How To Prevent And Manage Peri-procedural Aortic Regurgitation

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TCTAP 24 April 2013

Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial Interest /arrangement or affiliation with the organization(s) listed below

Affiliation / Financial Relationship	Company
Grant / Research Support:	
Consulting Fees / Honoraria:	**Edwards Lifesciences (consultant & proctor)**
Major Stock Shareholder / Equity Interest:	
Royalty Income:	
Ownership / Founder:	
Salary:	
Intellectual Property Rights:	
Other Financial Benefit:	

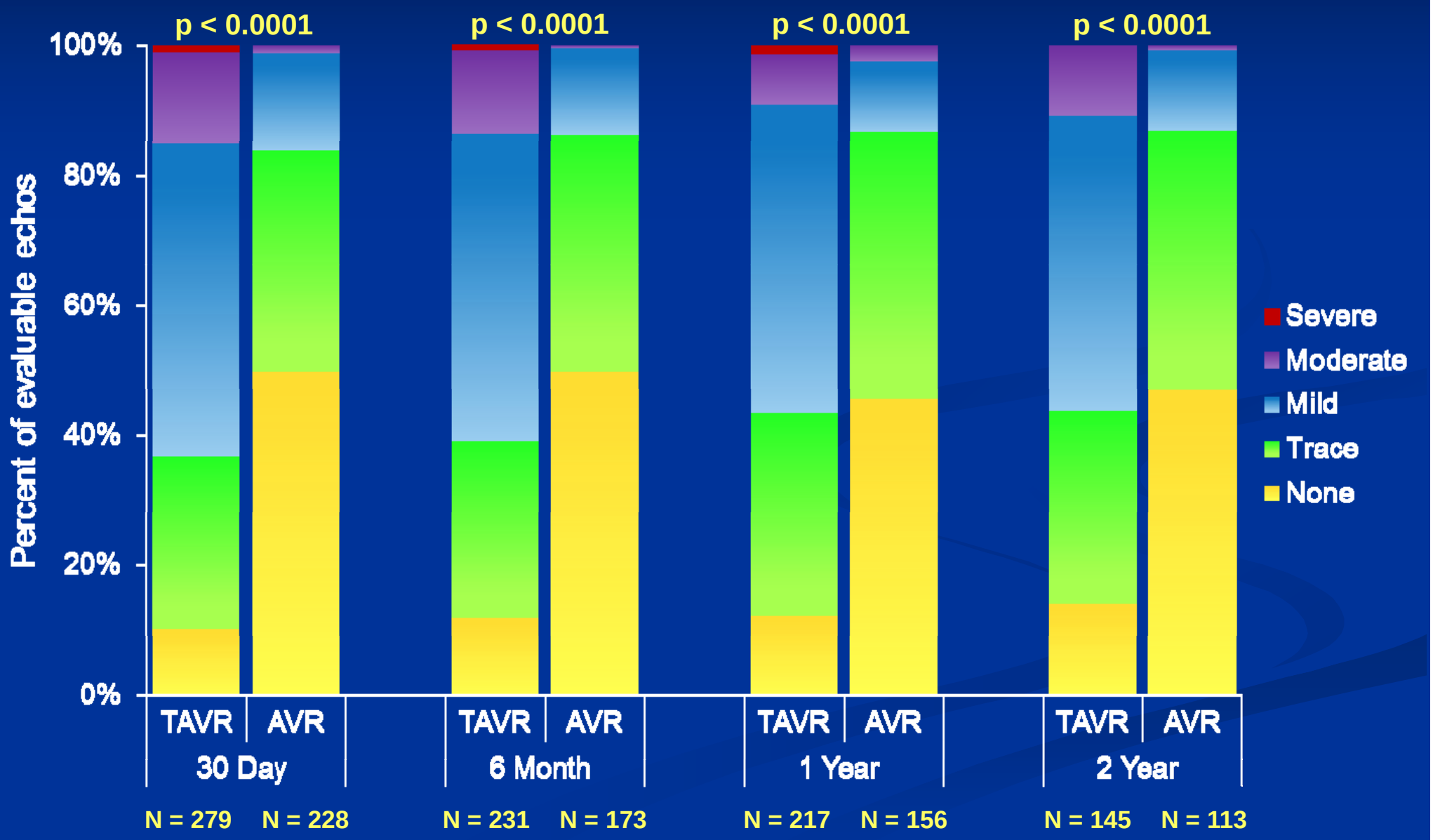
Paravalvular Leak After Transcatheter Aortic Valve Replacement

The New Achilles' Heel? A Comprehensive Review of

Philippe Généreux, MD,*†‡ Stuart J. Head, MSc,§ Rebecca Hahn, M
Susheel Kodali, MD,*† Mathew R. Williams, MD,*† Nicolas M. van
Maria C. Alu, MM,* Patrick W. Serruys, MD, PhD,‖ A. Pieter Kapp
Martin B. Leon, MD*†

New York, New York; Montréal, Québec, Canada; and Rotterdam, the Ne

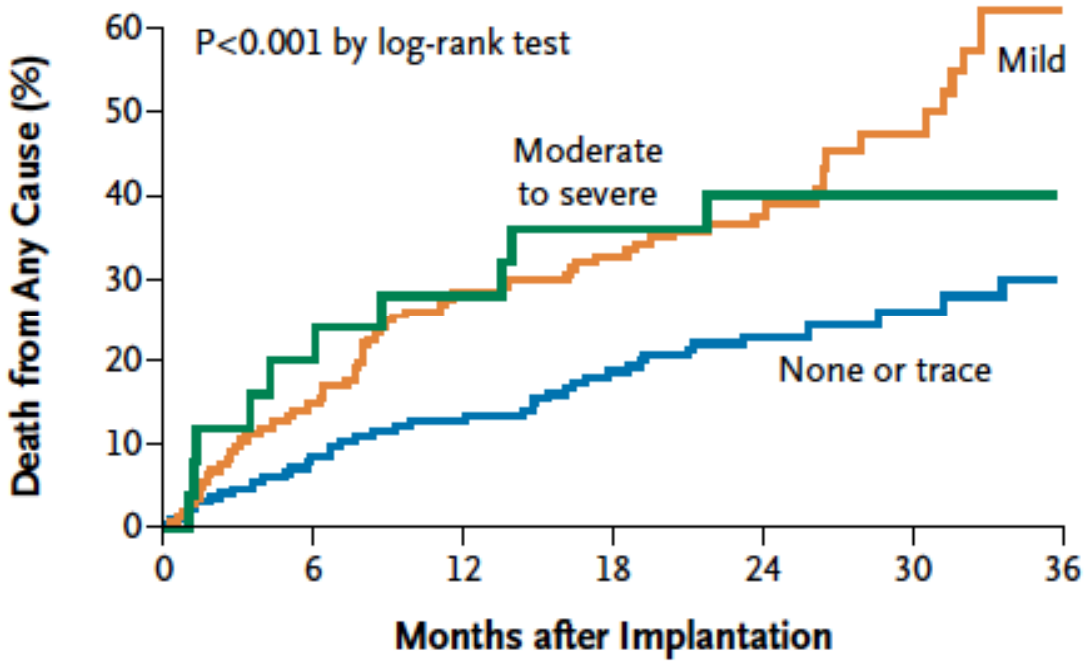
PARTNER COHORT A - Aortic Regurgitation (As Treated)



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

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

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

Kodali, et al., *NEJM,* 2012;366:1686-95

Incidence, Predictors, and Outcomes of Aortic Regurgitation After Transcatheter Aortic Valve Replacement

Meta-Analysis and Systematic Review of Literature

Ganesh Athappan, MD,*† Eshan Patvardhan, MD,* E. Murat Tuzcu, MD,*
Lars Georg Svensson, MD, PHD,‡ Pedro A. Lemos, MD,§ Chiara Fraccaro, MD, PHD,‖
Giuseppe Tarantini, MD, PHD,‖ Jan-Malte Sinning, MD,‖ Georg Nickenig, MD,¶
Davide Capodanno, MD, PHD,# Corrado Tamburino, MD, PHD,# Azeem Latib, MD,**
Antonio Colombo, MD,** Samir R. Kapadia, MD*

Cleveland, Ohio; São Paulo, Brazil; Padova, Catania, and Milan, Italy; and Bonn, Germany

- Meta-analysis of 45 studies between 2002-2012
- Edwards 7,279; CoreValve 5,261

- Incidence of moderate or severe PVL - 13.9%
  - Edwards 9.1%
  - CoreValve 16.0%

Paravalvular Regurgication Impacts on Mortality…

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**

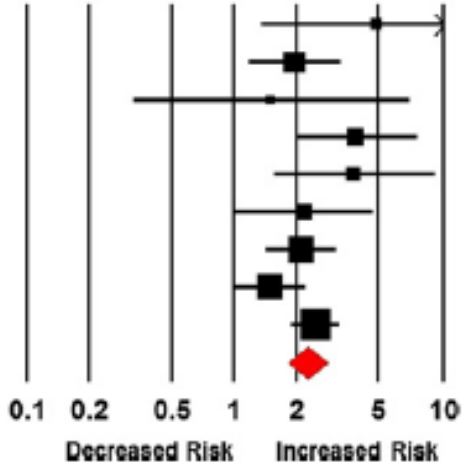


Figure 4 Forest Plot Showing the HRs of Moderate or Severe AR on Overall Mortality

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**

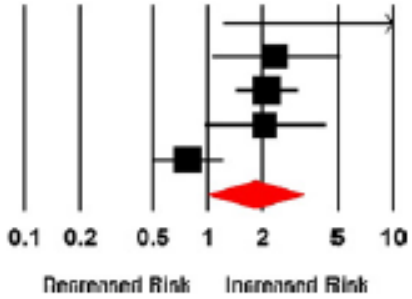
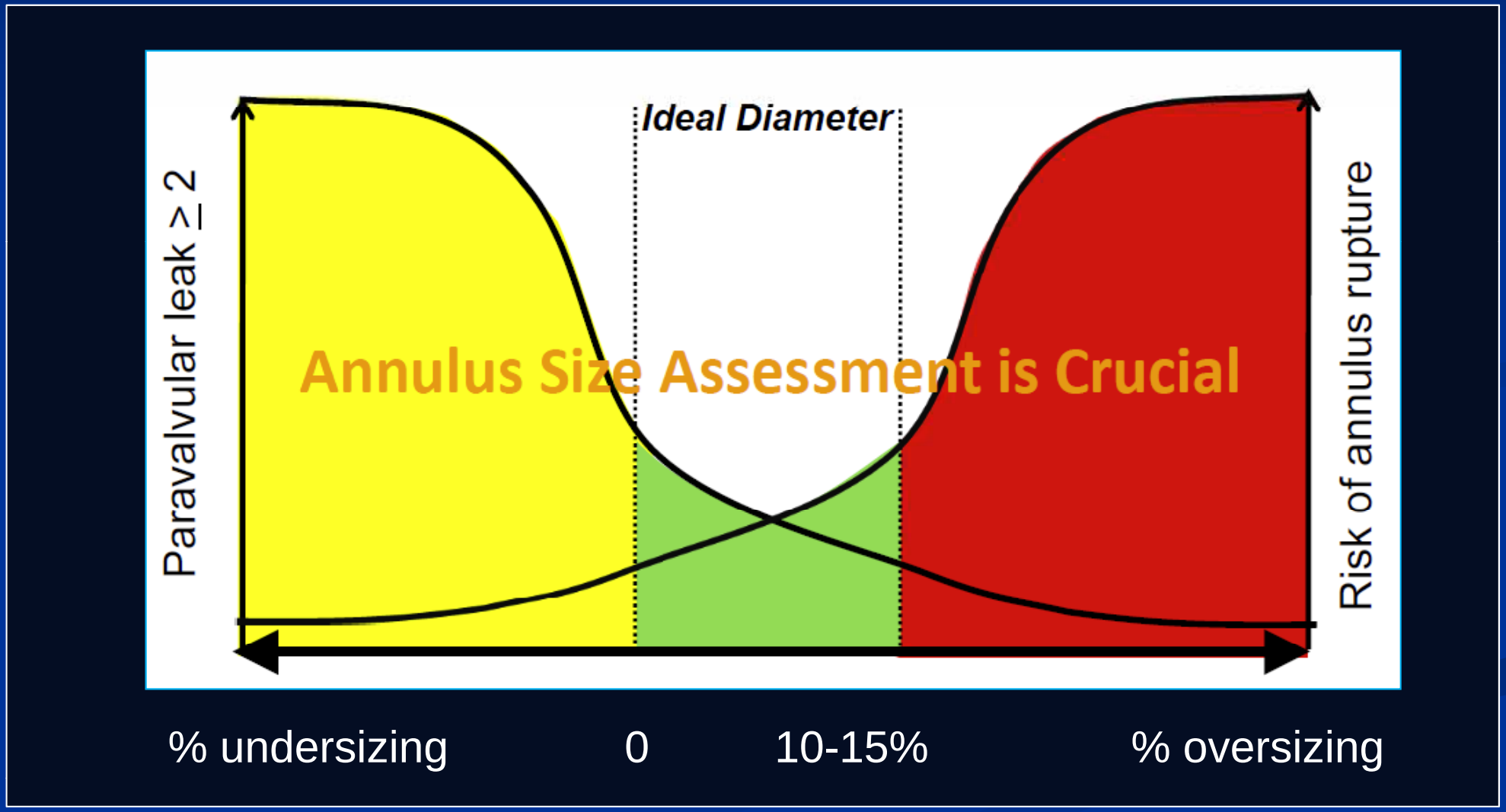


Figure 5 Forest Plot Showing the HRs of Mild AR on Overall Mortality

Predictors of Paravalvular Regurgitation

- Severe calcification – Agaston calcium score on CT
- Low implantation depth
- Markers of valve undersizing
  - Small cover index
  - Large annulus
  - “Prosthesis / annulus mismatch”

Preventing Para-Valvular AR



Adapted from Thierry Lefevre; London Valves, 2012

Multimodality Imaging with 3D TEE or MSCT important in sizing

CLINICAL RESEARCH Interventional Cardiology

Aortic
Aortic
3-Dime

Hasan Jilaih
Asim Rafiq
James Miro
Kazuaki Ok
Swaminatha
Takahiro Sh

Los Angeles,

CLINICAL RESEARCH Imaging in Transcatheter Aortic Valve Replacement

Cross-Sectional Computed Tomographic Assessment
Improve
Transcat
the Inci

Hasan Jilaiha
Azusa Furuge
Niraj Doctor,

Los Angeles, C

3-Dimensional Aortic Annular Assessment by Multidetector Computed Tomography Predicts Moderate or Severe Paravalvular Regurgitation After Transcatheter Aortic Valve Replacement

A Multicenter Retrospective Analysis

Alexander B. Willson, MBBS, MPH,* John G. Webb, MD,* Troy M. LaBounty, MD,† Stephan Achenbach, MD,‡ Robert Moss, MBBS,* Miriam Wheeler, MBBS,* Christopher Thompson, MD,* James K. Min, MD,† Ronen Gurvitch, MBBS,* Bjarne L. Norgaard, MD,§ Cameron J. Hague, MD,* Stefan Toggweiler, MD,* Ronald Binder, MD,* Melanie Freeman, MBBS,* Rohan Poulter, MBBS,* Steen Poulsen, MD,§ David A. Wood, MD,* Jonathon Leipsic, MD*

Vancouver, Canada; Los Angeles, California; Giessen, Germany; and Aarhus, Denmark

Possible Mechanisms of Severe Regurgitation Post-TAVR

- Central valvular regurgitation
- Low deployment
- Inadequate apposition
  - Calcium
  - Underzing

Assessment

- Confirm severity of aortic regurgitation
  - Echo – TEE
  - Aortography
  - Hemodynamics – AR index
- Assess valvular vs paravalvular
  - TEE
- Assess position of implantation
  - TEE
  - Aortography

Immediate Treatment of Severe Aortic Regurgitation During TAVR

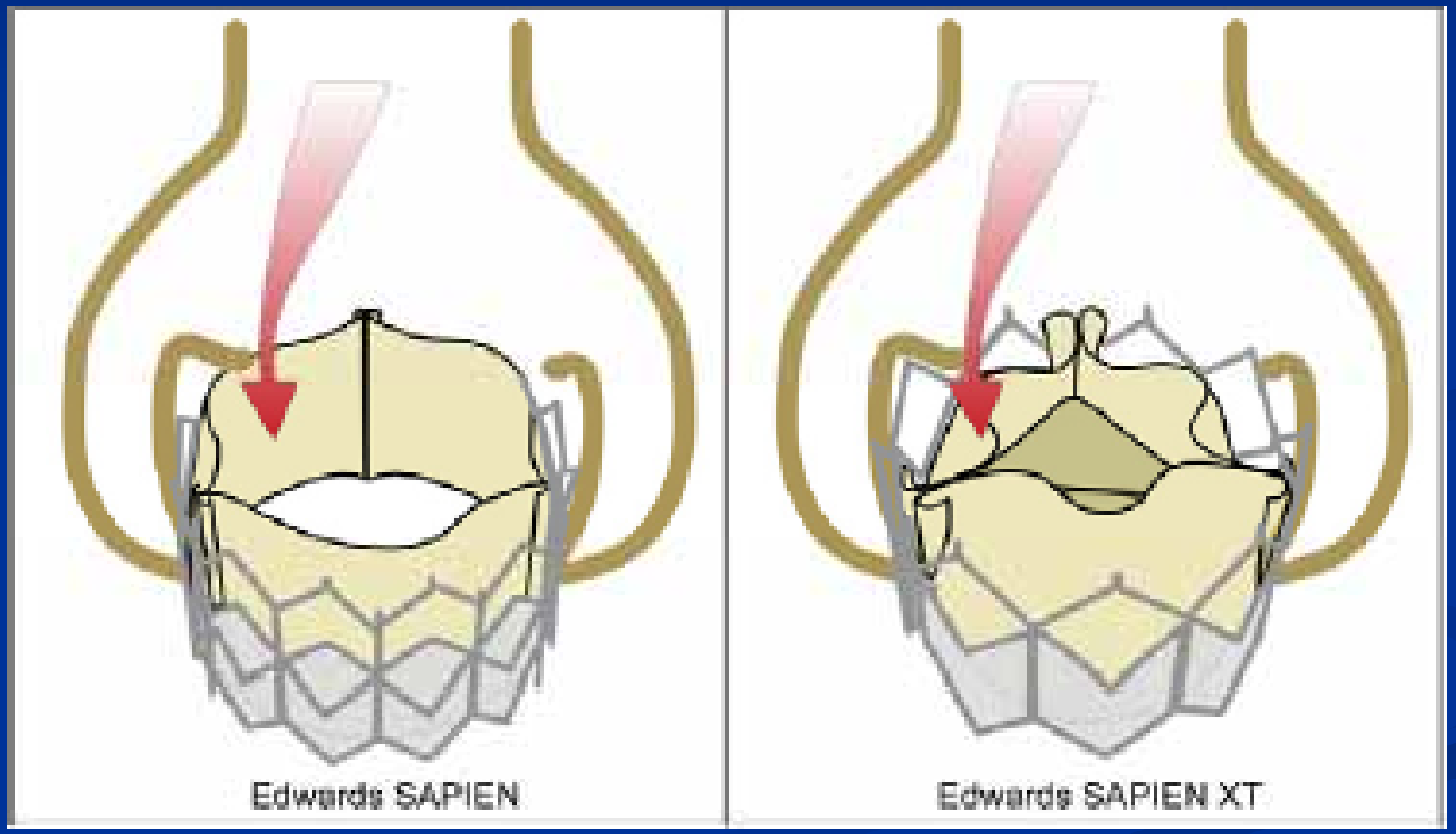
- Pace faster → reduce diastole
- Pressor support
- Mechanical support likely not helpful
- Urgency to institute definitive Rx
  - New valve
  - Post-dilate
  - Conversion to surgery

- Central valvular regurgitation
- Low deployment
- Inadequate apposition to leaflets / annulus due to severe valvular calcification +/- inadequate balloon dilatation

Central Valvular Regurgitation

- Frozen leaflets, overhanging leaflets
- Can attempt to loosen leaflet with diagnostic coronary catheter
- Prepare and replace valve with another valve as valve-in-valve bailout

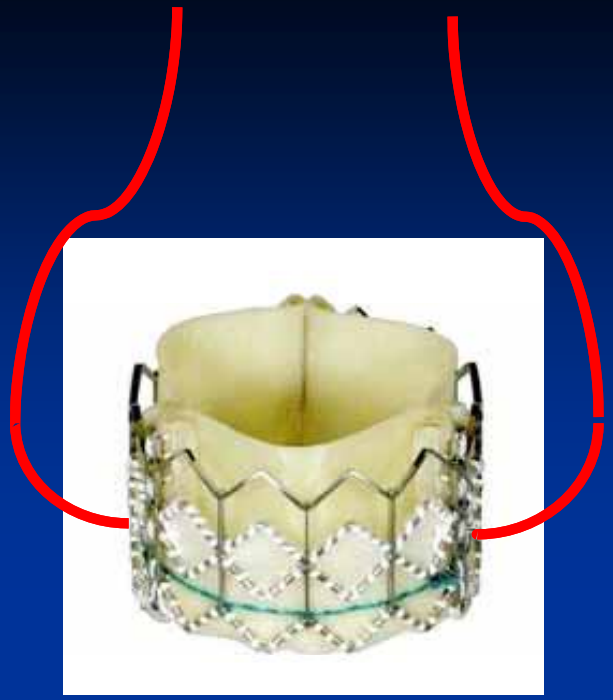
Frozen Leaflets due to Low Implantation

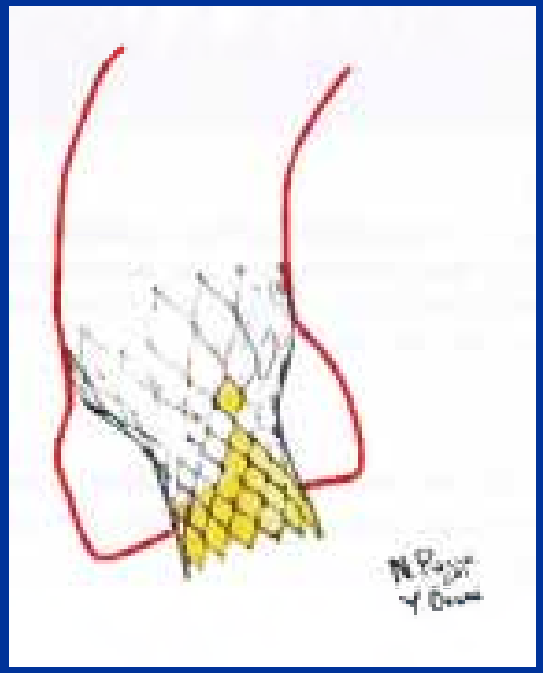


Toggweiler et al. J Am Coll Cardiol Intv 2012;5:571–7

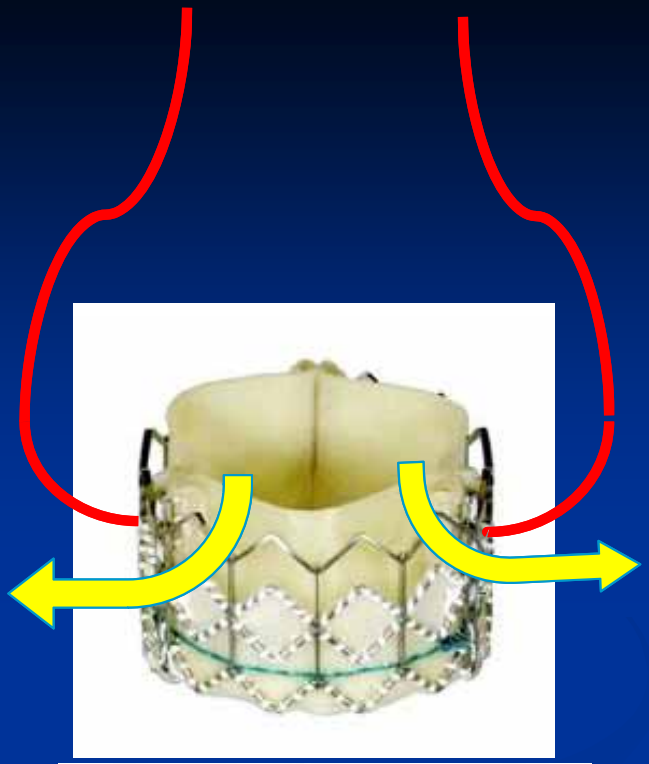
Possible Mechanisms of Severe Regurgitation Post-TAVI

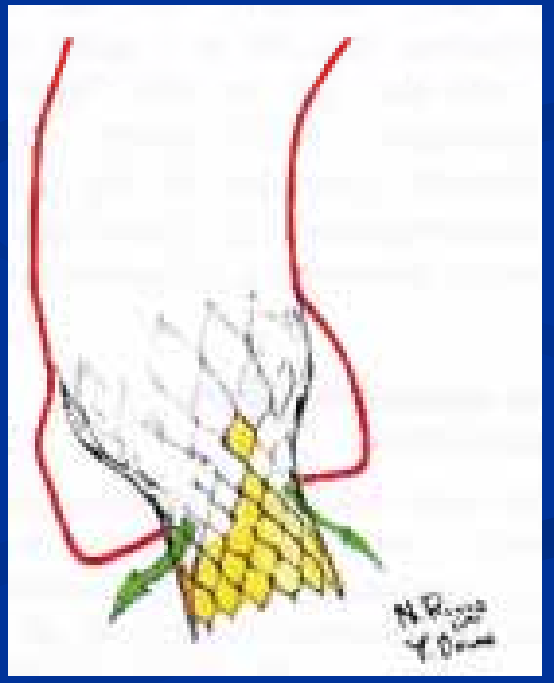
- Central valvular regurgitation
- Low deployment
- Inadequate apposition to leaflets / annulus due to severe valvular calcification +/- inadequate balloon dilatation



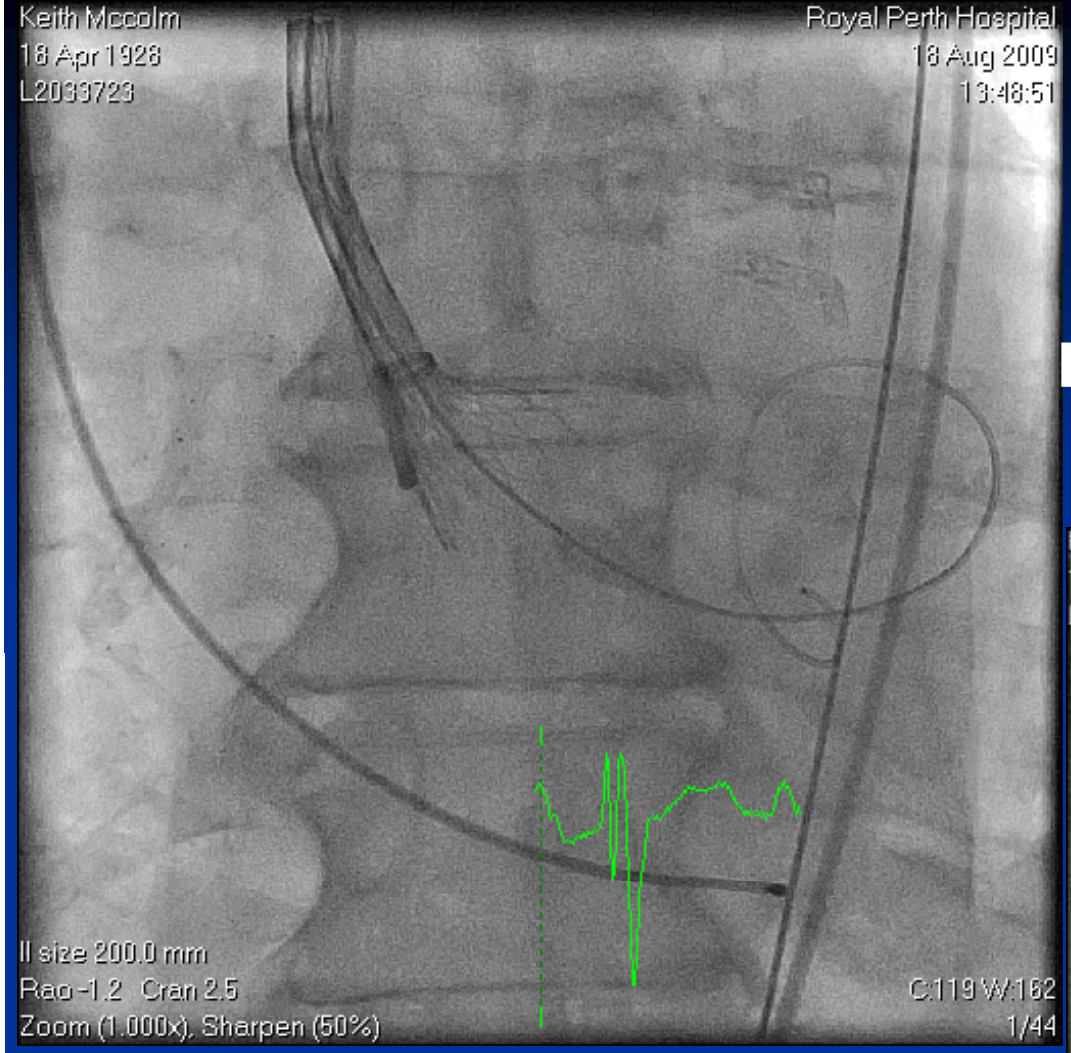


CORRECT POSITION

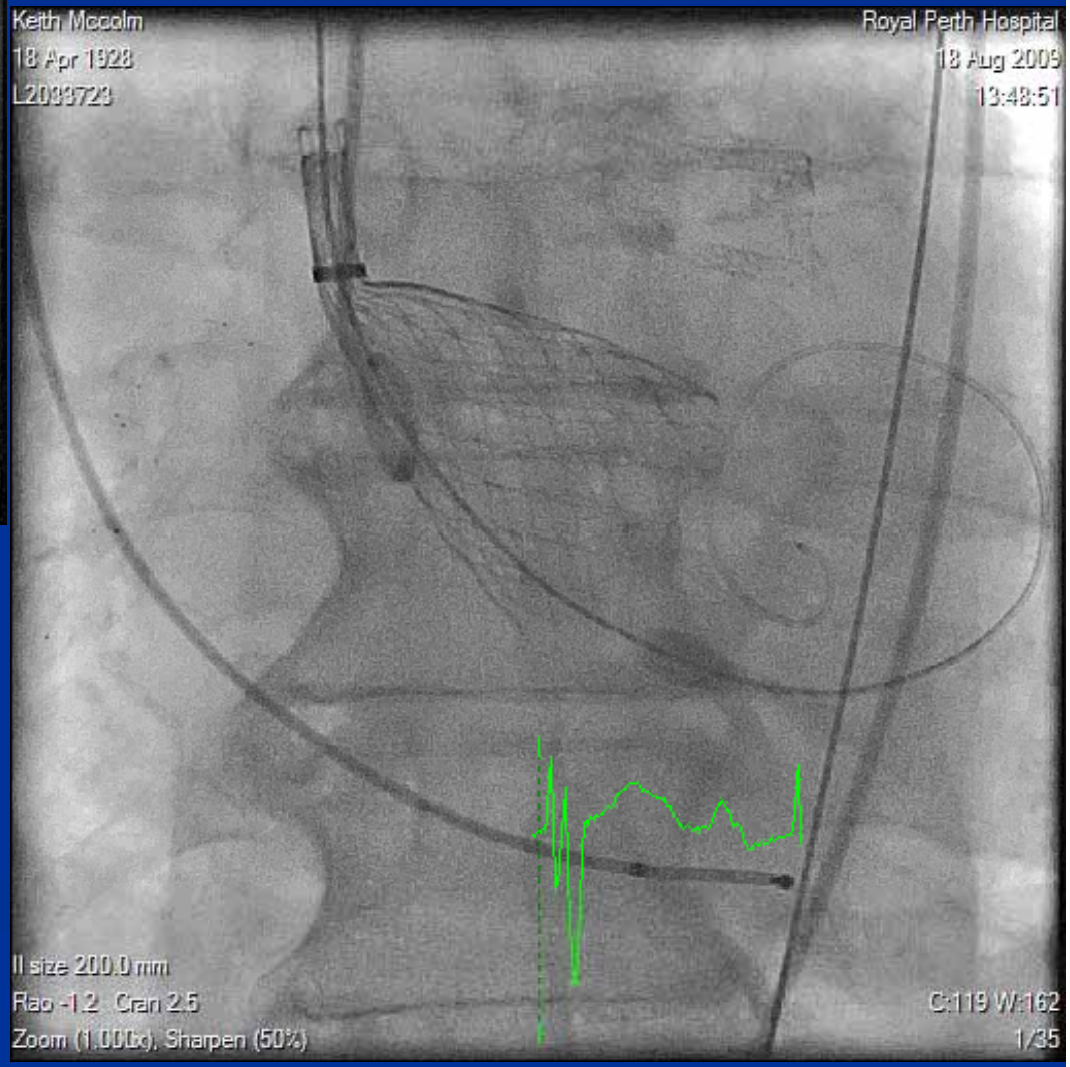




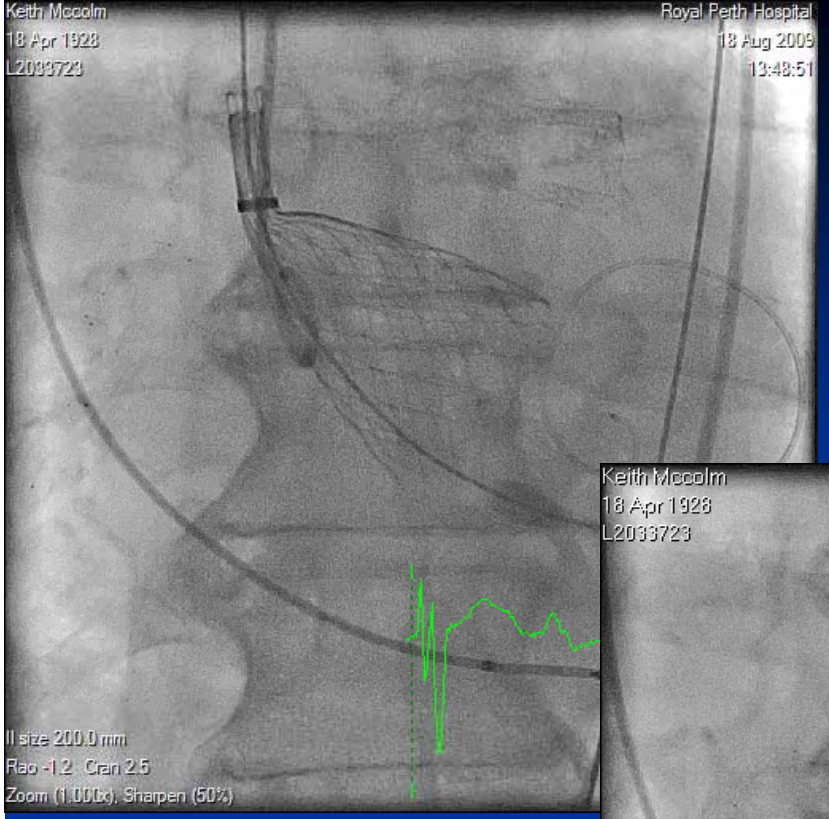
LOW POSITION

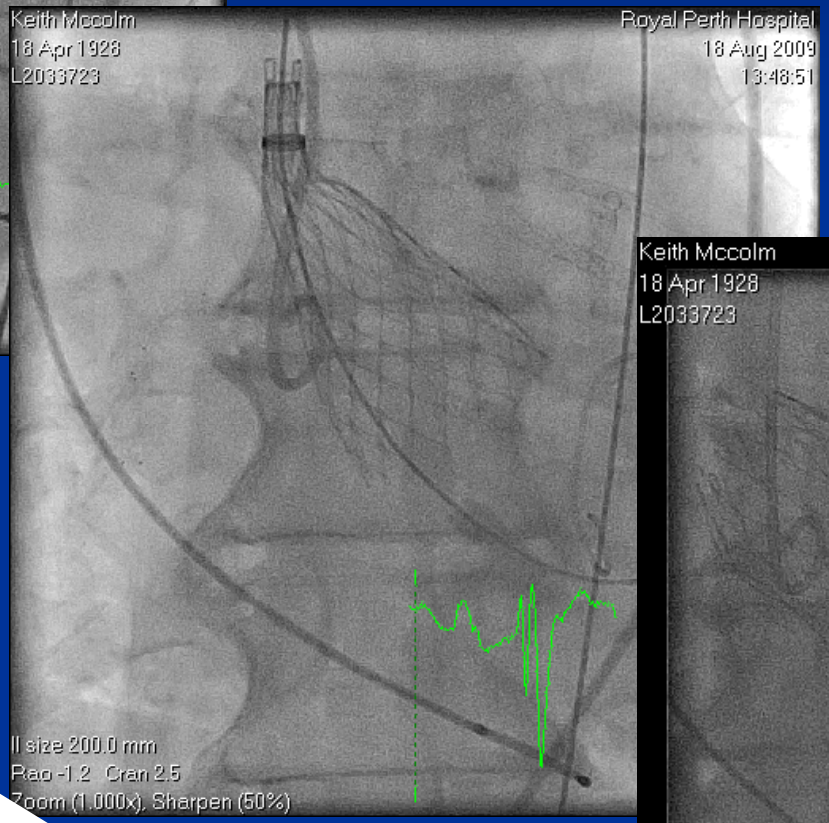


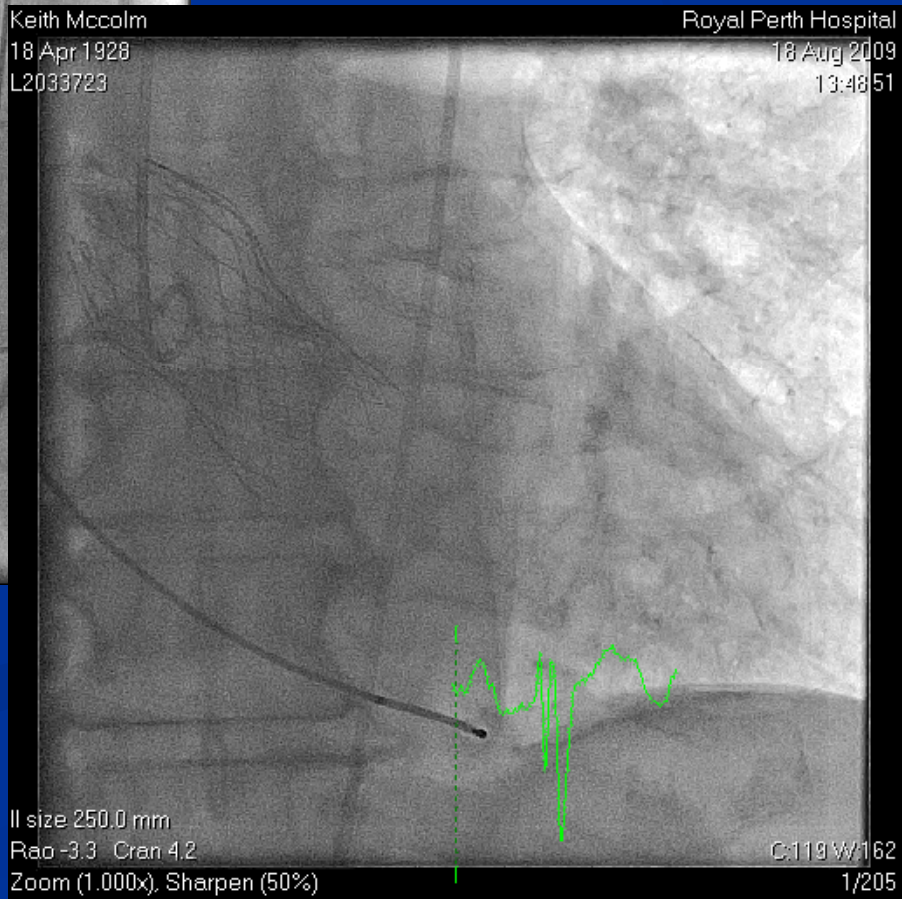
Valve dived ventricular!!



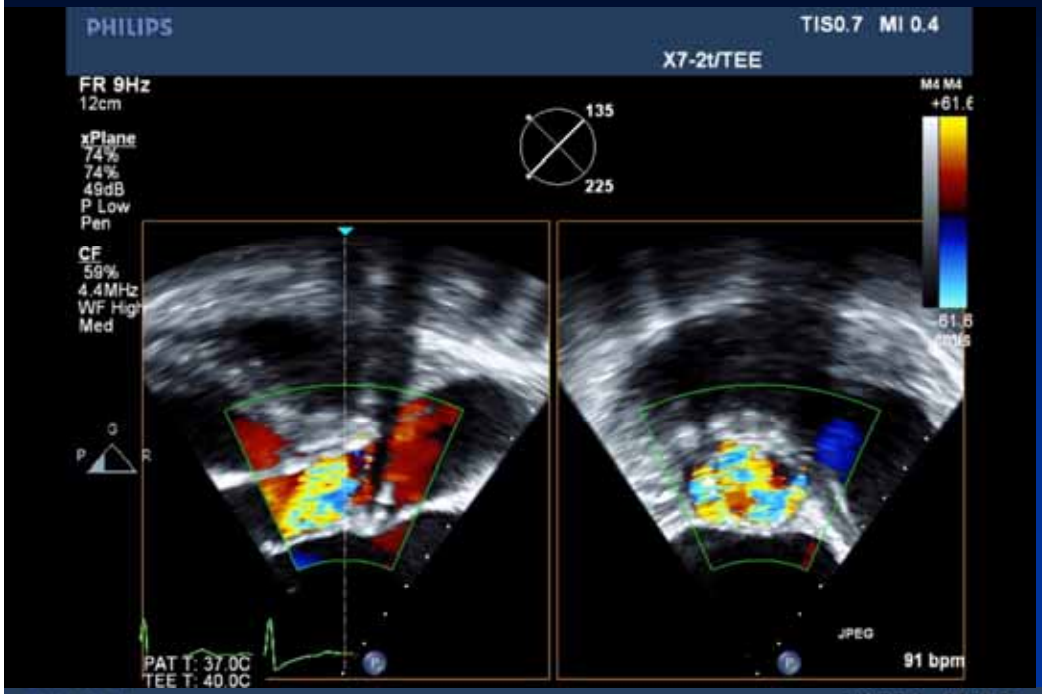
Gentle patient traction if valve not released yet....

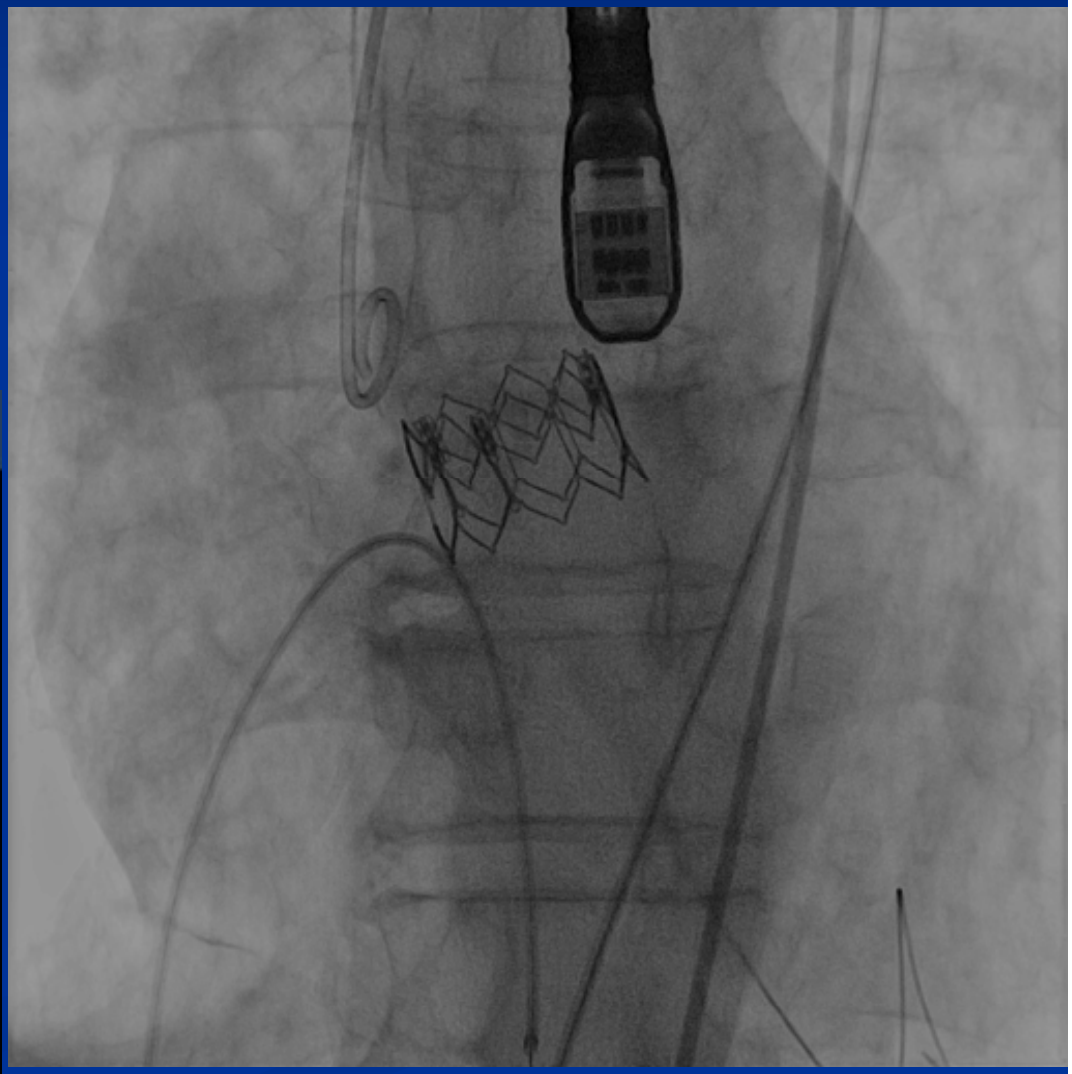


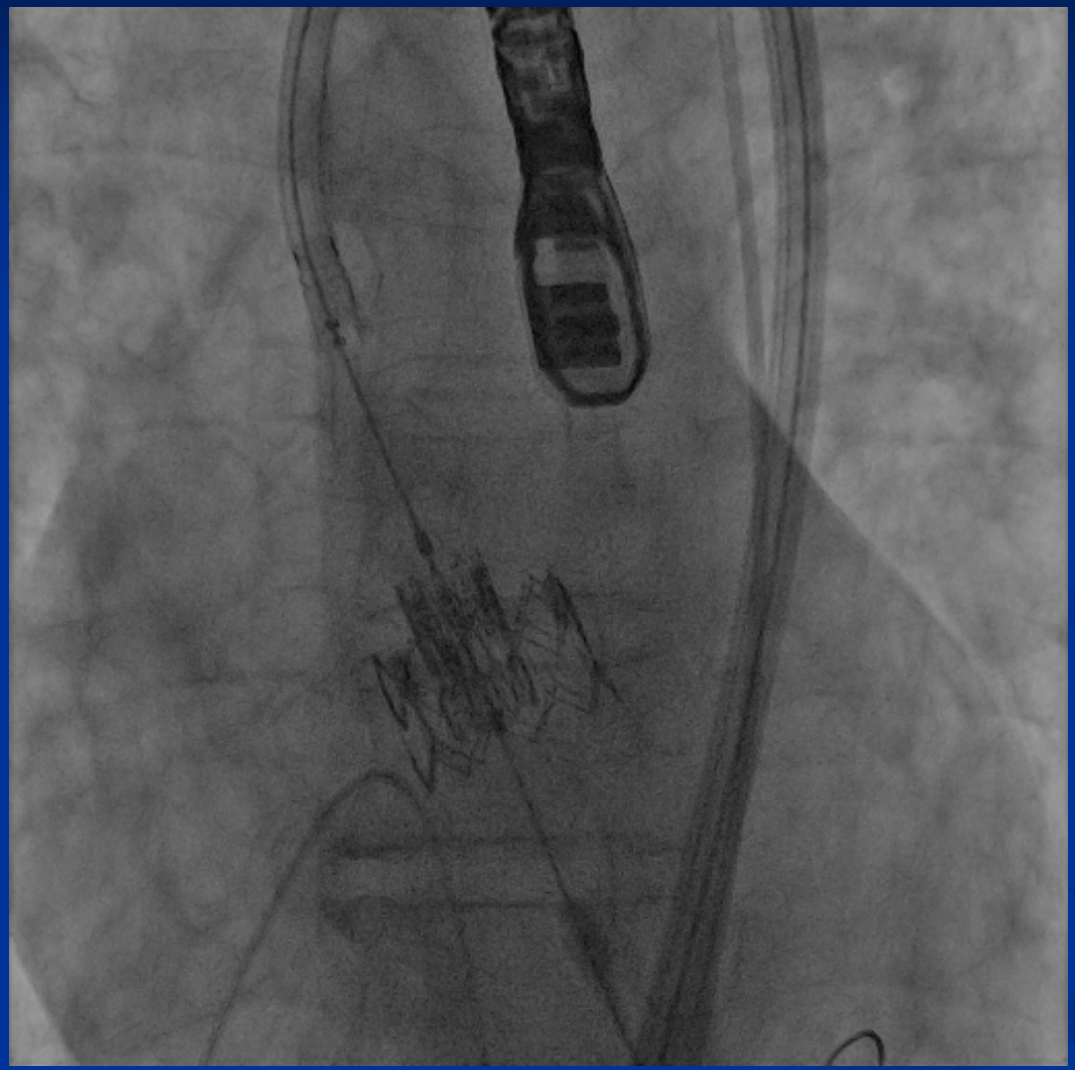


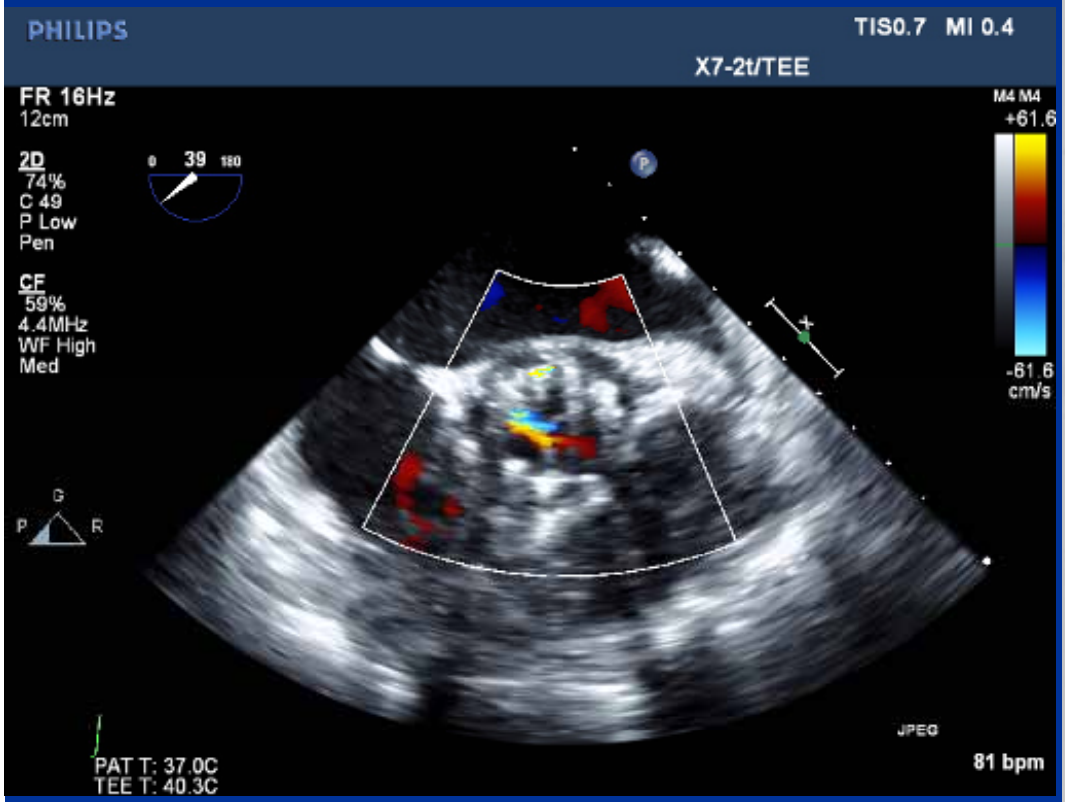


Severe PVL due to Low Positioning








PHILIPS
TIS0.7 MI 0.4
X7-2t/TEE
FR 16Hz
12cm
2D
74%
C 49
P Low
Pen
0 39 180
CF
59%
4.4MHz
WF High
Med
M4 M4
+61.6
-61.6
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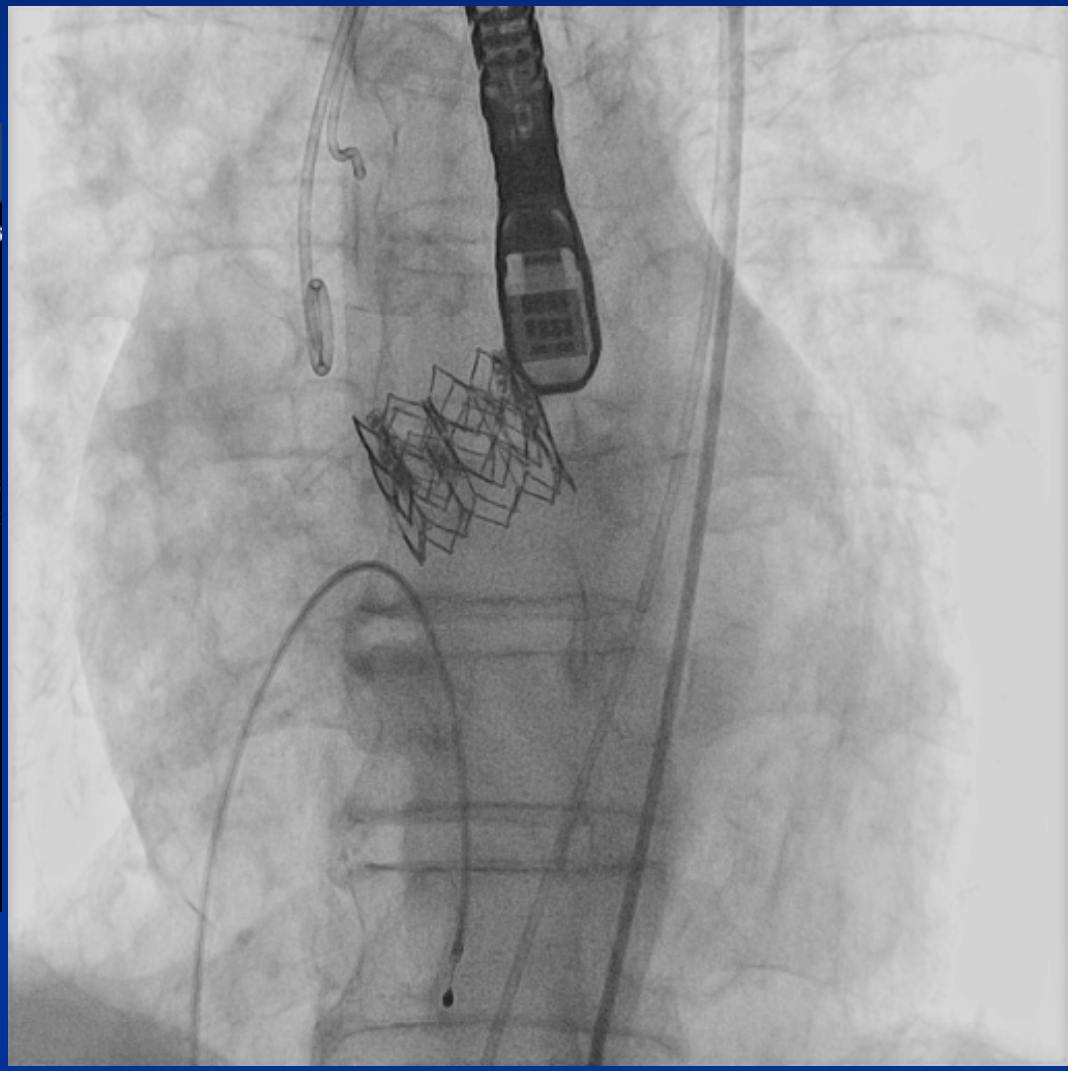
JPEG
81 bpm
PAT T: 37.0C
TEE T: 40.3C



Transcatheter Valve-In-Valve Implantation for Failed Balloon-Expandable Transcatheter Aortic Valves

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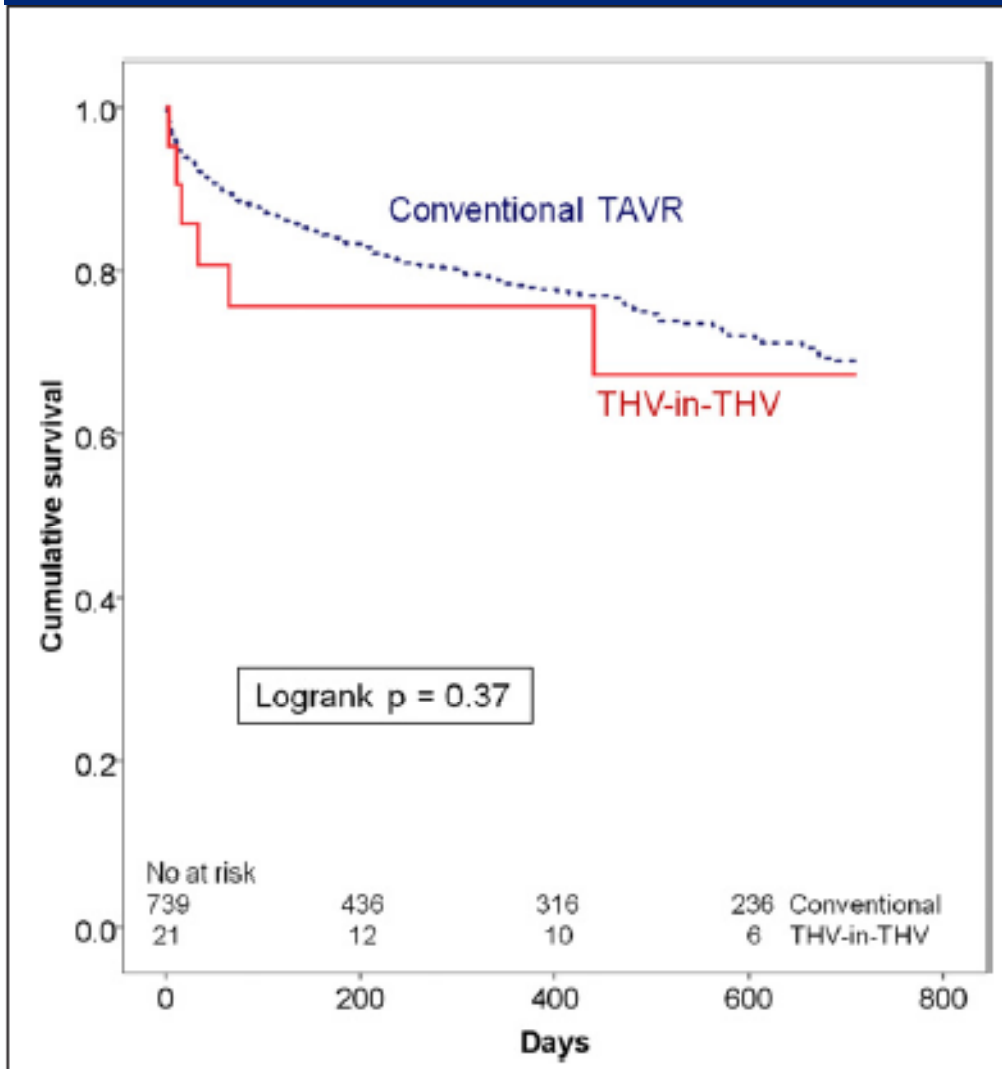
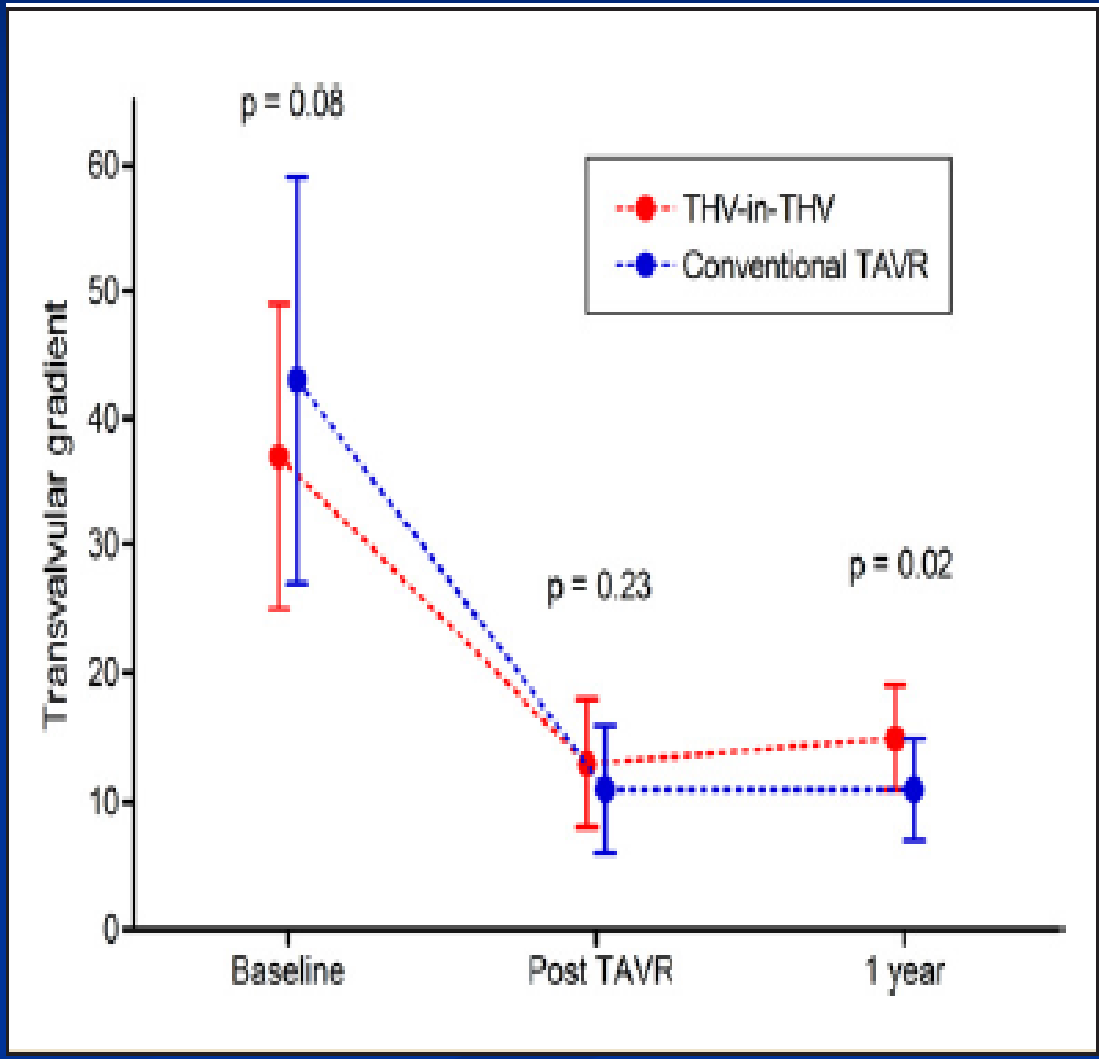
Samir Kapadia, MD,‡ Alexander B. Willson, MBBS, MPH,* Jian Ye, MD,*
Anson Cheung, MD,* Jonathon Leipsic, MD,* Ronald K. Binder, MD,*
Ronen Gurvitch, MBBS,* Melanie Freeman, MBBS,* Christopher R. Thompson, MD,*
Lars G. Svensson, MD,‡ Eric Dumont, MD,† E. Murat Tuzcu, MD,‡ John G. Webb, MD*

Vancouver, British Columbia, and Quebec City, Quebec, Canada; and Cleveland, Ohio

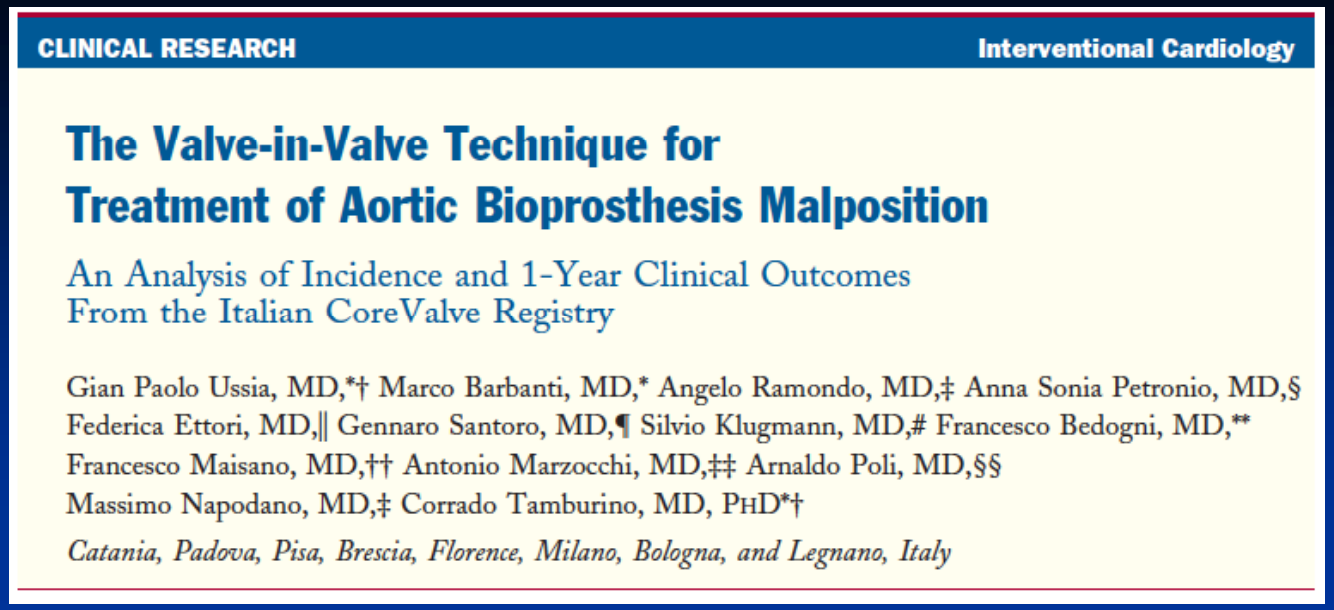
- 760 consecutive TAVR in 3 centers with balloon expandable valve
- THV-in-THV performed in 21 cases due to severe AR (2.8%)
- Reasons:
  - Malposition: 10 too aortic, 8 too ventricular
  - Valvular regurgitation: 3
- Technically successful in 19 patients
  - Unsuccessful in 2 patients due to ventricular embolization in both cases
- PPM - 2/21 (9.5%) (vs. 6% in conventional TAVR; p=NS))
- Stroke - 1/21 (4.7%) (vs. 2% in conventional TAVR; p=NS)

Toggweiler et al. J Am Coll Cardiol Intv 2012;5:571–7





Toggweiler et al. J Am Coll Cardiol Intv 2012;5:571–7



CLINICAL RESEARCH Interventional Cardiology

The Valve-in-Valve Technique for Treatment of Aortic Bioprosthesis Malposition

An Analysis of Incidence and 1-Year Clinical Outcomes From the Italian CoreValve Registry

Gian Paolo Ussia, MD,*† Marco Barbanti, MD,* Angelo Ramondo, MD,‡ Anna Sonia Petronio, MD,§ Federica Ettori, MD,‖ Gennaro Santoro, MD,¶ Silvio Klugmann, MD,# Francesco Bedogni, MD,** Francesco Maisano, MD,†† Antonio Marzocchi, MD,‡‡ Arnaldo Poli, MD,§§ Massimo Napodano, MD,‡ Corrado Tamburino, MD, PHD*†

Catania, Padova, Pisa, Brescia, Florence, Milano, Bologna, and Legnano, Italy

- 663 consecutives TAVR in 14 centers in Italy with CoreValve
- Valve-in-Valve rescue performed in 24 pts (3.6%)
- All successful technically
- No Coronary impairment
- Post-dilatation 50% (vs. 8.8% in conventional TAVR; $p<0.001$)
- PPM 33.3% (vs 14.5% in conventional TAVR; $p=0.02$)
- Stroke 0 (vs. 1.2% in conventional TAVR; p=NS)

Ussia et al. J Am Coll Cardiol 2011;57:1062–8

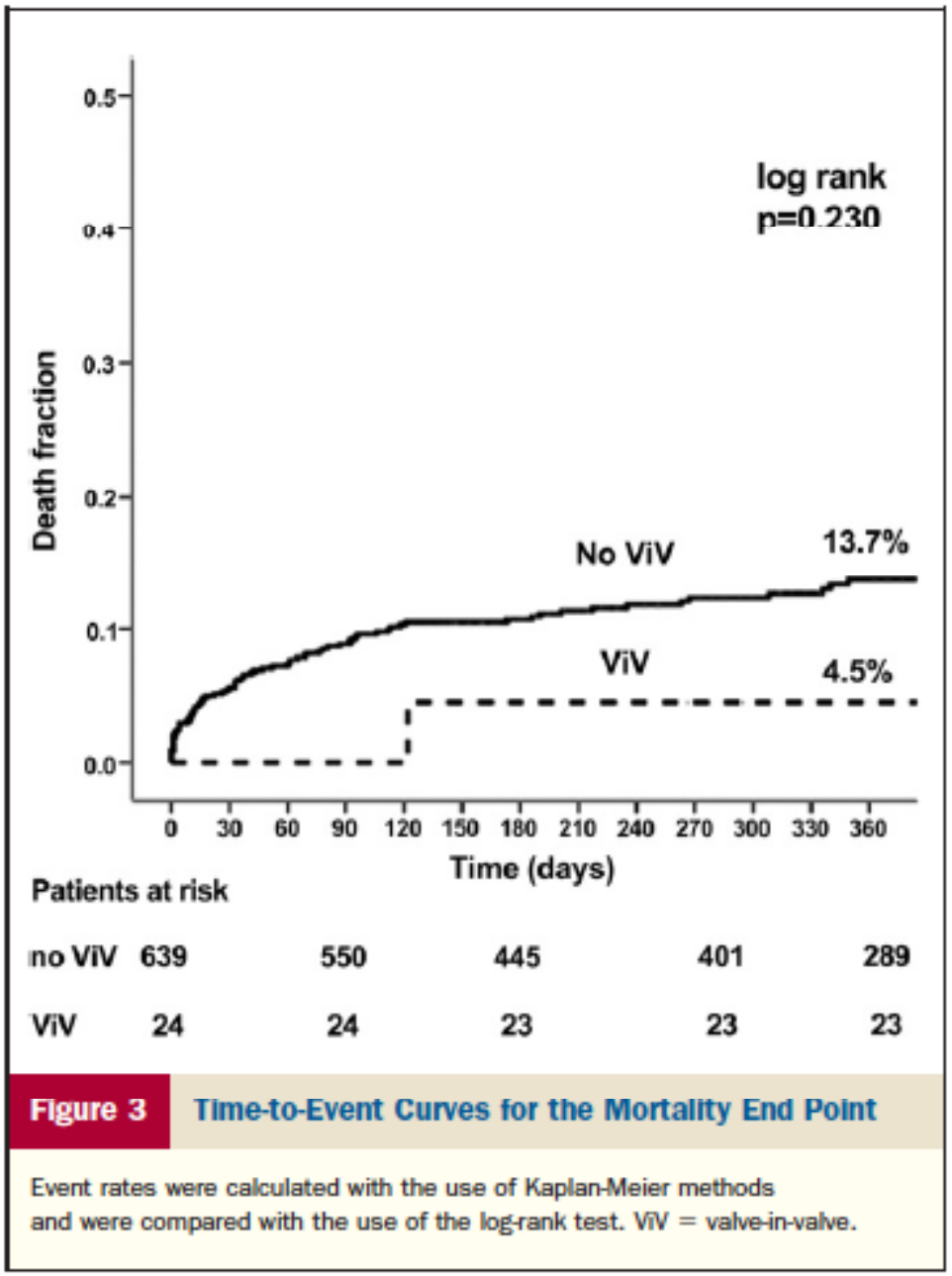


Figure 3 Time-to-Event Curves for the Mortality End Point

Event rates were calculated with the use of Kaplan-Meier methods and were compared with the use of the log-rank test. ViV = valve-in-valve.

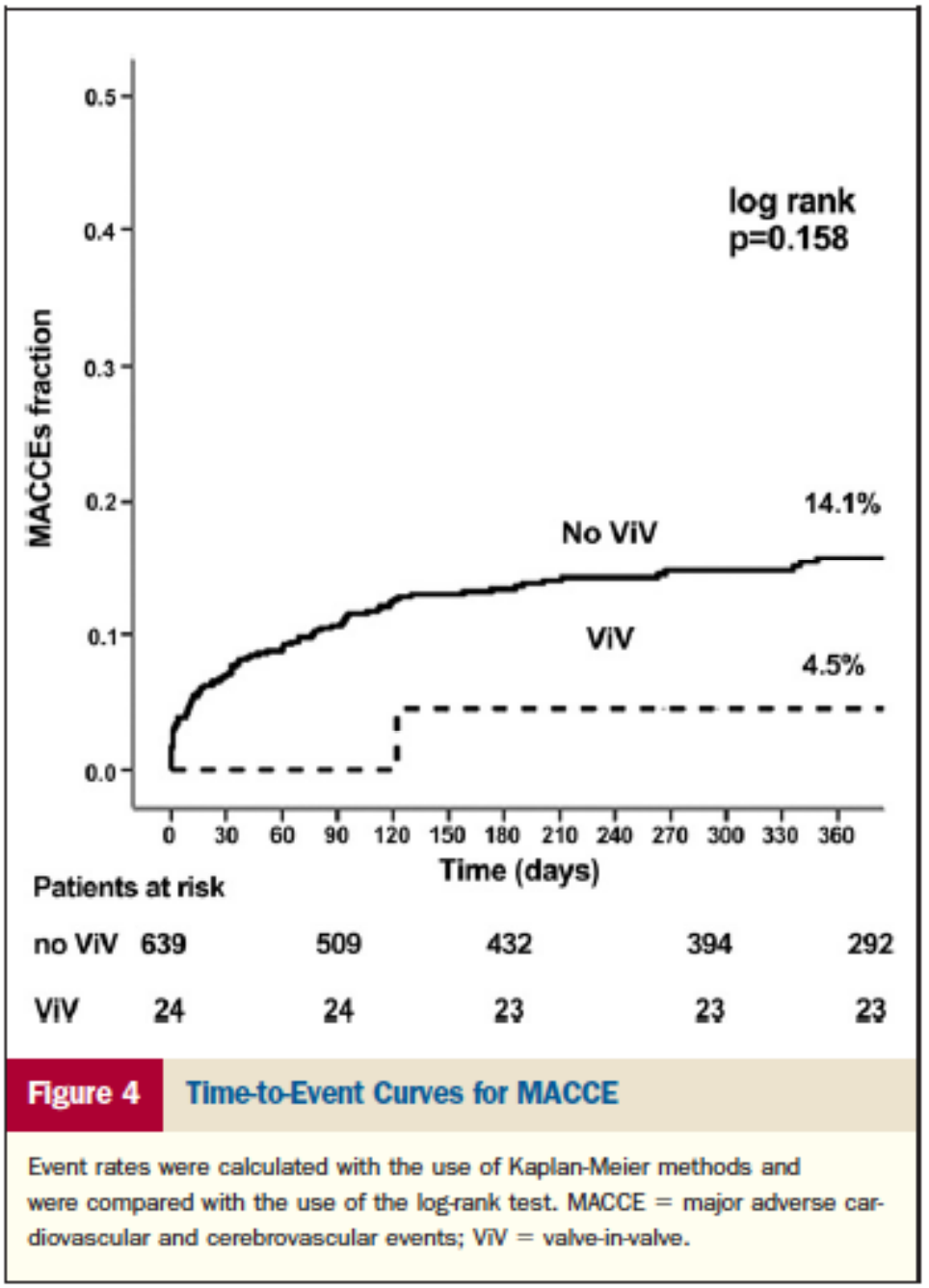


Figure 4 Time-to-Event Curves for MACCE

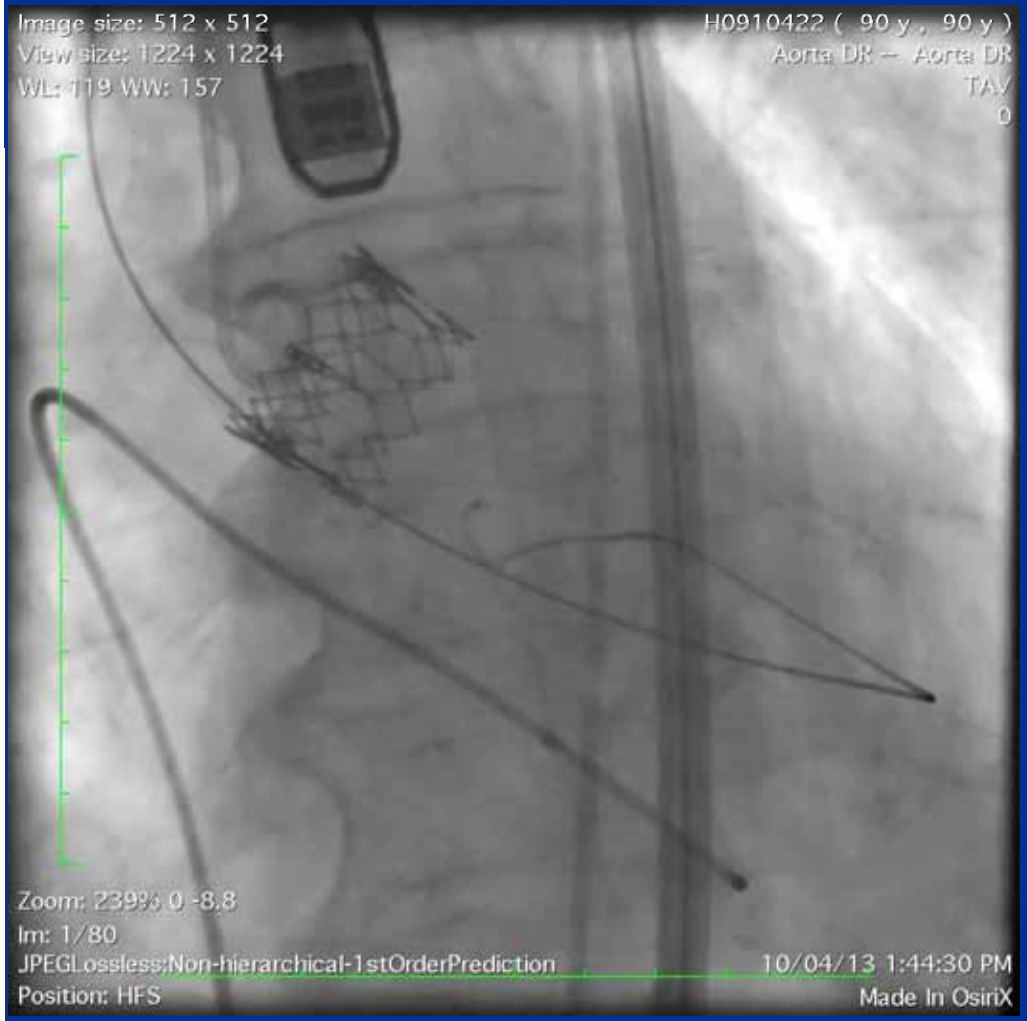
Event rates were calculated with the use of Kaplan-Meier methods and were compared with the use of the log-rank test. MACCE = major adverse cardiovascular and cerebrovascular events; ViV = valve-in-valve.

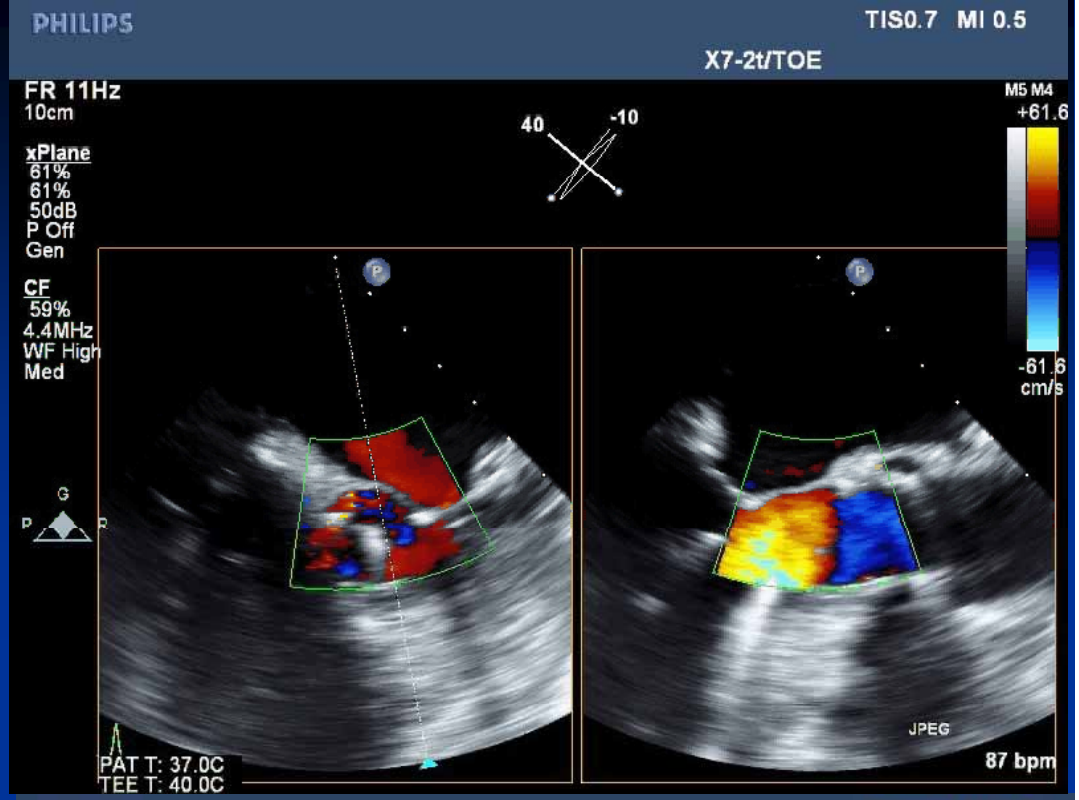
Ussia et al. J Am Coll Cardiol 2011;57:1062–8

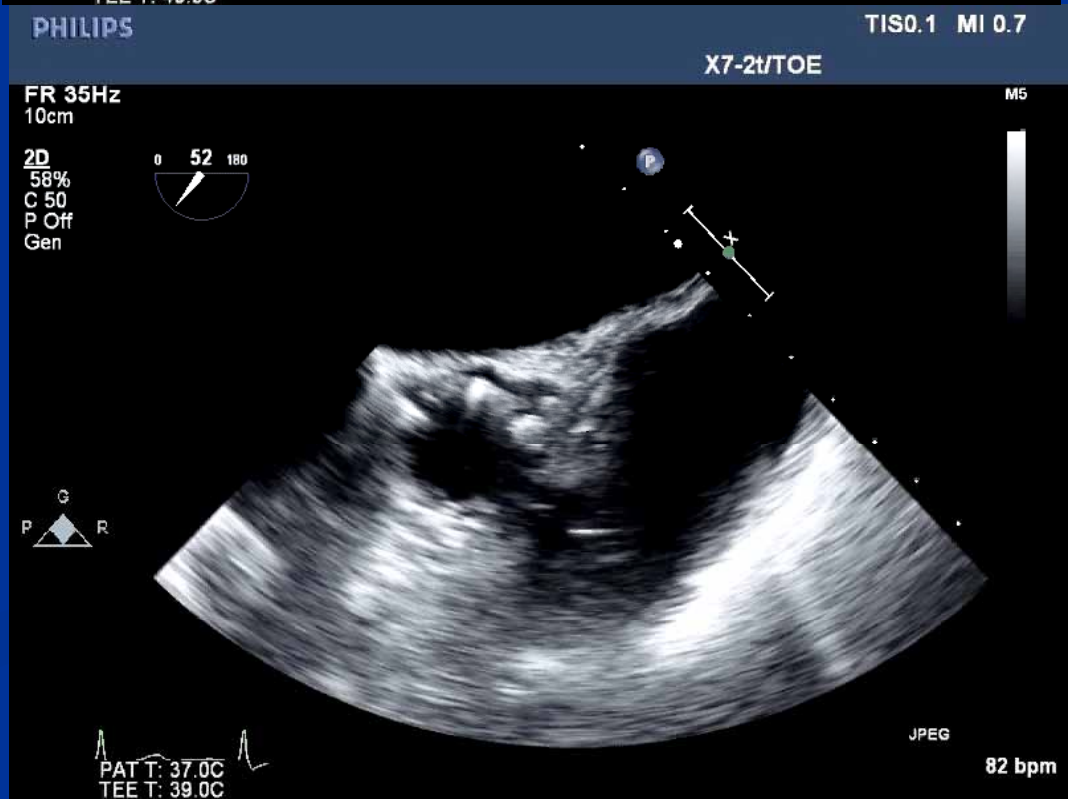
Possible Mechanisms of Severe Regurgitation Post-TAVI

- Central valvular regurgitation
- Low deployment
- Inadequate apposition to leaflets / annulus due to severe valvular calcification +/- inadequate balloon dilatation

Severe PVL post Edwards THV

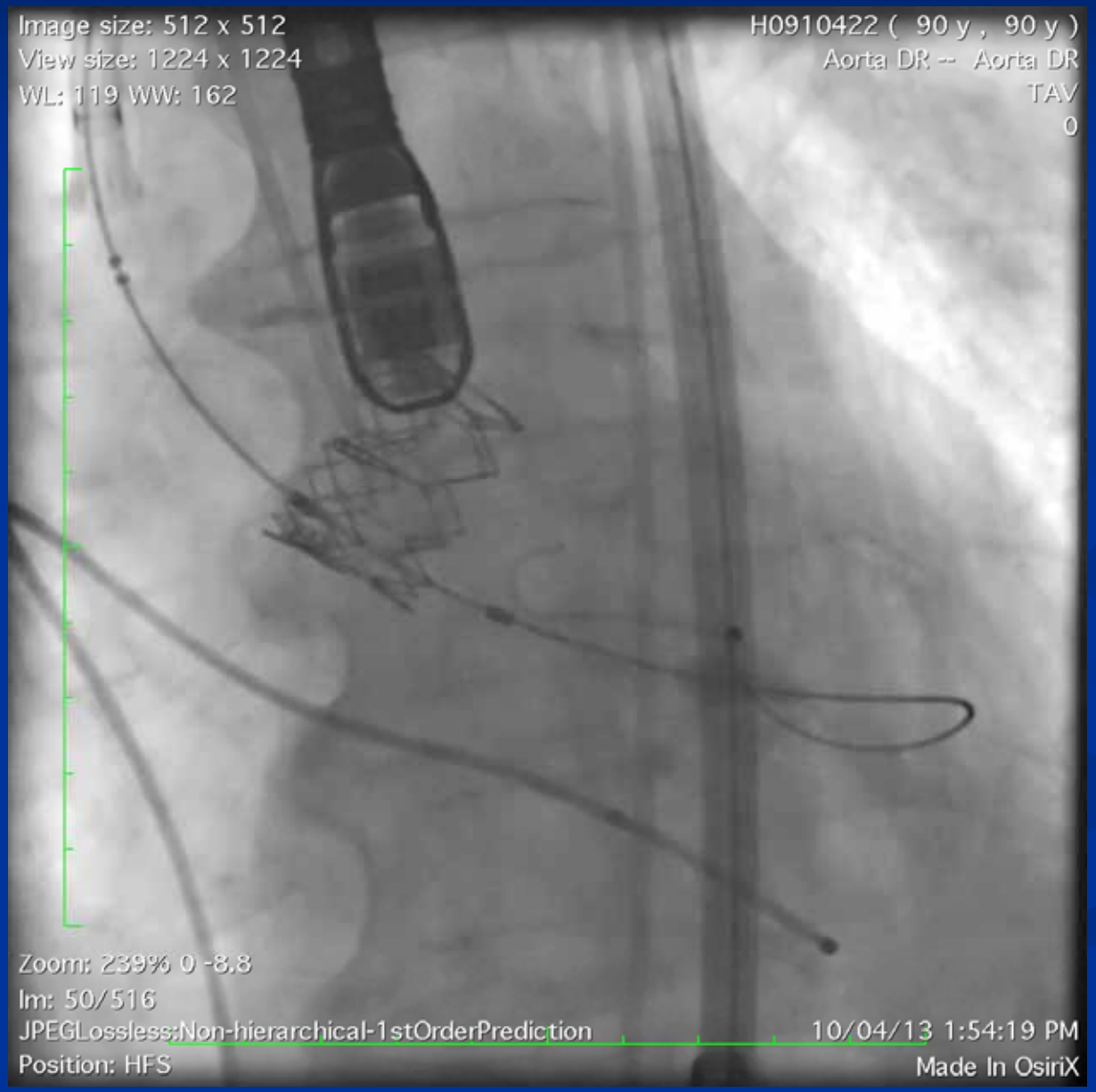




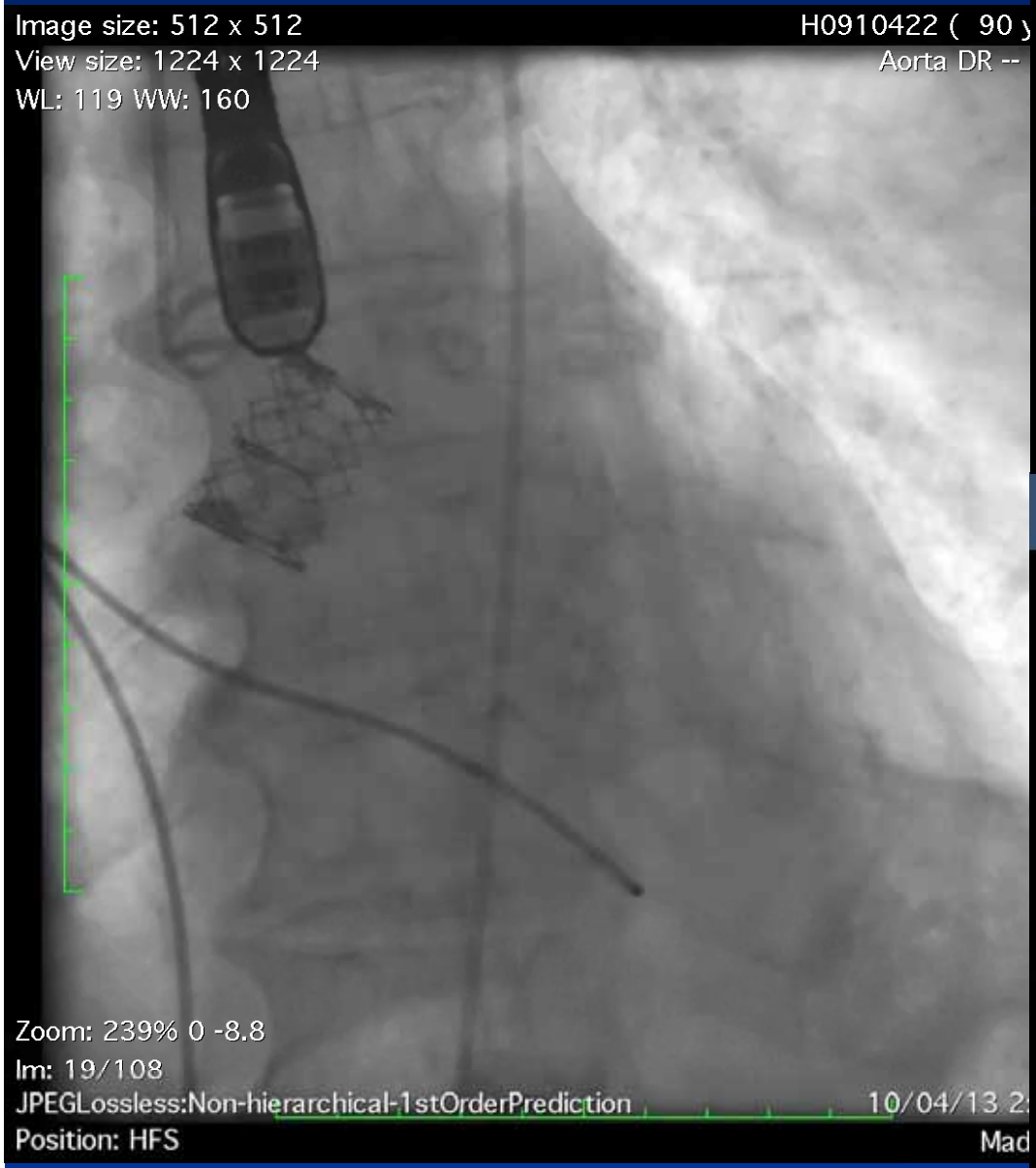


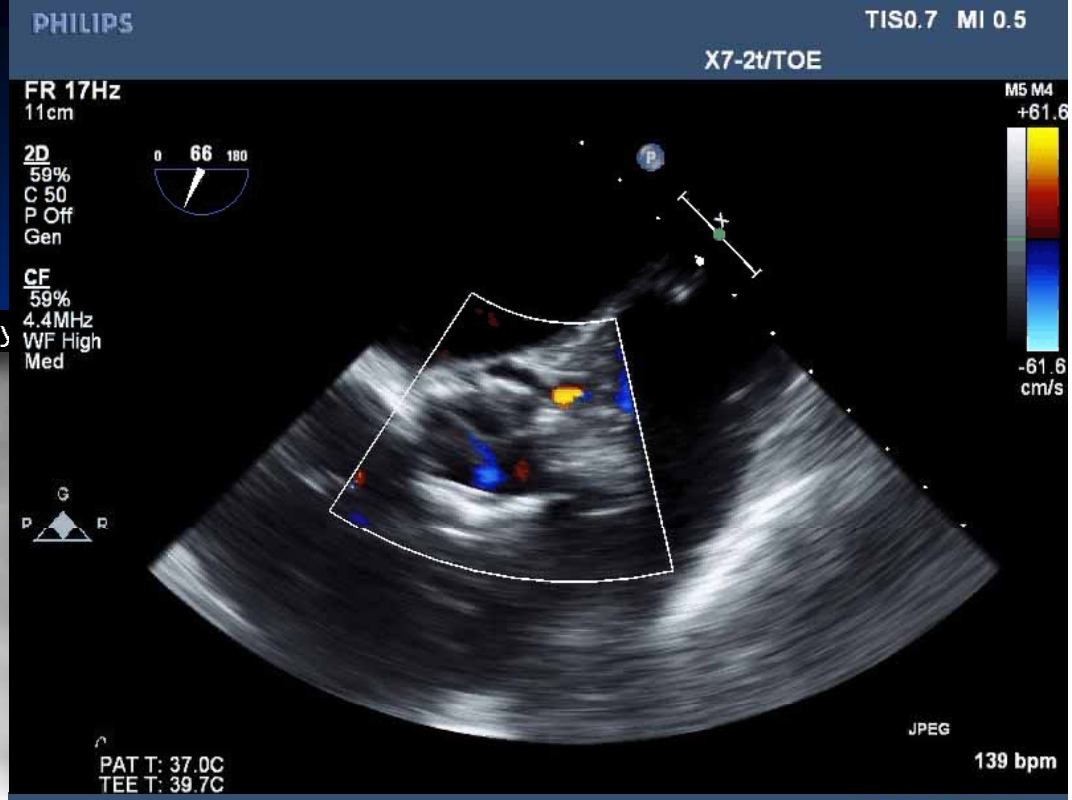
Severe Ca on non-coronary cusp and posterior annulus

Post-dilate – 26mm deployment balloon



Final Result





Post-Dilatation – Potential Complications

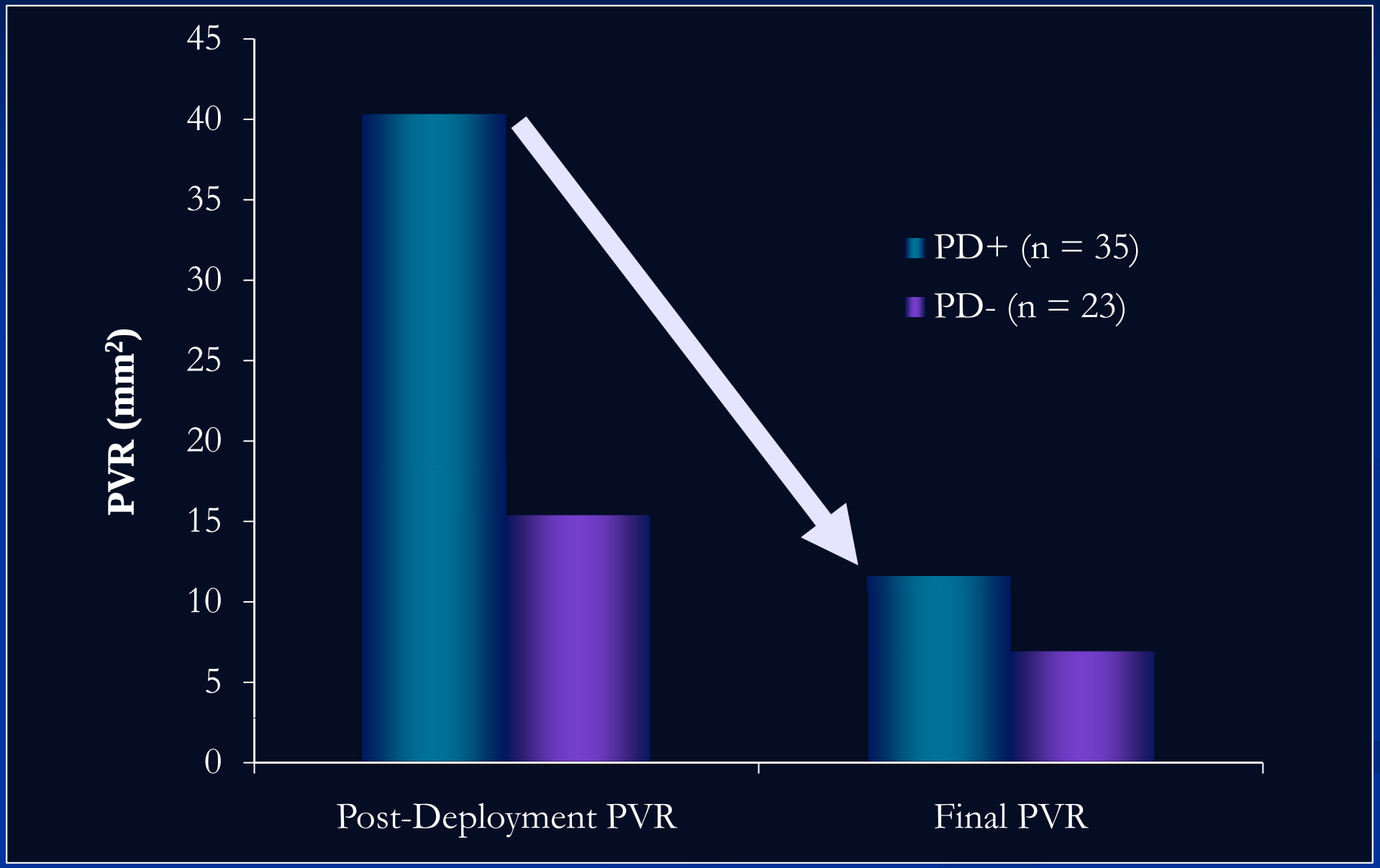
- Annular injury
- Valve embolisation
- Stroke
- Conduction system disturbance and PPM

Efficacy and Safety of Postdilatation to Reduce Paravalvular Regurgitation During Balloon-Expandable Transcatheter Aortic Valve Replacement

Benoit Daneault, MD; Elana Koss, MD; Rebecca T. Hahn, MD; Susheel Kodali, MD; Mathew R. Williams, MD; Philippe Généreux, MD; Jean-Michel Paradis, MD; Isaac George, MD; George R. Reiss, MD; Jeffrey W. Moses, MD; Craig R. Smith, MD; Martin B. Leon, MD

- 258 consecutive TAVR patients with balloon expandable valve in single centre
- Post-dilatation systematically performed if paravalvular regurgication ≥2+ - in 106 patients (41%)
- Same balloon as valve-deployment used
  - Between 0-2ml additional contrast added. Most common 1ml (86%)
- Post-dilatation patients
  - Larger annulus (on echo) – 23.2mm vs 21.9mm (p=0.009)
  - Lower cover index – 6.9% vs 10.1% (p=0.02)

Daneault, B., et al. *Circ Cardiovasc Interv.* 2013;6:85-91



Daneault, B., et al. *Circ Cardiovasc Interv.* 2013;6:85-91

30-day Clinical Outcomes
Post-dilatation vs No Post-dilatation

Table 3. Clinical Outcomes

	Postdilatation (n=106)	No Postdilatation (n=153)	OR (95% CI)	*P* Value
30-day mortality	2 (1.9%)	11 (7.2%)	0.25 (0.05–1.14)	0.06
30-day cardiac mortality	1 (0.9%)	6 (3.9%)	0.23 (0.03–1.97)	0.25
In-hospital cerebrovascular events				
All stroke or TIA	5 (4.7%)	2 (1.3%)	3.74 (0.71–19.64)	0.13
All stroke	4 (3.8%)	1 (0.7%)	5.96 (0.66–54.10)	0.16
Aortic dissection	1 (0.9%)	1 (0.7%)	1.45 (0.09–23.4)	1.00
Aortic wall hematoma	1 (0.9%)	3 (2.0%)	0.48 (0.05–4.64)	0.65
PPM implantation during index hospitalization	6 (5.7%)	13 (8.5%)	0.65 (0.24–1.76)	0.39

Daneault, B., et al. *Circ Cardiovasc Interv.* 2013;6:85-91

Conclusion

- Paravalvular regurgitation is common after TAVR
- Aortic regurgitation post-TAVR impacts on clinical outcomes
- Main method of avoidance
  - Avoid undersizing
  - Deploy at appropriate level

Conclusion

- Central valvular regurgitation
  - Rx – Deploy 2nd valve within first valve (Valve-in-valve)
- Low deployment
  - Rx - Attempt to retract valve – CoreValve
  - Rx - Valve in valve
- Inadequate apposition to leaflets / annulus due to severe valvular calcification +/- inadequate balloon dilatation
  - Post-dilate
  - Para-valvular plugs

Emerging devices with reduced rate of PVL

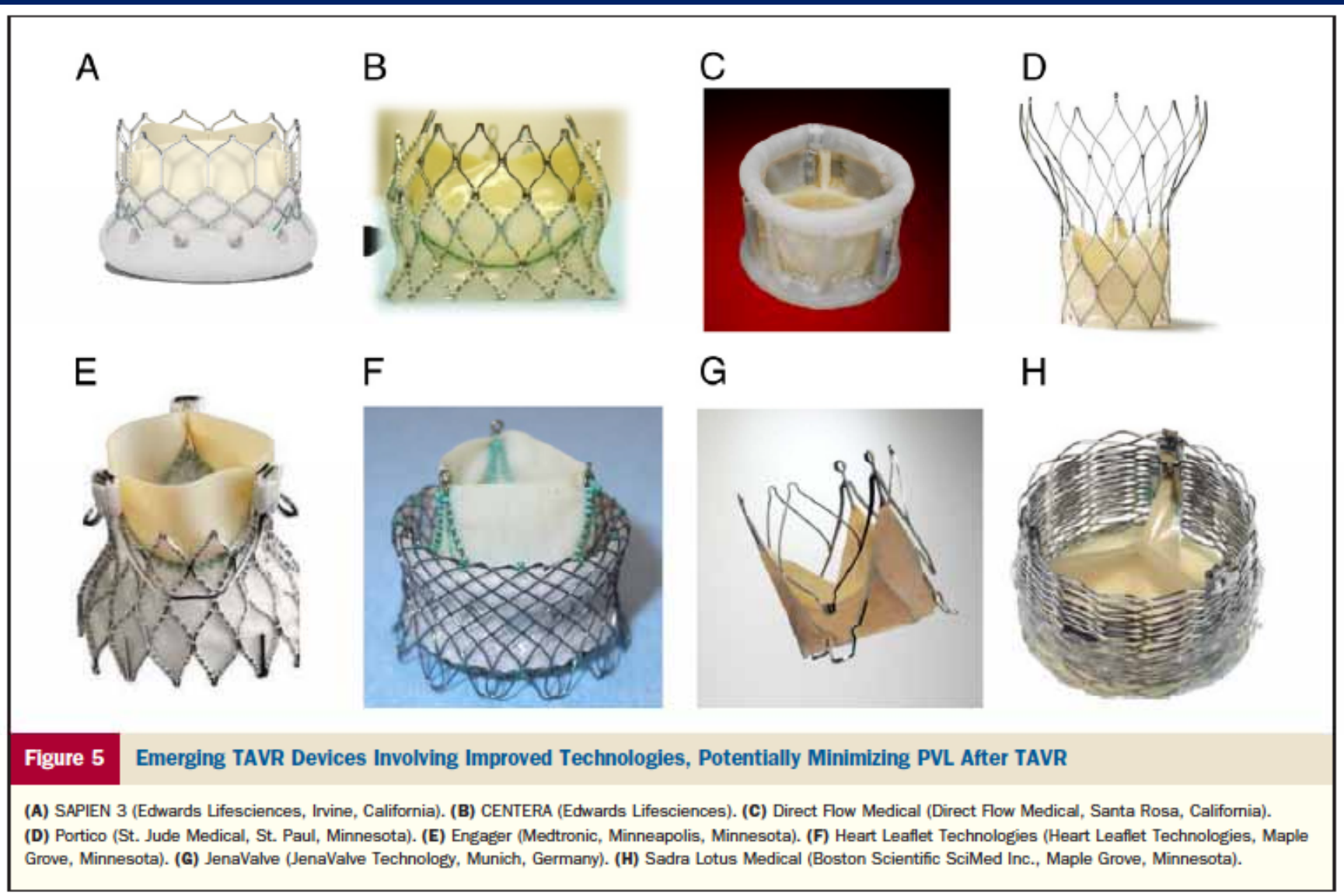


Figure 5 **Emerging TAVR Devices Involving Improved Technologies, Potentially Minimizing PVL After TAVR**

(A) SAPIEN 3 (Edwards Lifesciences, Irvine, California). **(B)** CENTERA (Edwards Lifesciences). **(C)** Direct Flow Medical (Direct Flow Medical, Santa Rosa, California). **(D)** Portico (St. Jude Medical, St. Paul, Minnesota). **(E)** Engager (Medtronic, Minneapolis, Minnesota). **(F)** Heart Leaflet Technologies (Heart Leaflet Technologies, Maple Grove, Minnesota). **(G)** JenaValve (JenaValve Technology, Munich, Germany). **(H)** Sadra Lotus Medical (Boston Scientific SciMed Inc., Maple Grove, Minnesota).

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THE IMPACT OF INTEGRATION OF A COMPUTED TOMOGRAPHY ANNULUS AREA SIZING ALGORITHM ON CLINICAL OUTCOMES OF TRANSCATHETER AORTIC VALVE REPLACEMENT: A PROSPECTIVE, MULTICENTER, CONTROLLED TRIAL

Oral Contributions
West, Room 2010
Sunday, March 10, 2013, 11:45 a.m.-Noon

Session Title: Valvular Heart Disease: Prognostic Features and Technical Advances to Optimize TAVR Outcomes
Abstract Category: 32. Valvular Heart Disease: Therapy
Presentation Number: 931-7

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Background: Appreciation of the complex non-circular geometry of the aortic annulus by three-dimensional imaging is important for accurate transcatheter heart valve (THV) size selection. We prospectively investigated the impact of integration of a multidetector computed tomography (MDCT) annular area sizing algorithm on transcatheter aortic valve replacement (TAVR) outcomes.

Methods: Patients planned for TAVR in four high-volume, experienced centers underwent pre-procedural MDCT. Recommendations for THV size were based on a MDCT sizing algorithm with an optimal goal of modest annulus area over sizing (5 % - 10 %). Consecutive patients, who underwent TAVR with the implementation of the algorithm (MDCT group), were compared to consecutive patients, who underwent TAVR without the algorithm (control group, CG) prior to trial initiation. Primary endpoint was the incidence of more than mild paravalvular regurgitation (PAR) and the secondary endpoint was the composite of in-hospital death, aortic annular rupture, THV-in-THV implantation and THV embolization.

Results: Of 324 patients, in the trial, 108 patients underwent TAVR (SAPIEN XT THV) with the implementation of the MDCT sizing algorithm (MDCT group) and 216 patients without the algorithm (CG). Post procedural aortic valve area was 1.6 ± 0.3 cm2 in the MDCT group and 1.6 ± 0.4 cm2 in the CG (p = 0.578). Moderate or severe PAR was apparent in 3.7 % (4/108) in the MDCT group and 10.2 % (22/216) in the CG (p = 0.043). The combined secondary endpoint occurred in 2.8 % in the MDCT group and in 9.3 % in the CG (p = 0.032). There were 3 (2.8 %) in-hospital deaths in the MDCT group and 12 (5.6 %) in the CG (p = 0.262). The rates of annular rupture were 0.9 % vs 1.4 % (p = 0.722), THV-in-THV implantation 0 % vs 1.9 % (p = 0.155) and THV embolization 0 % vs 3.2 % (p = 0.059) in the MDCT group vs CG respectively.

Conclusion: In this prospective, multicenter, controlled trial the implementation of a MDCT annulus area sizing algorithm for TAVR significantly reduced PAR and the combined endpoint of in-hospital death, annular rupture, THV-in-THV implantation and THV embolization. Three-dimensional aortic annular assessment and annular area sizing by MDCT should be recommended for TAVR.