Paravalvular leak: acceptable or not

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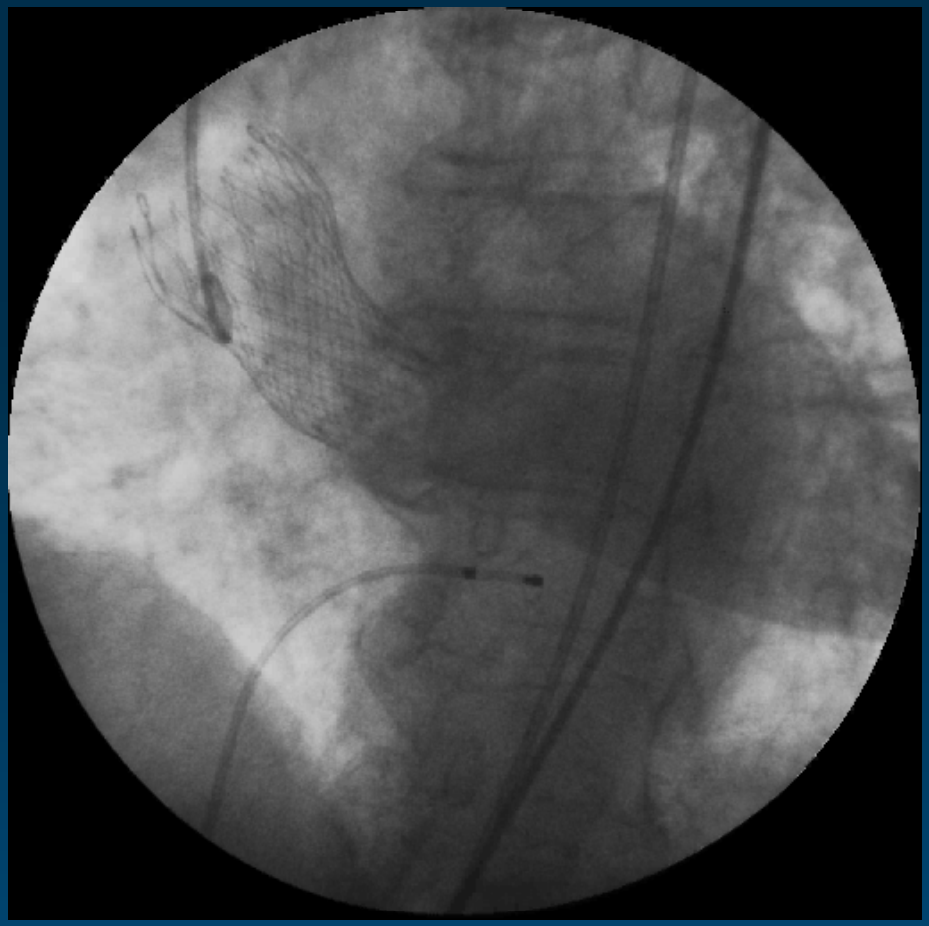
Disclosure Statement of Financial Interest

I, Corrado Tamburino, DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation

Para-valvular leak after TAVI

Just a cosmetic issue?



Para-valvular leak after TAVI

What we have learnt

- Very common finding after TAVI
- Usually trivial or mild
- Multimodal degree quantification
- Long-term impact

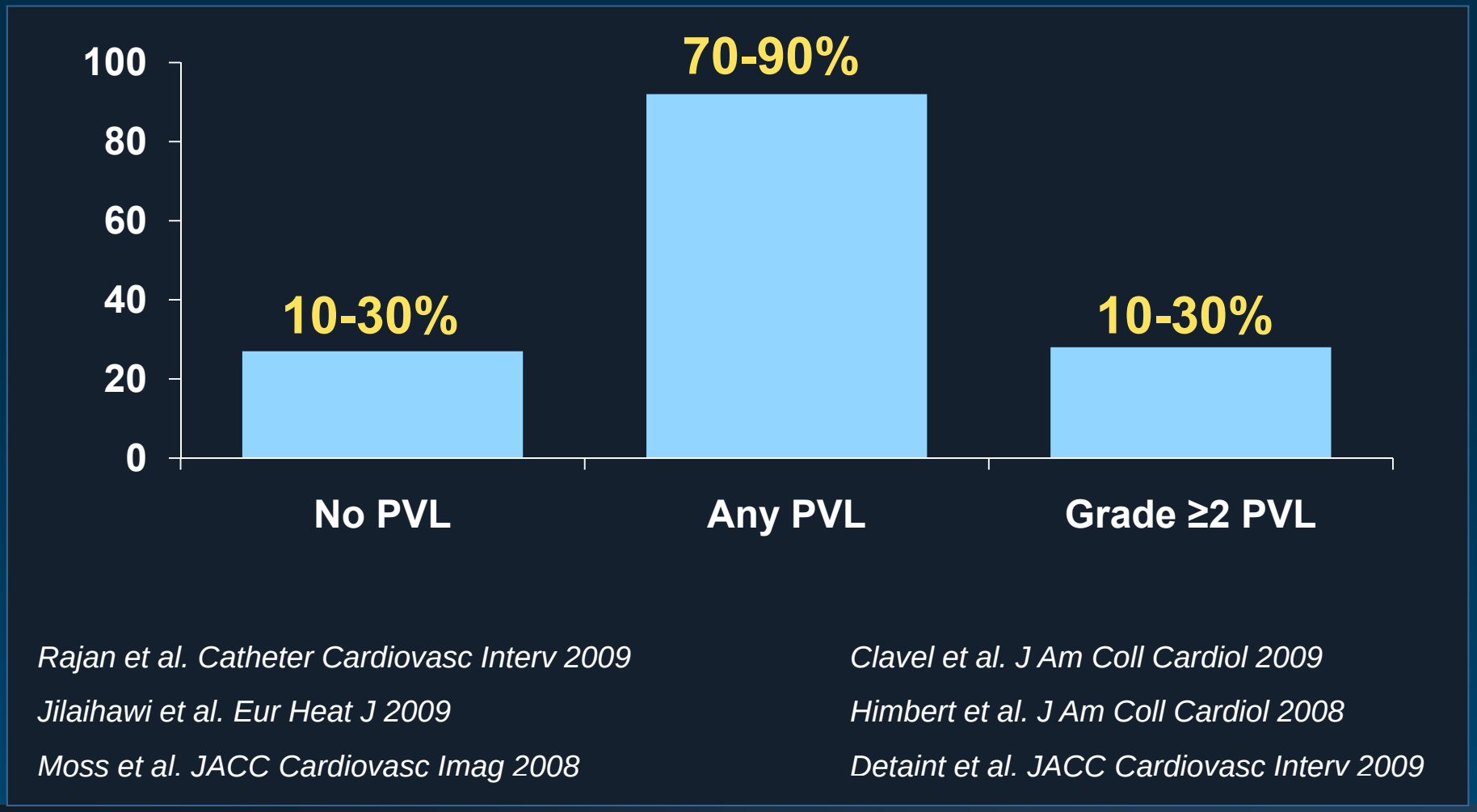
Para-valvular leak after TAVI

Roadmap of the lecture

- **What is the incidence?**
- **Is it associated with worse outcomes?**
- **Is it predictable?**
- **How to manage it?**

Para-valvular leak after TAVI

Incidence, ES & CRS



Rajan et al. Catheter Cardiovasc Interv 2009

Jilaihawi et al. Eur Heat J 2009

Moss et al. JACC Cardiovasc Imag 2008

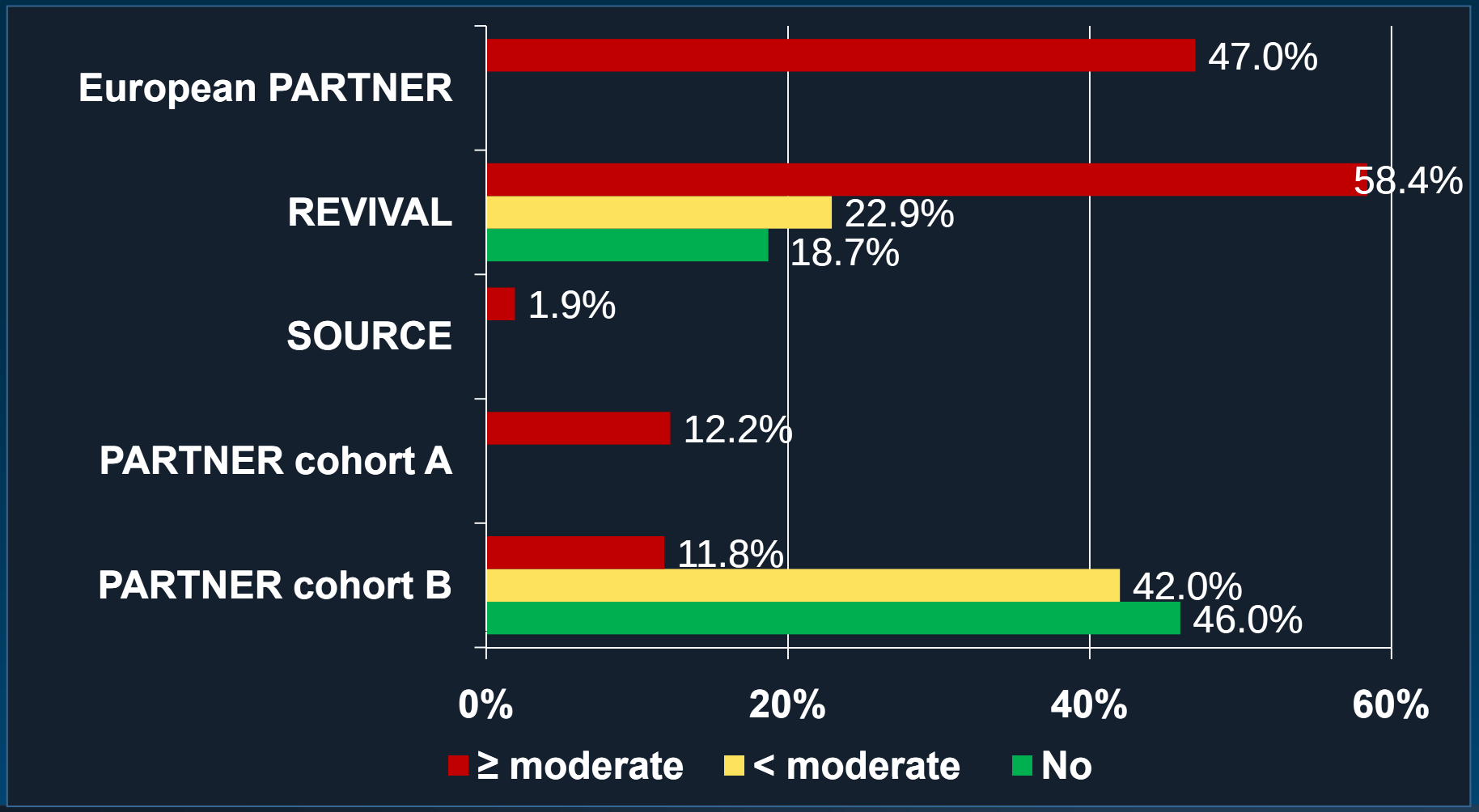
Clavel et al. J Am Coll Cardiol 2009

Himbert et al. J Am Coll Cardiol 2008

Detaint et al. JACC Cardiovasc Interv 2009

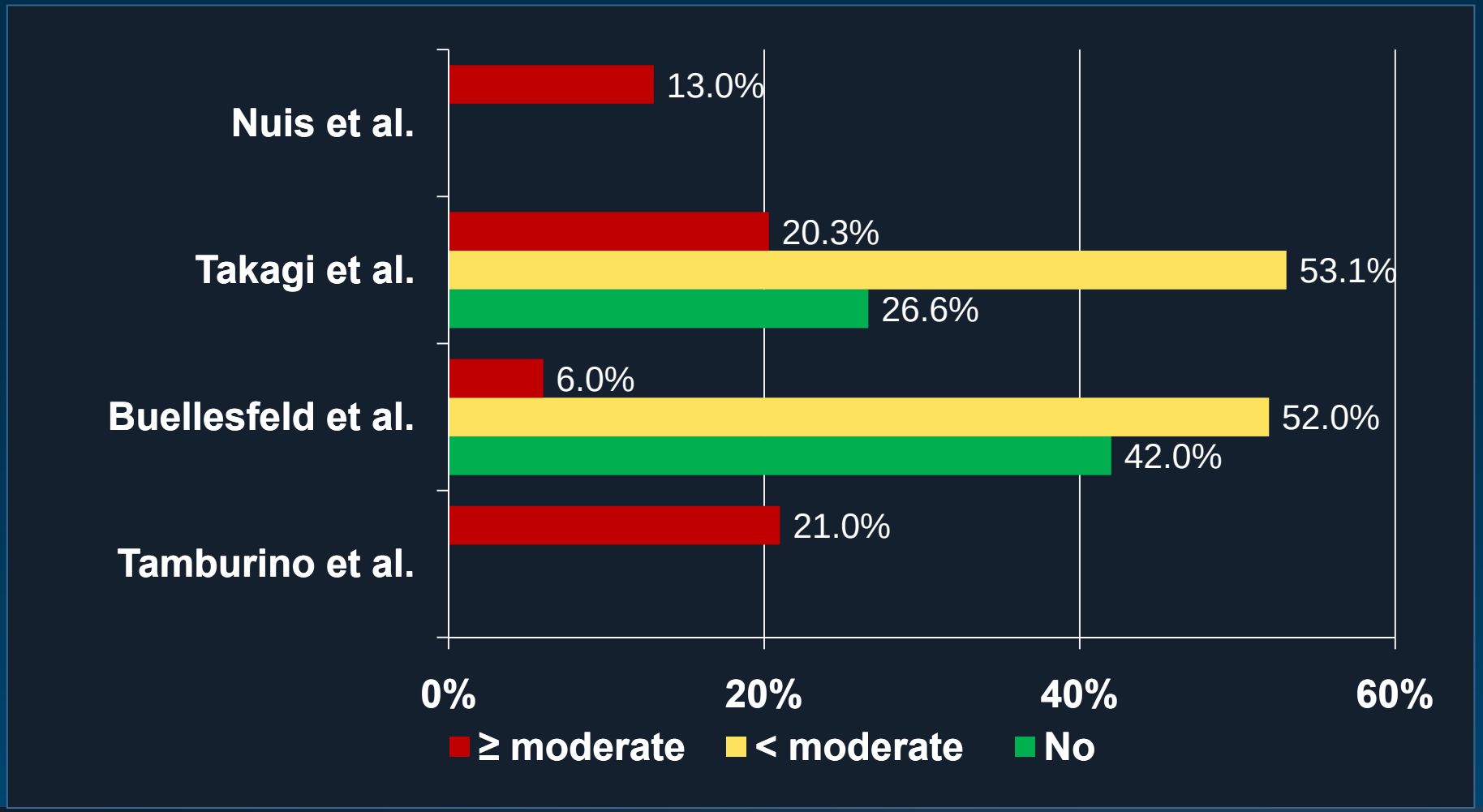
Para-valvular leak after TAVI

Incidence, Edwards-SAPIEN



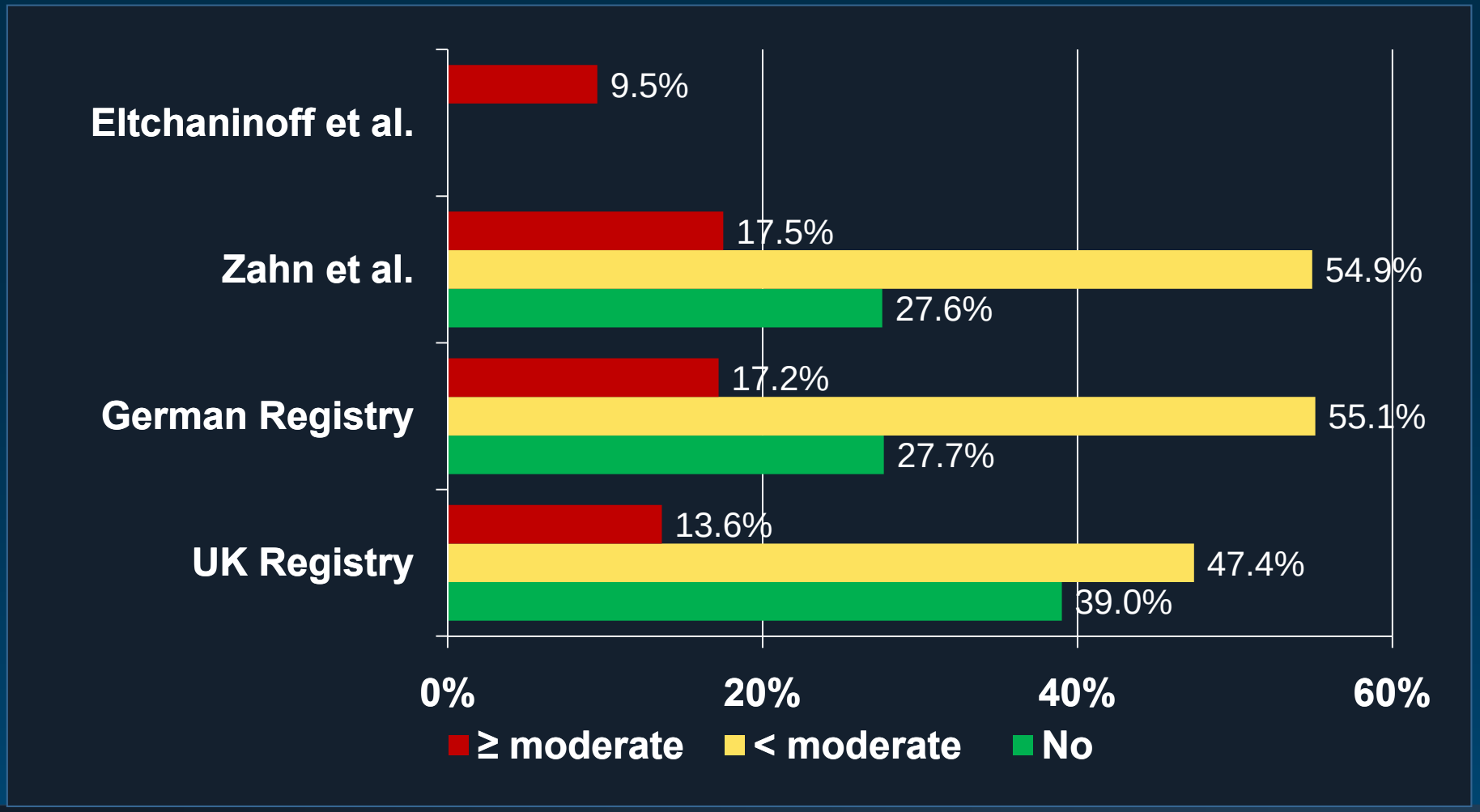
Para-valvular leak after TAVI

Incidence, CoreValve



Para-valvular leak after TAVI

Incidence, ES & CRS



Para-valvular leak after TAVI

Impact on outcomes

Valvular Heart Disease

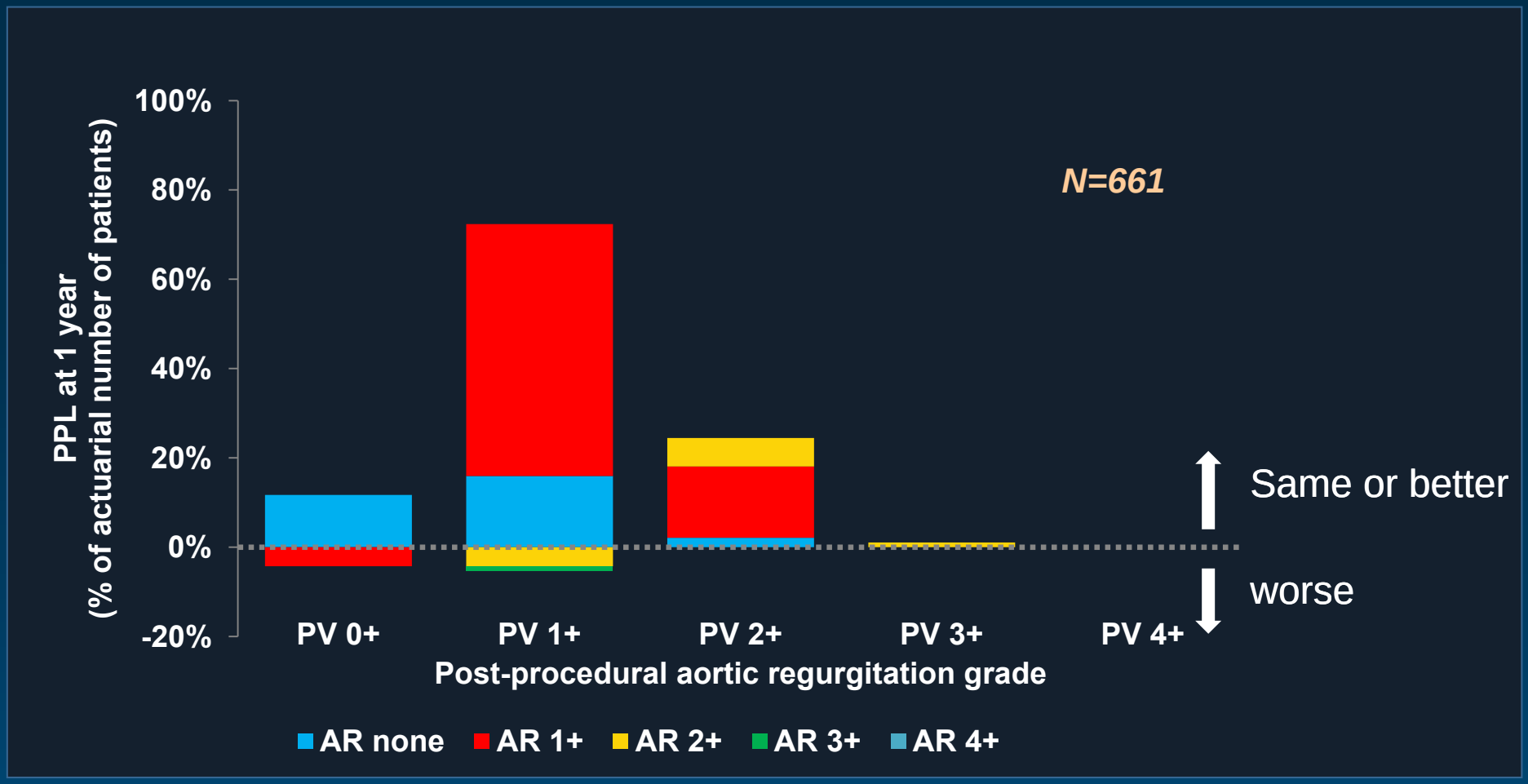
Incidence and Predictors of Early and Late Mortality After Transcatheter Aortic Valve Implantation in 663 Patients With Severe Aortic Stenosis

Corrado Tamburino, MD, PhD; Davide Capodanno, 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; David Antoniucci, MD; Massimo Napodano, MD; Marco De Carlo, MD, PhD; Claudia Fiorina, MD; Gian Paolo Ussia, MD

Tamburino et al. Circulation 2011

Para-valvular leak after TAVI

Impact on outcomes



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Tamburino et al. Circulation 2011

Para-valvular leak after TAVI

Impact on outcomes

Overall mortality	Hazard ratio	95% LCL	95% UCL	p value
Intraprocedural stroke	15.76	3.27	75.90	0.001
Pre-procedural mitral regurgitation 3+ or 4+	4.62	1.66	12.87	0.003
Systolic pulmonary artery pressure > 60 mmHg	3.21	1.19	8.71	0.02
Prior acute pulmonary edema	2.75	1.32	5.72	0.007
Diabetes mellitus	2.45	1.19	5.07	0.02
Early mortality	**Odds ratio**	**95% LCL**	**95% UCL**	**p value**
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
Late mortality	**Hazard ratio**	**95% LCL**	**95% UCL**	**p value**
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

Tamburino et al. Circulation 2011

Para-valvular leak after TAVI

Impact on outcomes

Aortic Regurgitation Index Defines Severity of Peri-Prosthetic Regurgitation and Predicts Outcome in Patients After Transcatheter Aortic Valve Implantation

Jan-Malte Sinning, MD, Christoph Hammerstingl, MD, Mariuca Vasa-Nicotera, MD, Viktoria Adenauer, MD, Sisa Josefina Lema Cachiguango, MD, Anne-Cathérine Scheer, MD, Sven Hausen, MD, Alexander Sedaghat, MD, Alexander Ghanem, MD, Cornelius Müller, MD, Eberhard Grube, MD, Georg Nickenig, MD, Nikos Werner, MD

Bonn, Germany

AR index=[(DBP -LVEDP)/SBP] x100

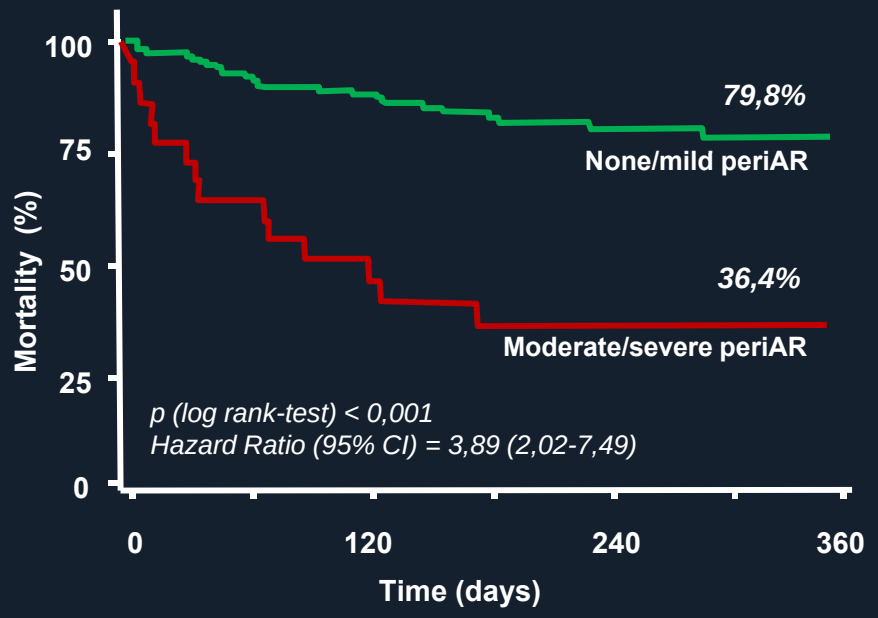
- **146 consecutive TAVI with Medtronic CoreValve**
- **PVL assessed by Echo, angio, and measurement of the AR index**
- **Patients with AR index <25 had a significantly increased 1-year mortality risk compared with patients with AR index ≥25**

Sinning et al., J Am Coll Cardiol 2012

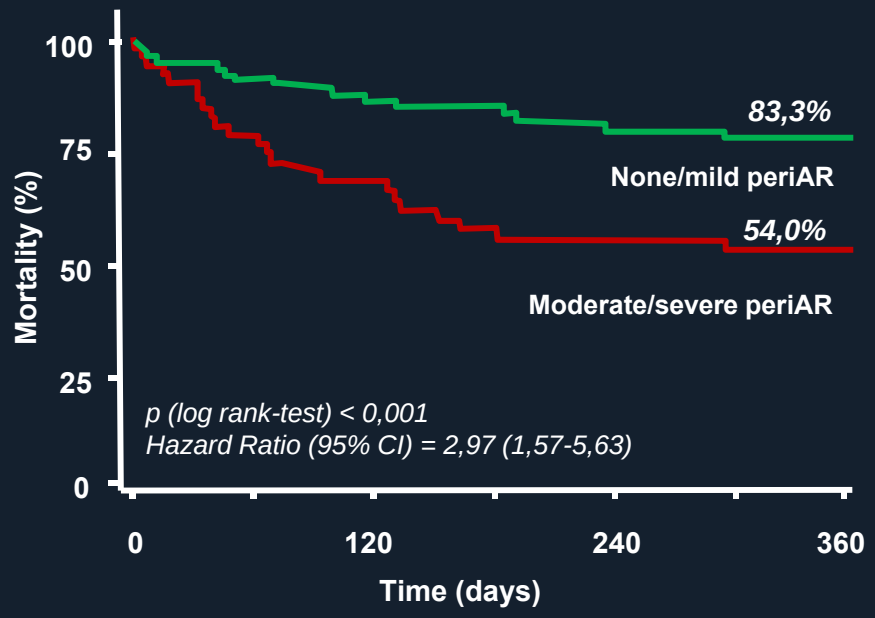
Para-valvular leak after TAVI

Impact on outcomes

AR index <25



AR index ≥25



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Sinning et al., J Am Coll Cardiol 2012

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

Susheel K. Kodali, M.D., Mathew R. Williams, M.D., Craig R. Smith, M.D., Lars G. Svensson, M.D., Ph.D., John G. Webb, M.D., Raj R. Makkar, M.D., Gregory P. Fontana, M.D., Todd M. Dewey, M.D., Vinod H. Thourani, M.D., Augusto D. Pichard, M.D., Michael Fischbein, M.D., Ph.D., Wilson Y. Szeto, M.D., Scott Lim, M.D., Kevin L. Greason, M.D., Paul S. Teirstein, M.D., S. Chris Malaisrie, M.D., Pamela S. Douglas, M.D., Rebecca T. Hahn, M.D., Brian Whisenant, M.D., Alan Zajarias, M.D., Duolao Wang, Ph.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., and Martin B. Leon, M.D., for the PARTNER Trial Investigators*

that subsequent device generations and increased operator experience with TAVR may improve outcomes.[18,38-40]

In conclusion, this 2-year follow-up of patients in the PARTNER trial supports the use of TAVR as an alternative to surgery in selected high-risk patients with aortic stenosis. The two treatments were similar with respect to mortality, reduction in cardiac symptoms, and improved valve hemodynamics. The early increase in the risk of stroke with TAVR was attenuated over time. A new, important observation was the association of paravalvular regurgitation after TAVR with late mortality. Work now should be directed toward

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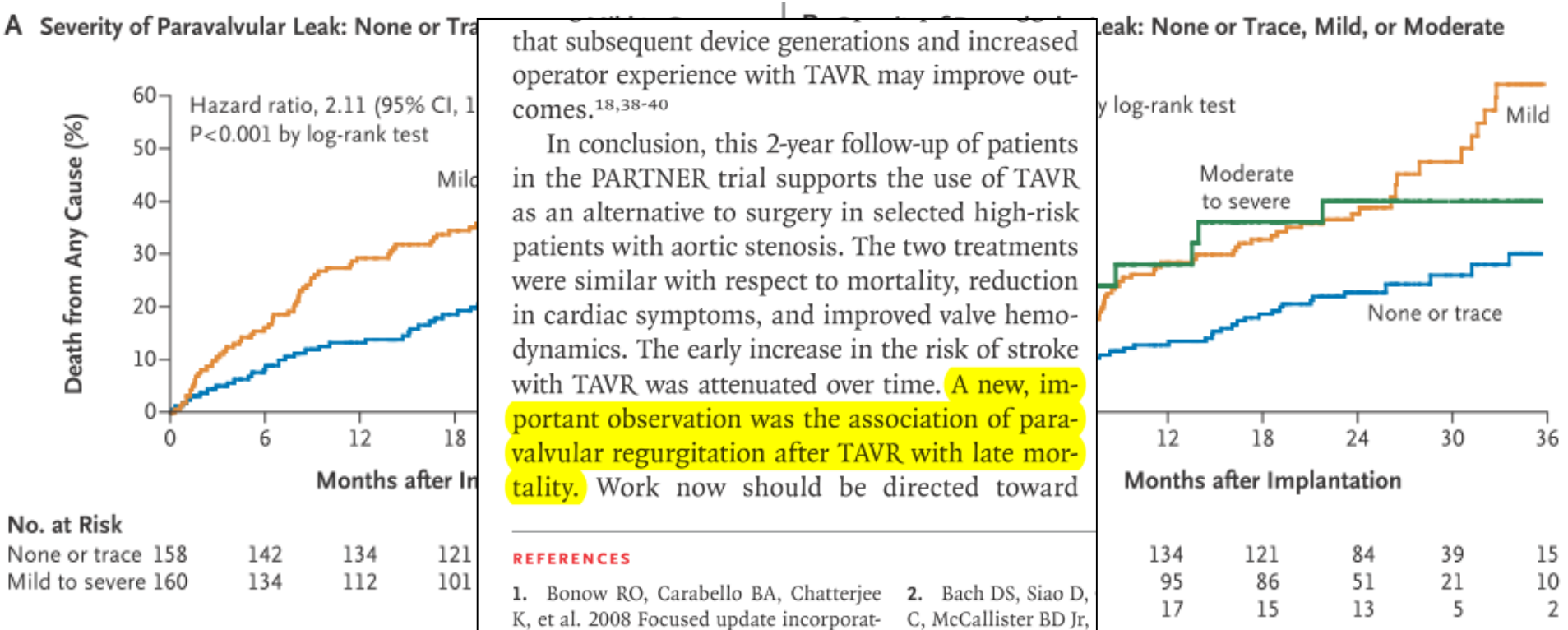
1. Bonow RO, Carabello BA, Chatterjee K, et al. 2008 Focused update incorporated into the ACC/AHA 2006 guidelines for

2. Bach DS, Siao D, C, McCallister BD Jr, tion of patients with



Para-valvular leak after TAVI

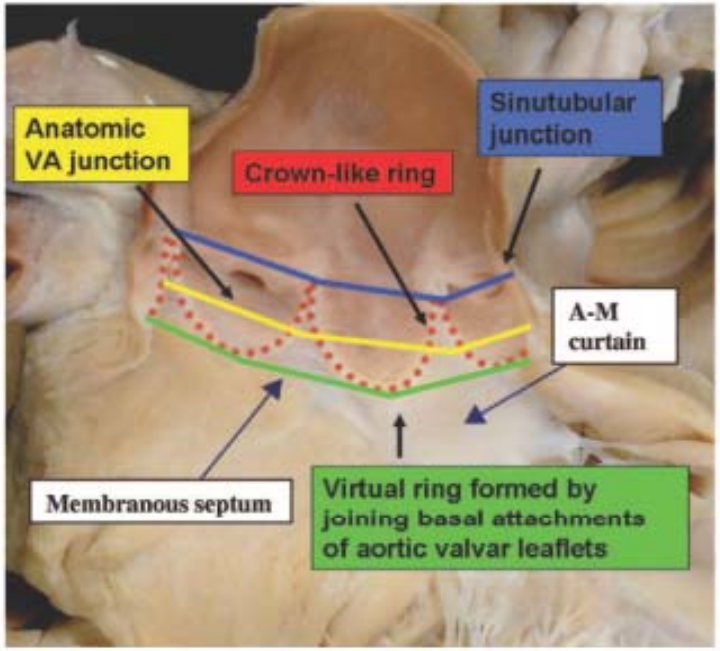
Is it predictable?

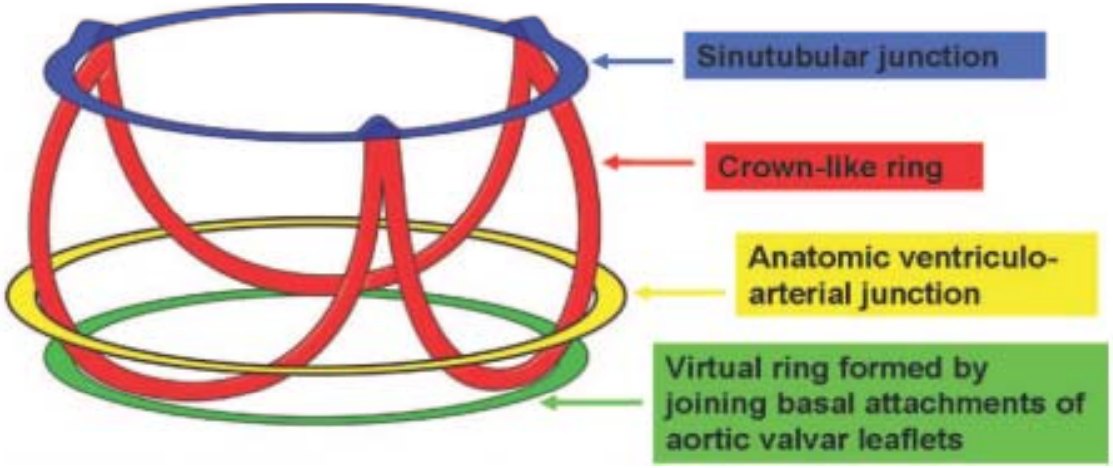
- **Annulus measurement**
- **Calcium burden evaluation**
- **Operator experience**

MSCT is mandatory!!!

Para-valvular leak after TAVI

Aortic root anatomy…not so simple!





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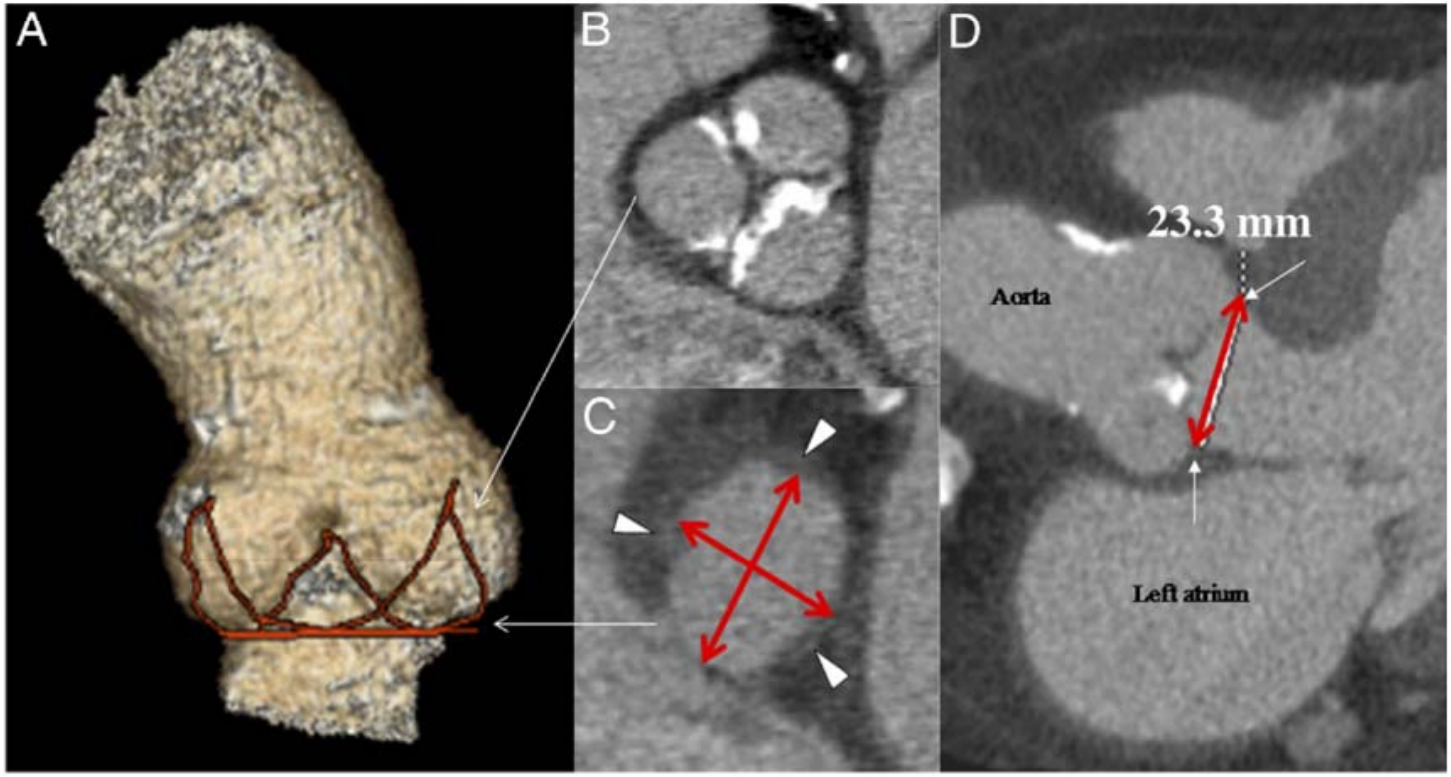
CLINICAL RESEARCH — Interventional Cardiology

Multimodal Assessment of the Aortic Annulus Diameter

Implications for Transcatheter Aortic Valve Implantation

David Messika-Zeitoun, MD, PHD,*‡ Jean-Michel Serfaty, MD, PHD,† Eric Brochet, MD,‡ Gregory Ducrocq, MD,‡ Laurent Lepage, MD,‡ Delphine Detaint, MD,‡ Fabien Hyafil, MD,‡ Dominique Himbert, MD,‡ Nicoletta Pasi, MD,† Jean-Pierre Laissy, MD, PHD,† Bernard Iung, MD,‡ Alec Vahanian, MD‡

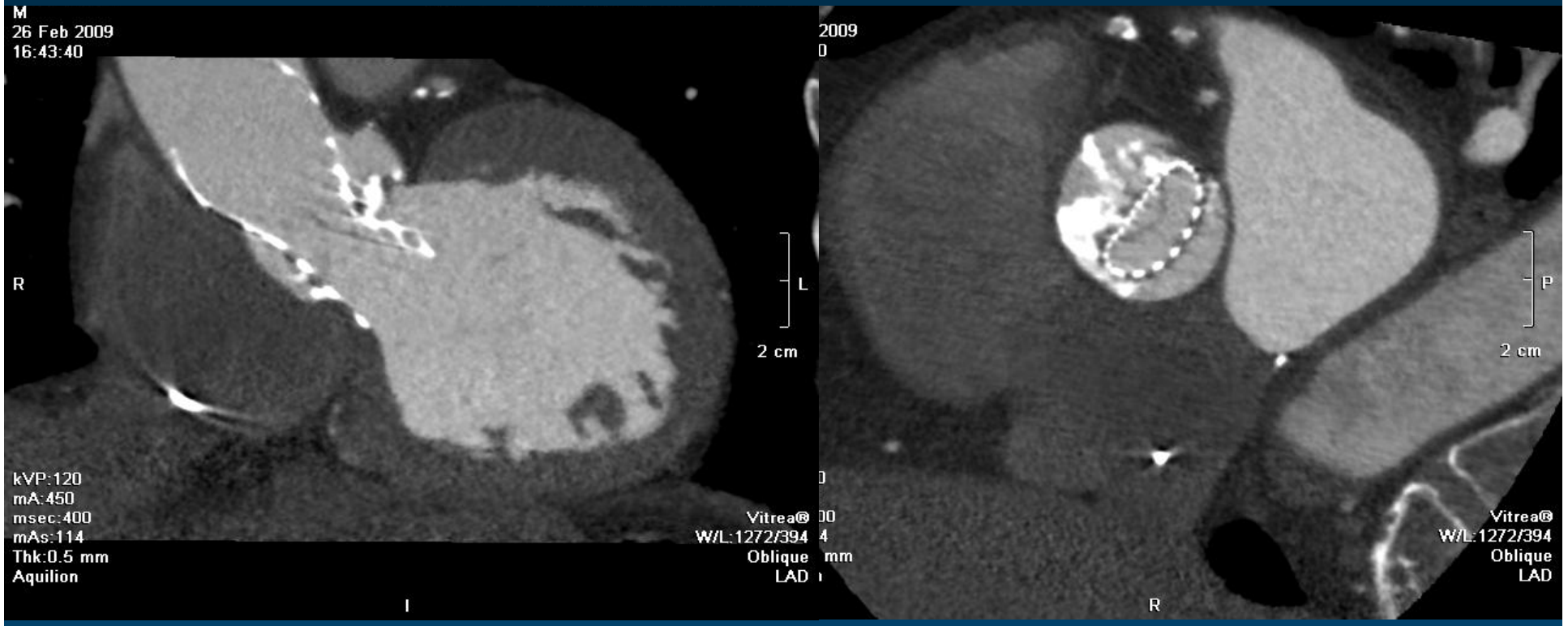


Para-valvular leak after TAVI

Aortic root anatomy…and lot of calcium!

Para-valvular leak after TAVI

Heavy calcifications → prosthesis underexpansion



Para-valvular leak after TAVI

Is it predictable?

CLINICAL RESEARCH

Determinants of Significant Paravalvular Regurgitation After Transcatheter Aortic Valve Implantation

Impact of Device and Annulus Discongruence

Delphine Détaint, MD, Laurent Lepage, MD, Dominique Himbert, MD, Eric Brochet, MD, David Messika-Zeitoun, MD, Bernard Iung, MD, Alec Vahanian, MD

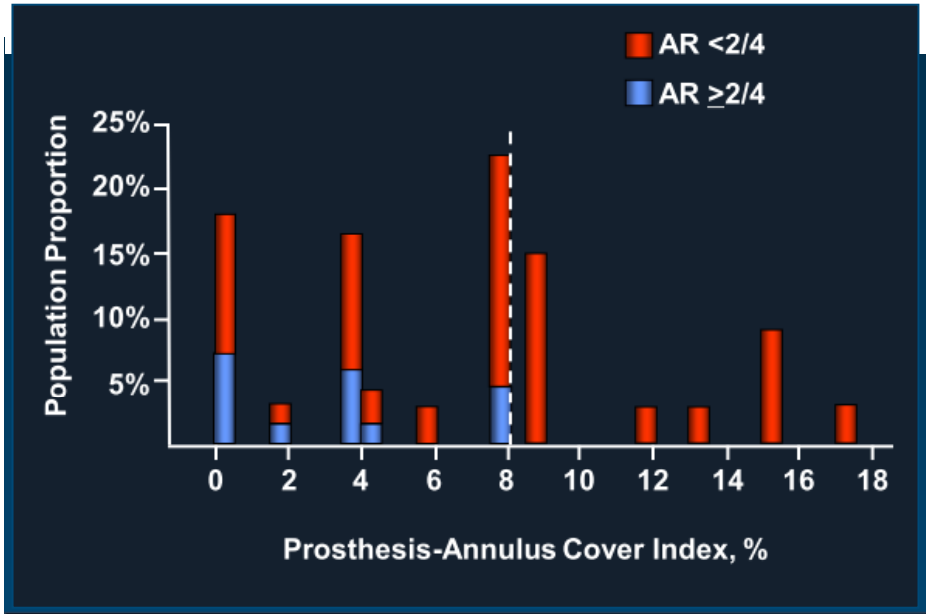


Table 2. Comparison of the Clinical, Echocardiographic, and Procedure Characteristics of Patients Undergoing TAVI Between the 2 Time-Frame Periods of the Study

Variables	Period 1* (n = 20)	Period 2* (n = 54)	p Value
Age, yrs	85 ± 6	82 ± 9	0.12
Sex (men)	13 (65%)	25 (46%)	0.15
Weight, kg	66 ± 16	71 ± 14	0.23
Height, cm	164 ± 11	162 ± 8	0.52
BSA, m^2	1.7 ± 0.2	1.8 ± 0.2	0.46
TTE systolic aortic annulus, mm	22.8 ± 2.1	22.9 ± 1.5	0.61
TEE systolic aortic annulus, mm	23.6 ± 2.3	23.3 ± 1.7	0.84
Ejection fraction, %	46 ± 16	53 ± 18	0.17
Aortic valve area, cm^2	0.58 ± 0.1	0.70 ± 0.2	0.003
Aortic valve mean gradient, mm Hg	44 ± 14	52 ± 14	0.03
Implantation access (femoral)	14 (70%)	32 (59%)	0.40
Prosthesis size (26 mm)	14 (70%)	36 (67%)	0.79
Cover index†, %	6.6 ± 6	6.7 ± 5	0.92
AR ≥2/4 immediately after TAVI	8 (40%)	8 (15%)	0.02

Values are mean ± SD or n (%). *Period 1: October 9, 2006 to January 9, 2008; and Period 2: January 16, 2008 to December 23, 2008. †Cover Index defined as 100 × ([prosthesis diameter – TEE annulus diameter]/prosthesis diameter).

Abbreviations as in Table 1.

Détaint et al. JACC Cardiovasc Interv 2009

Para-valvular leak after TAVI

Is it predictable?

CLINICAL RESEARCH

Determinants of Significant Paravalvular Regurgitation After Transcatheter Aortic Valve Implantation

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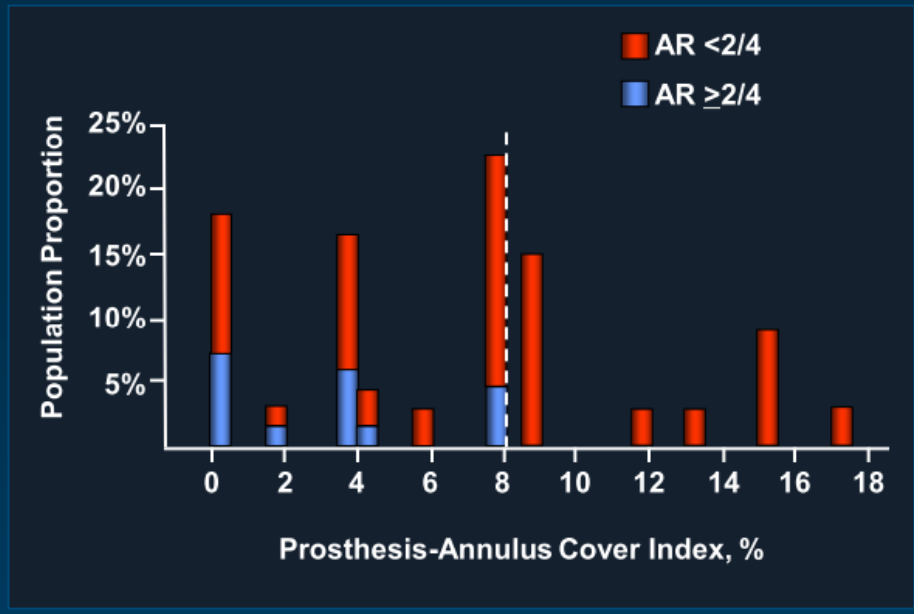
Delphine Détaint, MD, Laurent Lepage, MD, Dominique Himbert, MD, Eric Brochet, MD, David Messika-Zeitoun, MD, Bernard Iung, MD, Alec Vahanian, MD

Paris, France



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University of Catania

Détaint et al. JACC Cardiovasc Interv 2009

Para-valvular leak after TAVI

Is it predictable?

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

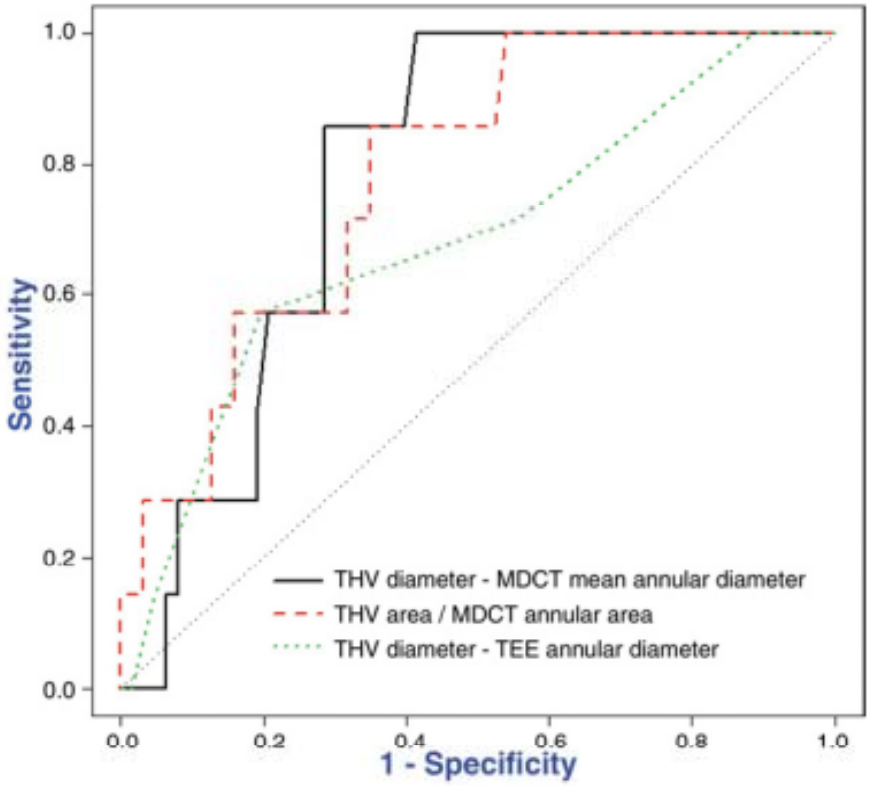
A Multicenter Retrospective Analysis

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

Table 4 The Relationship Between Undersizing a THV Relative to the MDCT Annular Size and Increasing Grade of PAR

Grade of PAR	THV Diameter – Mean Annular Diameter (mm)	Percentage Difference Between the THV Area and Annular Area*
None/trivial	1.5 ± 1.8	14.2 ± 18.3
Mild	0.4 ± 1.8	4.3 ± 14.2
Moderate/severe	−0.7 ± 1.4	−7.0 ± 9.5
p value	<0.01	<0.01

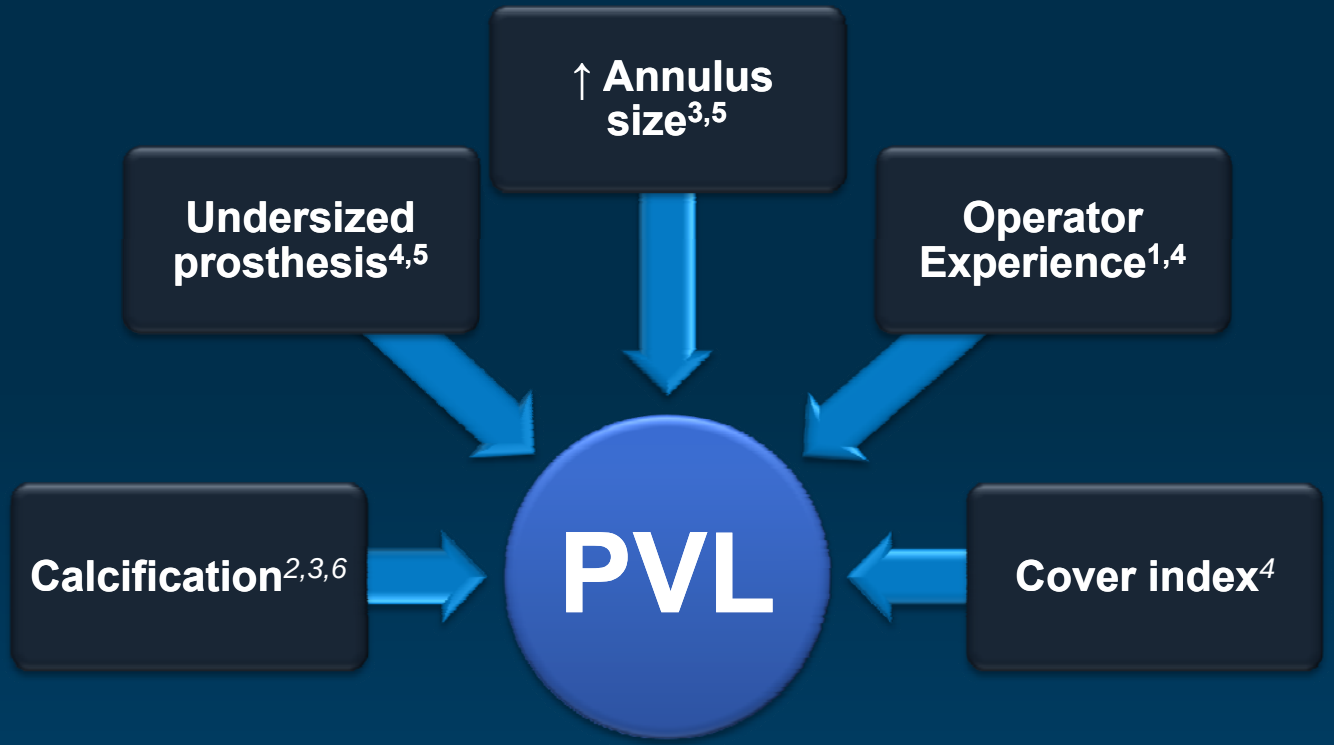


MDCT mean diameter (0.81, 95%CI: 0.68-0.88), MDCT area (0.80, 95%CI: 0.65-0.90), TEE diameter (0.70, 95%CI: 0.51-0.88).

Willson et al. J Am Coll Cardiol 2012

Para-valvular leak after TAVI

Is it predictable?



[1]*Detaint et al. JACC Interv 2009*

[2]*Coli et al. Circulation 2009*

[3]*Delgado et al. Circulation 2009*

[4]*Willson et al. J Am Coll Cardiol 2012*

[5]*Takagi et al. Catheter Cardiovasc Interv 2011*

[6]*John et al. JACC Cardiovasc Interv 2010*

Para-valvular leak after TAVI

How to prevent it?

1. **Accurate aortic root assessment**
   - *MSCT has to be the preferred tool*
2. **Oversize the device**
   - *Pay attention to damage on the aortic root*

Para-valvular leak after TAVI

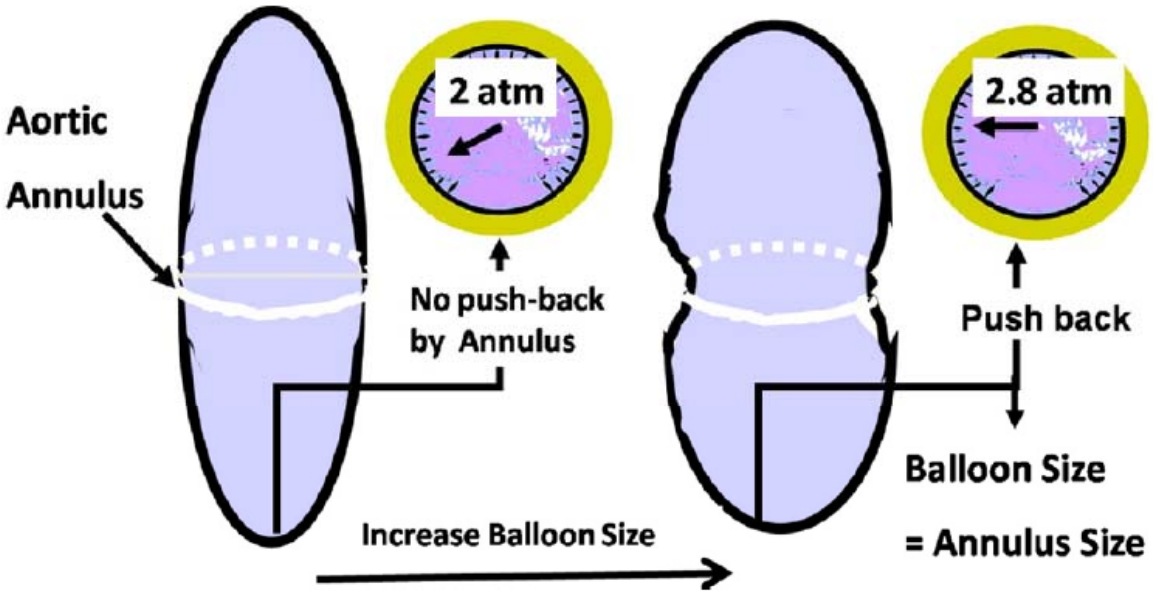
How to prevent it?

Use of Balloon Aortic Valvuloplasty to Size the Aortic Annulus Before Implantation of a Balloon-Expandable Transcatheter Heart Valve

Vasilis C. Babaliaros, MD, Zahid Junagadhwalla, MD, Stamatios Lerakis, MD, Vinod Thourani, MD, David Liff, MD, Edward Chen, MD, Thomas Vassiliades, MD, Clay Chappell, MD, Nathan Gross, BS, Ateet Patel, BA, Sharon Howell, BS, Jacob T. Green, MD, Emir Veledar, PHD, Robert Guyton, MD, Peter C. Block, MD

Atlanta, Georgia

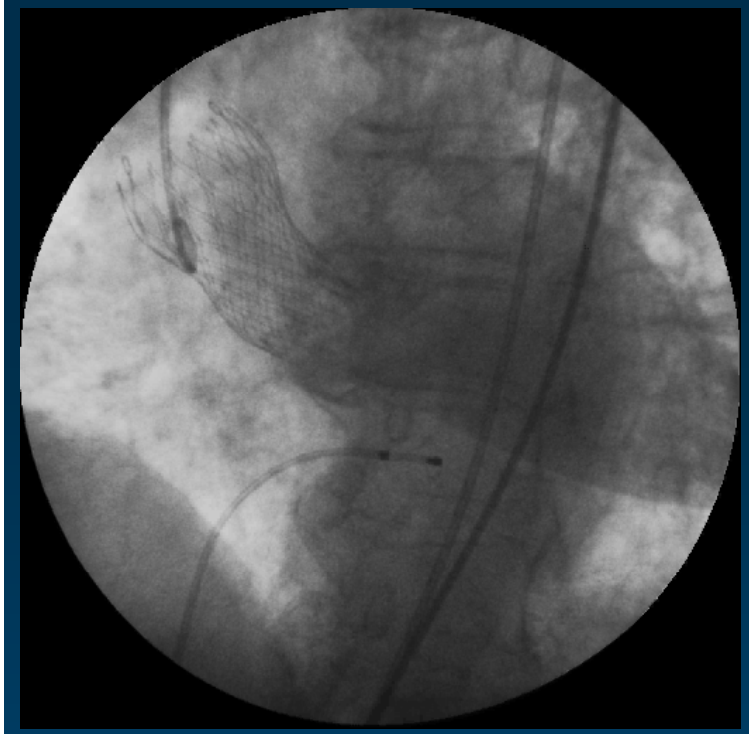
JACC cardiovascular Interventions

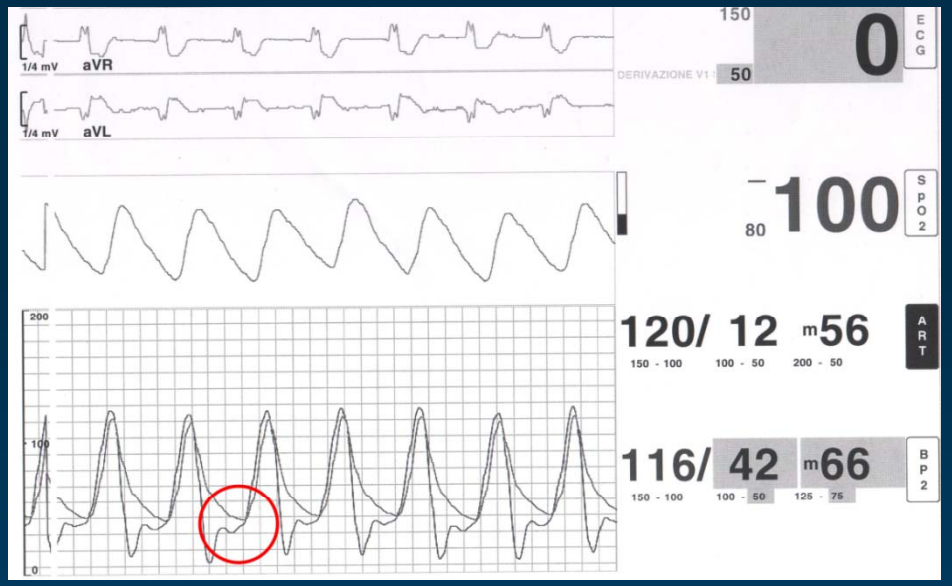


Babaliaros et al. JACC Cardiovasc Interv 2011

Para-valvular leak after TAVI

How to manage it?





No doubt...It has to be treated!

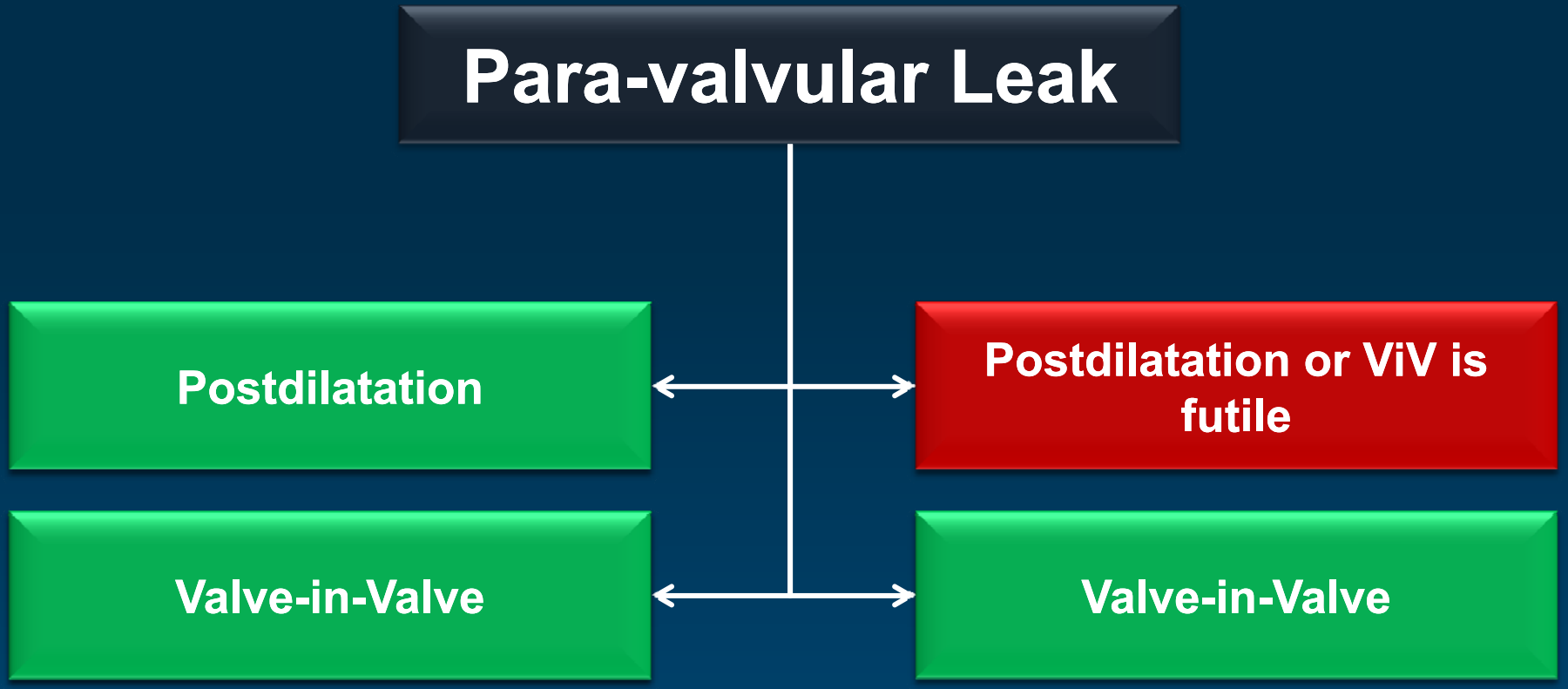
Para-valvular leak after TAVI

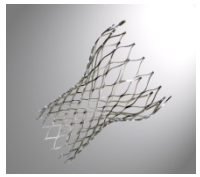
How to manage it?

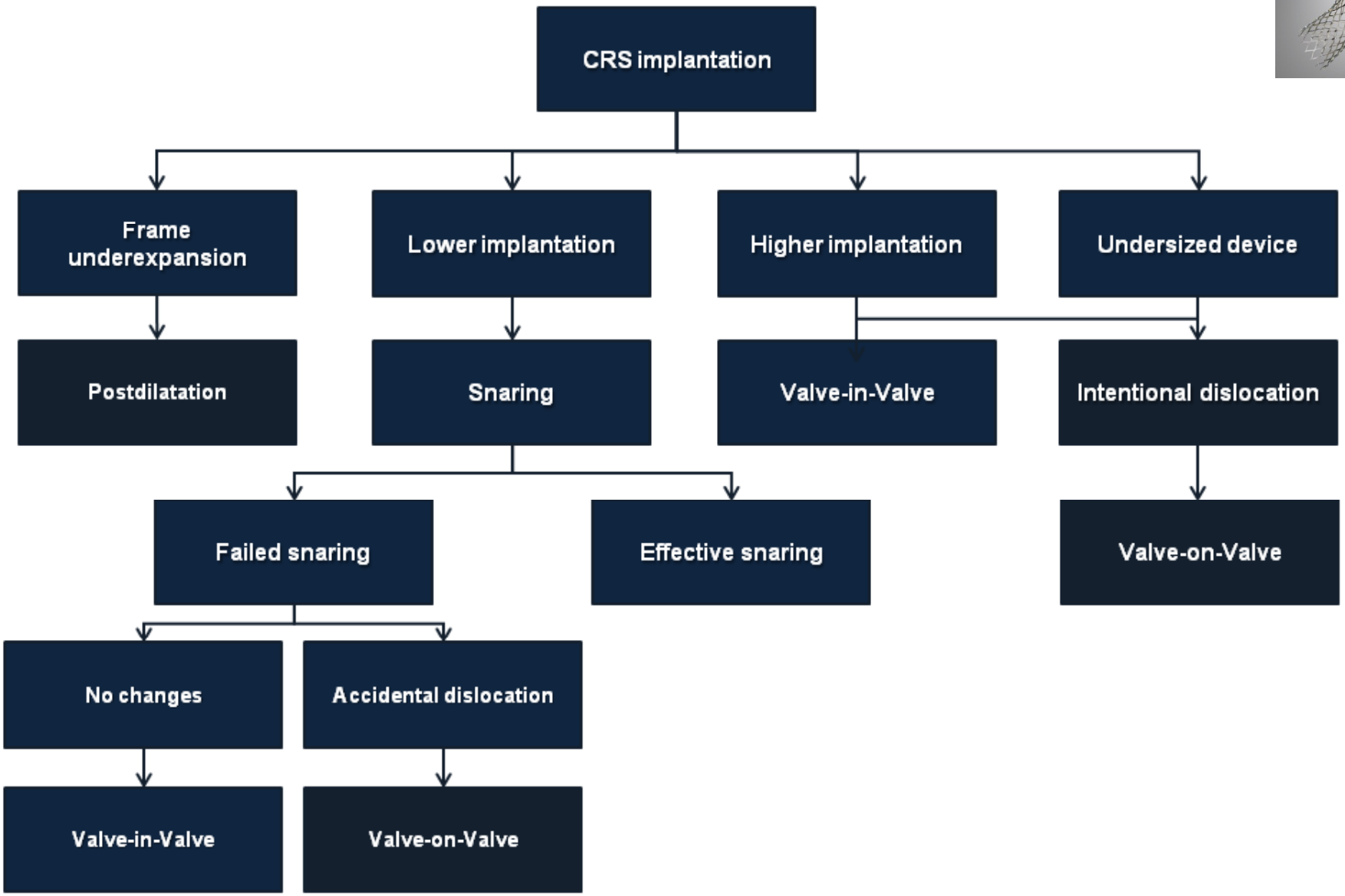
1. Post-dilatation……CRS & ES
2. Snaring……CRS
3. Valve-in-Valve……CRS & ES
4. Anchoring balloon……ES

Para-valvular leak after TAVI

How to manage it?






CRS implantation
Frame underexpansion
Lower implantation
Higher implantation
Undersized device
Postdilatation
Snaring
Valve-in-Valve
Intentional dislocation
Failed snaring
Effective snaring
Valve-on-Valve
No changes
Accidental dislocation
Valve-in-Valve
Valve-on-Valve

Edwards implantation

Frame underexpansion

Lower implantation

Higher implantation

Undersized device

Postdilatation

Check prosthesis position

Valve-in-Valve

Intentional dislocation

Prosthesis into LV

Prosthesis in LVOT

Prosthesis in annulus

Valve-on-Valve

Surgery

Too deep into the LV

Contact with annulus

Balloon anchoring

Failed anchoring

Effective anchoring

No changes

Accidental dislocation

Valve-in-Valve

Valve-on-Valve

Para-valvular leak after TAVI

Conclusions

- **Mild PVL complicates the majority of TAVI procedures**
- **Accurate aortic root evaluation is mandatory (MSCT)**
- **Prefer oversize prosthesis…***but be careful!*
- **Work now should be directed toward reducing PVL with improved device designs, techniques for more precise valve sizing and positioning, and judicious use of post-TAVI dilation**