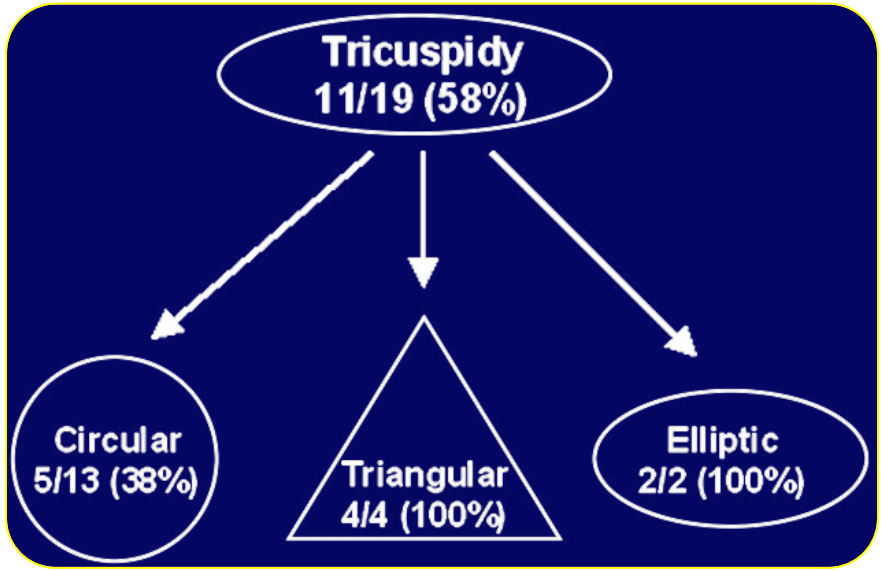




- Per- procedure →→ Complications



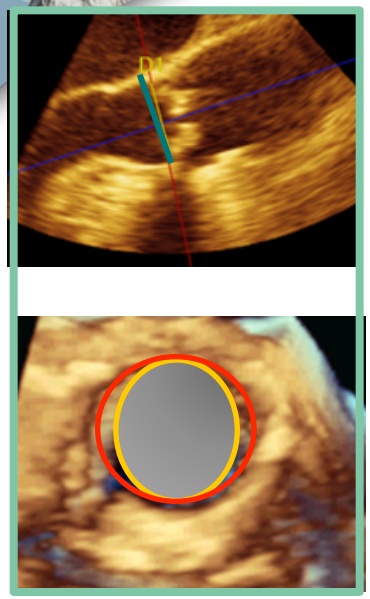
Zegdi, R. et al. J Am Coll Cardiol 2008;51:579-584



Factors influencing circularity

- Ammount of calcium and distribution
- Involvement of intervalvular fibrosa
- Mitral Prosthesis or rings

Paravalvular regurgitation: an integrated approach



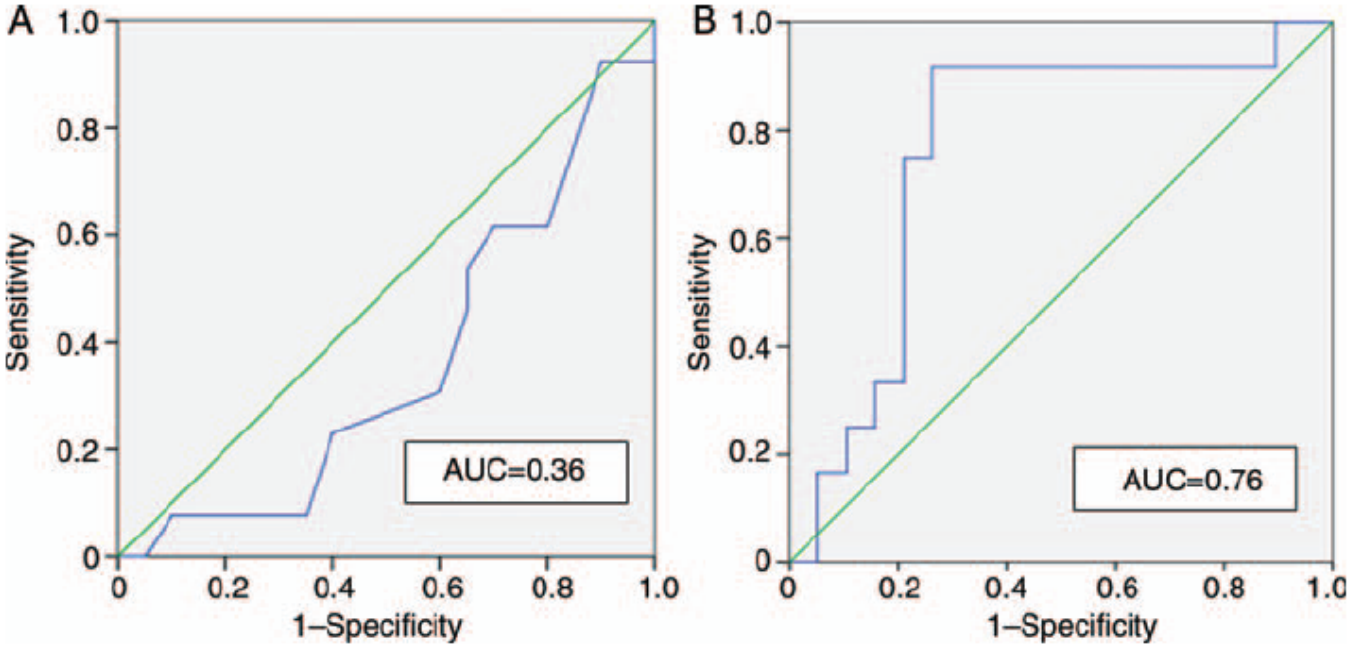
	No AR N=26	Parav AR N=27	P Value
Aortic annulus diameter (mm)	20.5 ± 2.0	21.8±2.3	0,046
Non-coaptation index	0.18±0.22	0.36±0.2	0,011

Non-coaptation index≥0.3 – increased risk of AR [7.1 IC95% (1.8-28.9)].

A. Gonçalves et al. Euro Heart J 2011 (Abst.)

Paravalvular regurgitation: an integrated approach

Prosthesis/annulus discongruence assessed by three-dimensional transoesophageal echocardiography: A predictor of significant paravalvular aortic regurgitation after transcatheter aortic valve implantation



ROC curves for post-TAVI significant AR prediction obtained by 'mismatch index' derived from 2D circular area (A) and 3D planimetered area (B).

Santos N. , Zamorano J et al. Eur Heart Journal – Cardiovascular Imaging, 2012

Paravalvular regurgitation: an integrated approach

Mechanisms of AR after TAVI

- Aortic valve calcification
- Asymmetry of the aortic valve calcification
- Device landing zone calcification
- Larger annulus or oval shaped annulus
- Cover/ Eccentricity/ Non-coaptation/ Mismatch Indexes

Paravalvular regurgitation: an integrated approach

GUIDELINES AND STANDARDS

Recommendations for Evaluation of Prosthetic Valves With Echocardiography and Doppler Ultrasound

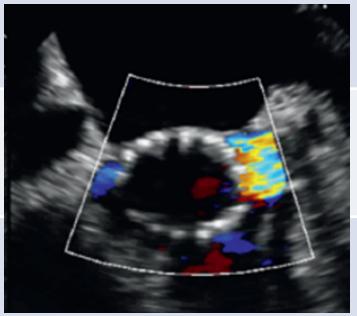
Table 6 Parameters for evaluation of the severity of prosthetic aortic valve regurgitation

Parameter	Mild	Moderate	Severe
Valve structure and motion			
Mechanical or bioprosthetic	Usually normal	Abnormal†	Abnormal†
Structural parameters			
LV size	Normal‡	Normal or mildly dilated‡	Dilated‡
Doppler parameters (qualitative or semiquantitative)			
Jet width in central jets (% LVO diameter): color*	Narrow (≤25%)	Intermediate (26%-64%)	Large (≥65%)
Jet density: CW Doppler	Incomplete or faint	Dense	Dense
Jet deceleration rate (PHT, ms): CW Doppler§	Slow (>500)	Variable (200-500)	Steep (<200)
LVO flow vs pulmonary flow: PW Doppler	Slightly increased	Intermediate	Greatly increased
Diastolic flow reversal in the descending aorta: PW Doppler	Absent or brief early diastolic	Intermediate	Prominent, holodiastolic
Doppler parameters (quantitative)			
Regurgitant volume (mL/beat)	<30	30-59	>60
Regurgitant fraction (%)	<30	30-50	>50

Paravalvular regurgitation: an integrated approach

Measurement of paravalvular AR

For paravalvular jets	
Mild	10% of the sewing ring
Moderate	10–20% of the sewing ring
Severe.	20% of the sewing ring



However, this assumes continuity of the jet which may not be the case for transcatheter valves.

Three-Dimensional Echocardiography in Paravalvular Aortic Regurgitation Assessment after Transcatheter Aortic Valve Implantation

Journal of the JASE American Society of Echocardiography

Aortic Regurgitation

	None (n=29)	Mild (n=35)	p value*	Moderate (n=8)	p value**
LV ejection fraction (%)	63.9 (11.4)	60.4 (10.6)	0.227	58.6 (13.2)	0.696
LV mass (g/m^2)	121.9 (39.1)	125.4 (42.6)	0.769	130.0 (27.7)	0.784
Ao peak pres grad (mmHg)	17.6 (10.0)	14.9 (7.4)	0.245	17.4 (7.8)	0.437
Mean Ao pres grad (mmHg)	8.4 (4.5)	7.5 (3.4)	0.418	9.0 (5.1)	0.395
LV end diast volume (ml/m^2)	44.0 (16.3)	48.4 (21.9)	0.477	66.1 (18.6)	0.044
Aortic valvular area (cm^2)	1.9 (0.6)	2.0 (0.6)	0.605	1.9 (0.6)	0.680
AR volume (ml)	----------	22.2 (5.5)	----------	41.3 (6.4)	<0.001
Vena contracta width (mm)	----------	1.9 (0.16)	----------	2.1(0.53)	0.139
Vena contracta planimetry (cm^2)	----------	0.09 (0.06)	----------	0.29 (0.1)	0.001

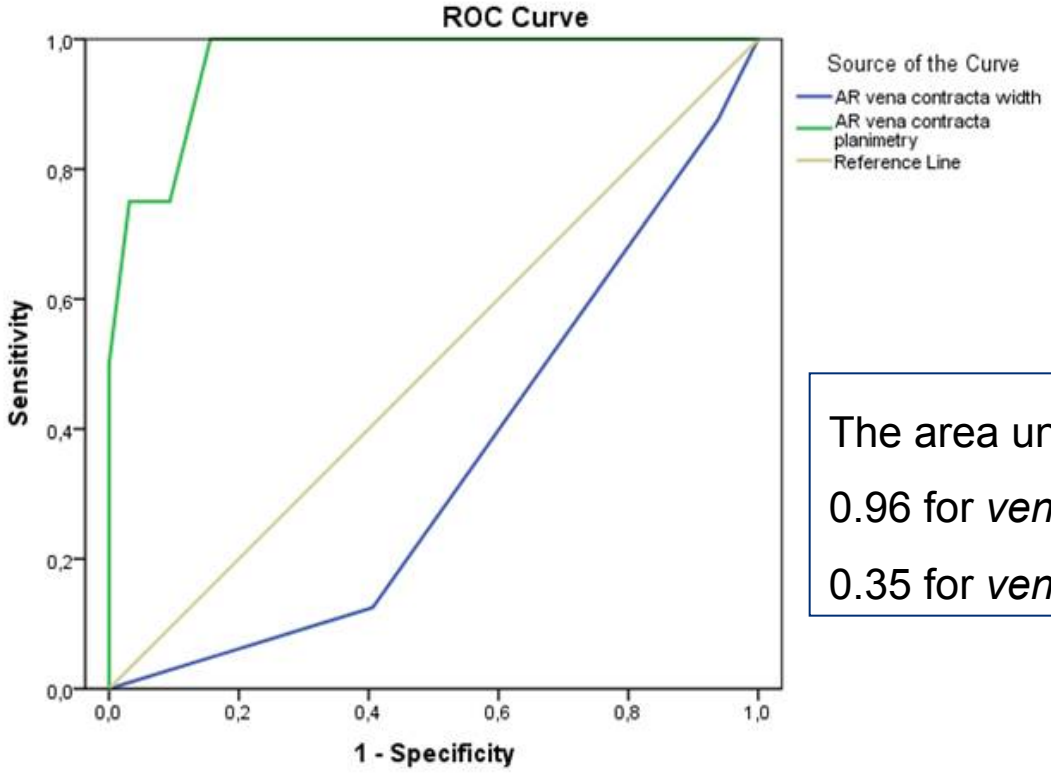
* p value from none AR vs. mild AR
** p value from mild AR vs. moderate AR

J Am Soc Echocardiogr 2012

Three-Dimensional Echocardiography in Paravalvular Aortic Regurgitation Assessment after Transcatheter Aortic Valve Implantation

Journal of the JASE American Society of Echocardiography

Alexandra Gonçalves, MD, Carlos Almeria, MD, Pedro Marcos-Alberca, MD, PhD, FESC, Gisela Feltes, MD, Rosana Hernández-Antolín, MD, PhD, Enrique Rodríguez, MD, José C. Silva Cardoso, MD, PhD, Carlos Macaya, MD, PhD, FESC, and José Luis Zamorano, MD, PhD, FESC, *Madrid, Spain; Porto, Portugal*



The area under the ROC curve:

0.96 for *vena contracta* planimetry

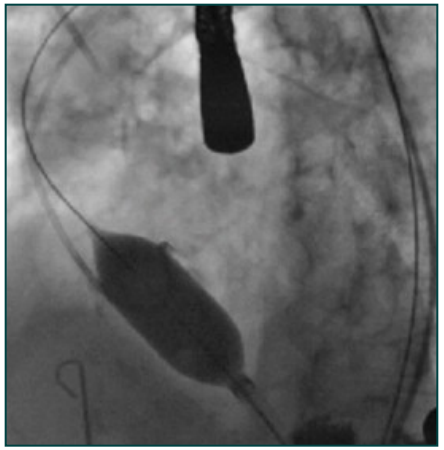
0.35 for *vena contracta* width

3D TTE *vena contracta* planimetry correlation with AR volume: 0.82, $p<0.001$

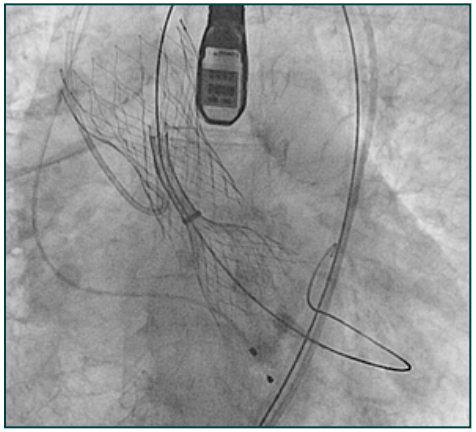
2D TTE *vena contracta* width correlation with AR volume: 0.66, $p<0.001$

Treatment of Paravalvular AR

Post implant ballon dilatation

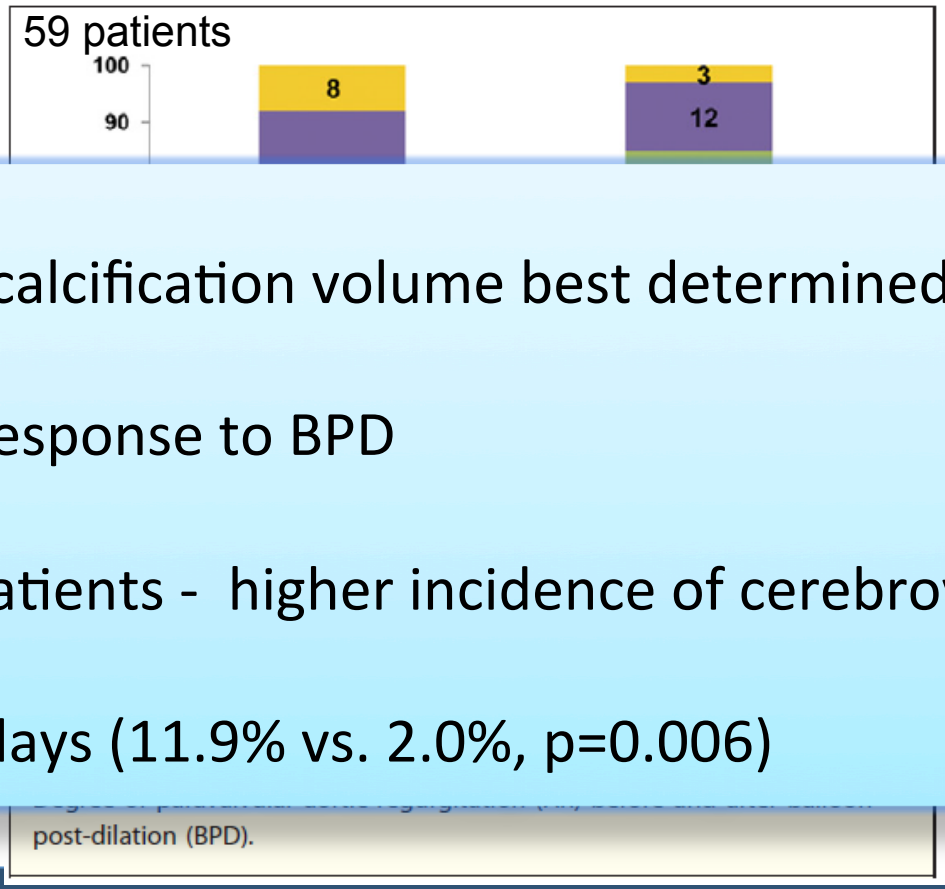


Valve in valve



Paravalvular regurgitation: an integrated approach

Predictive Factors, Efficacy, and Safety of Balloon Post-Dilation After Transcatheter Aortic Valve Implantation With a Balloon-Expandable Valve

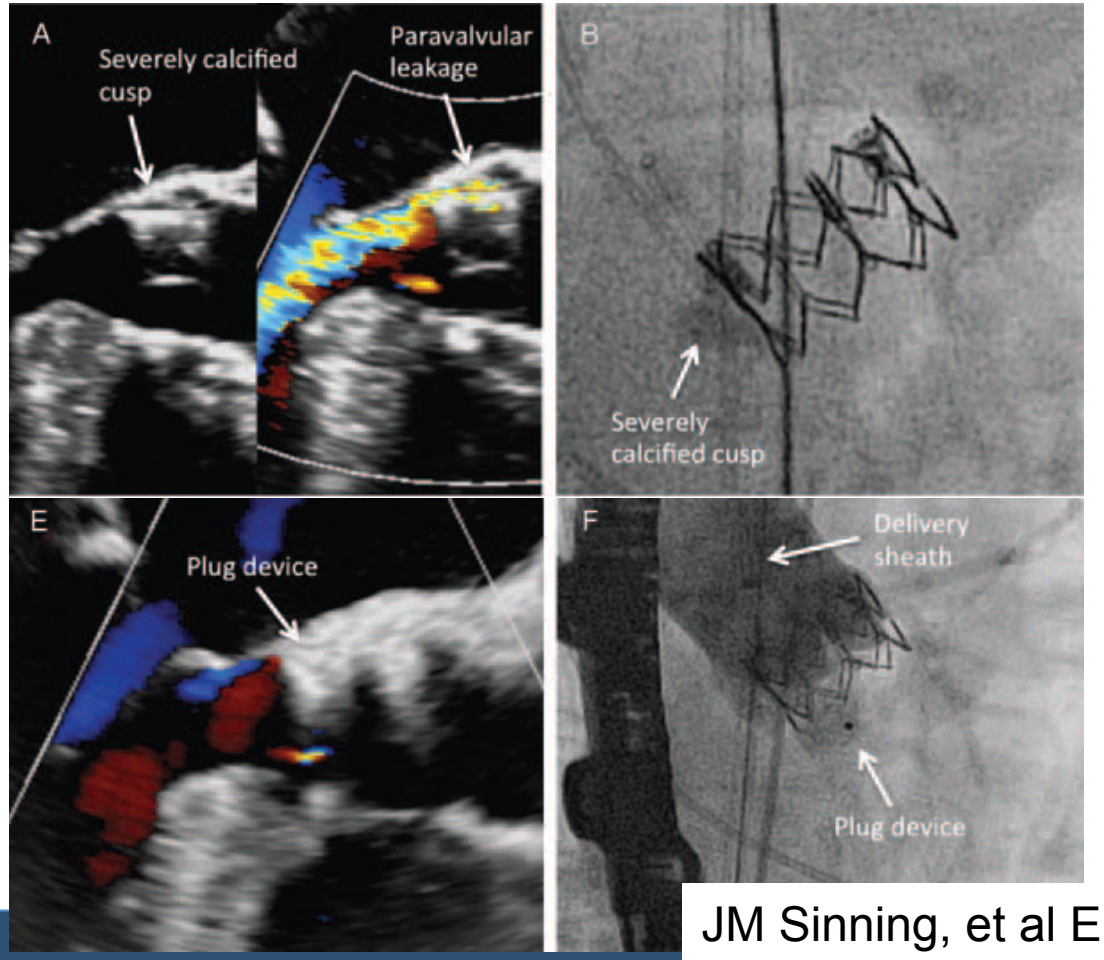


- Valve calcification volume best determined the need and a poor response to BPD
- BPD patients - higher incidence of cerebrovascular events at 30 days (11.9% vs. 2.0%, p=0.006)

Nombela-Franco et al J Am Coll Cardiol Intv 2012

Paravalvular regurgitation: an integrated approach

Interventional closure of paravalvular leakage after transcatheter aortic valve implantation

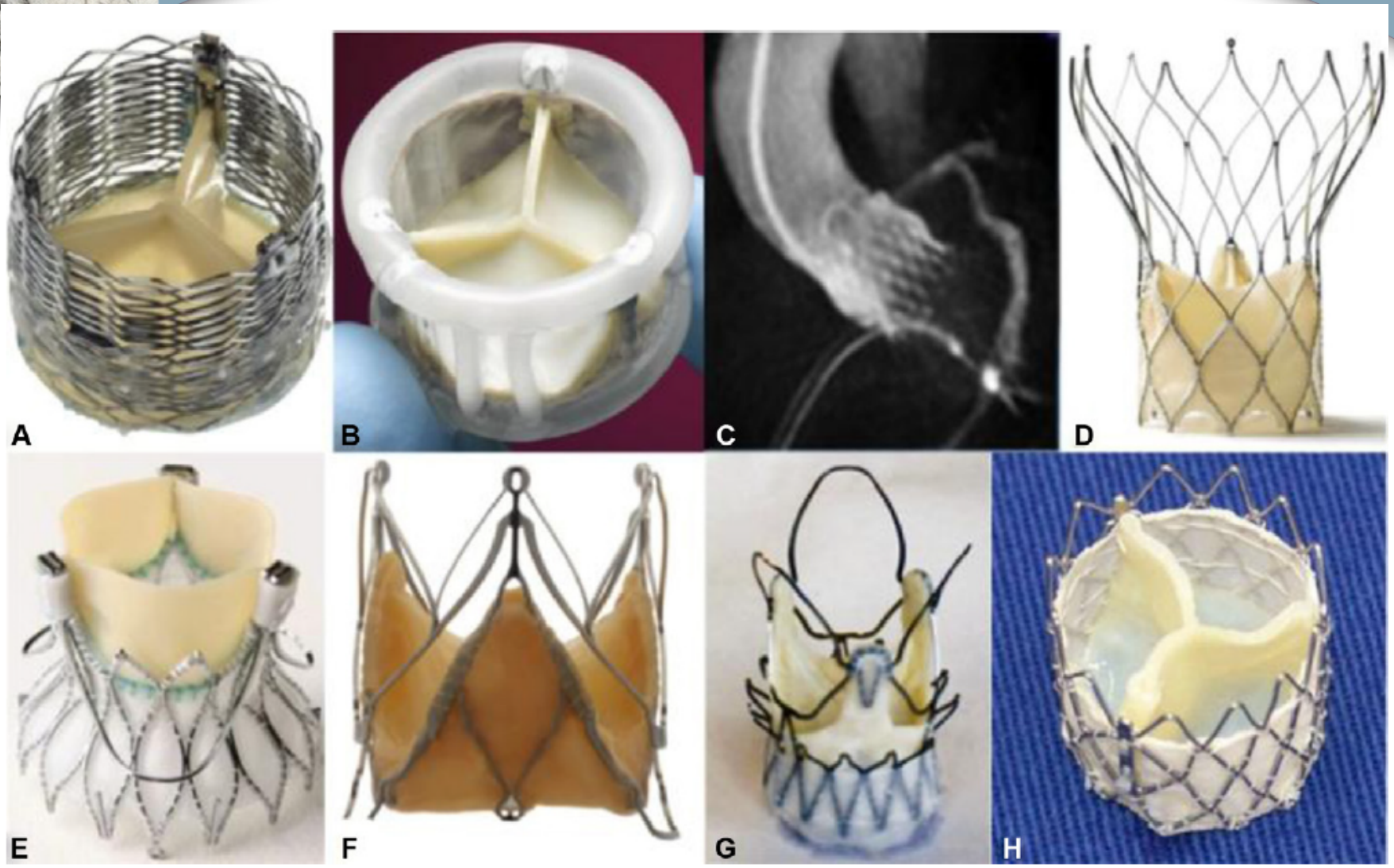


JM Sinning, et al Eur Heart J 2012

Prevention

- Proper study of aortic valve and root anatomy
- Training
- Imaging procedure guidance
- Improvements in the deployment technique

Paravalvular regurgitation: an integrated approach

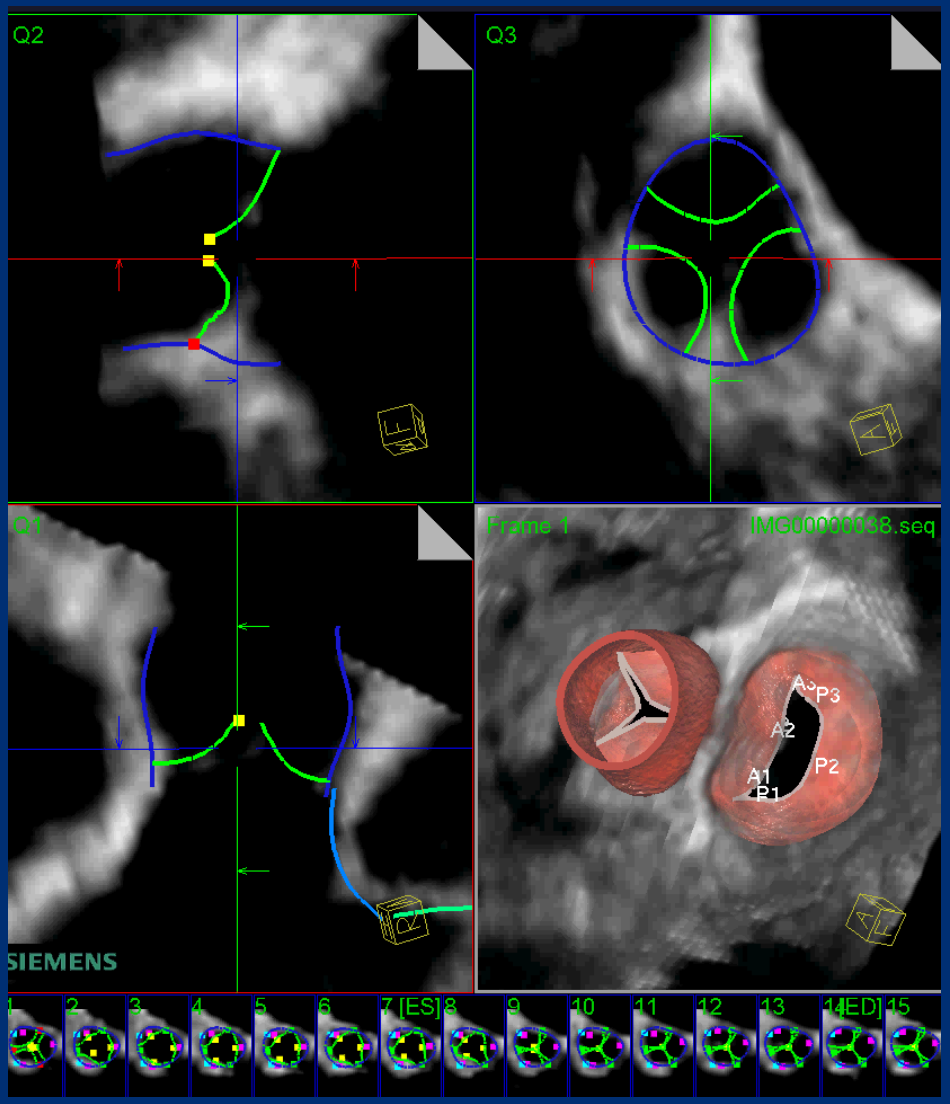


Webb J. Arch Cardio Disease 2012

JM Sinning, et al Eur Heart J 2012

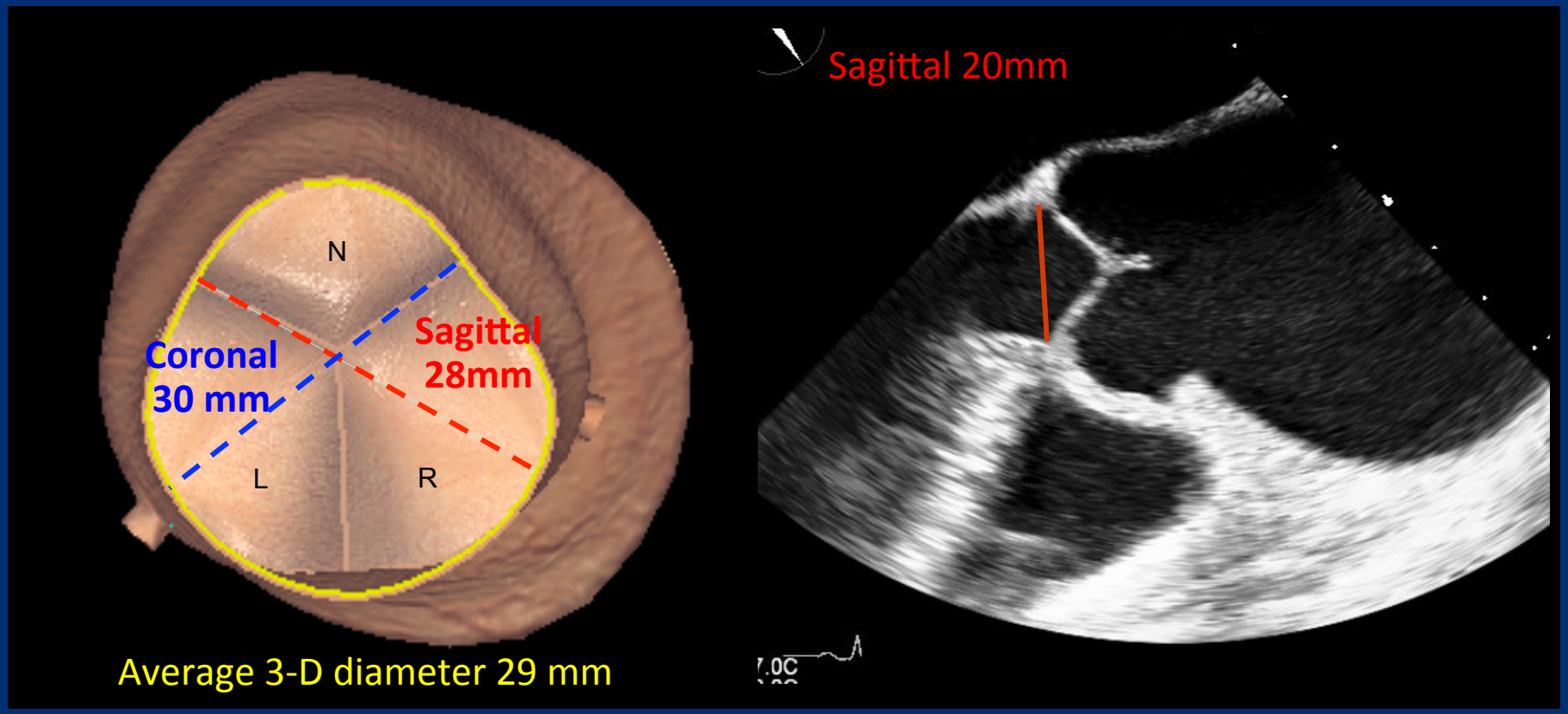
Automated Quantitative Modeling

3-D TEE



Automated Quantitative 3-D TEE

Annulus Diameters



Graft size 30 mm

Conclusion

- AR is the most frequent complication after TAVI
- Accurate measurement of paravalvular AR is challenging
- Significant AR is a main contributor to in-hospital death and an independent predictor of 1-year morbidity and mortality

Conclusion

- There is no effective treatment available
- Prevention of AR is essential for best TAVI results