TAVI Complication: Status, prediction and prevention

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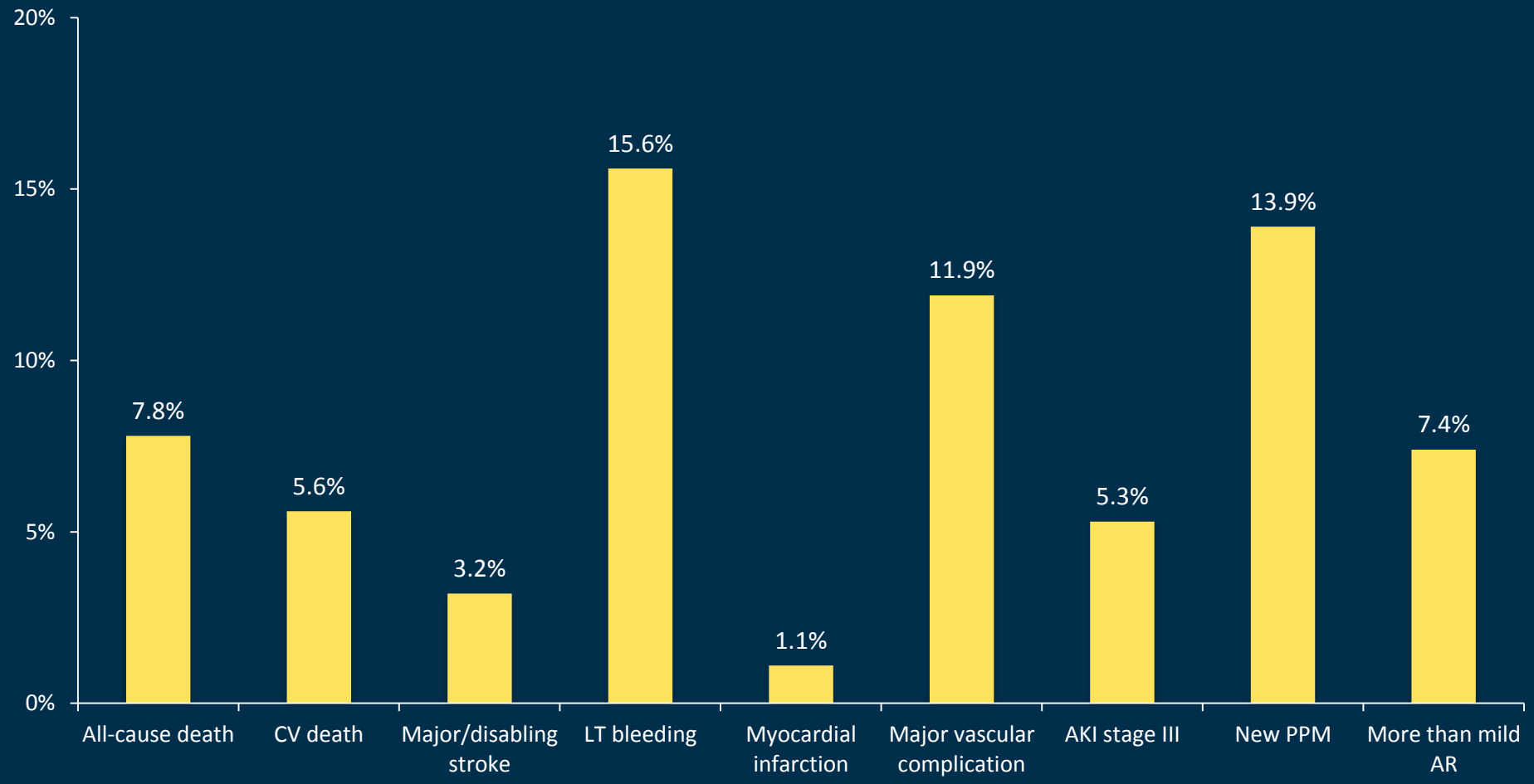
Transcatheter Aortic Valve Implantation

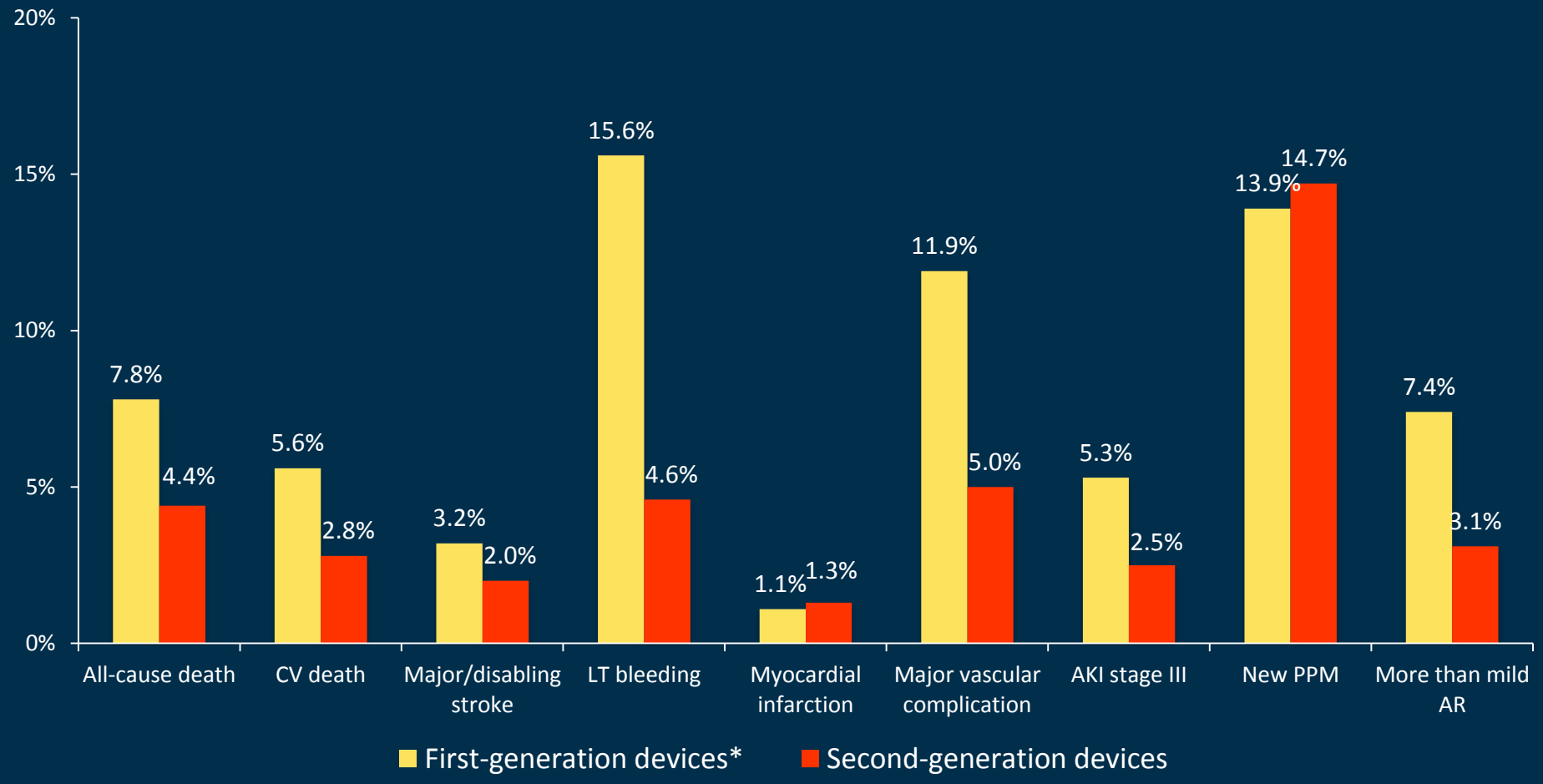
First-generation devices



Genereux et al. JACC 2013

Conduction disturbances and TAVI

First- vs. Second-generation devices



Transcatheter Aortic Valve Implantation
Potential complications

- Paravalvular regurgitation
- Cerebrovascular events
- Conduction disturbances
- Prosthesis durability
- Annulus rupture and coronary occlusion

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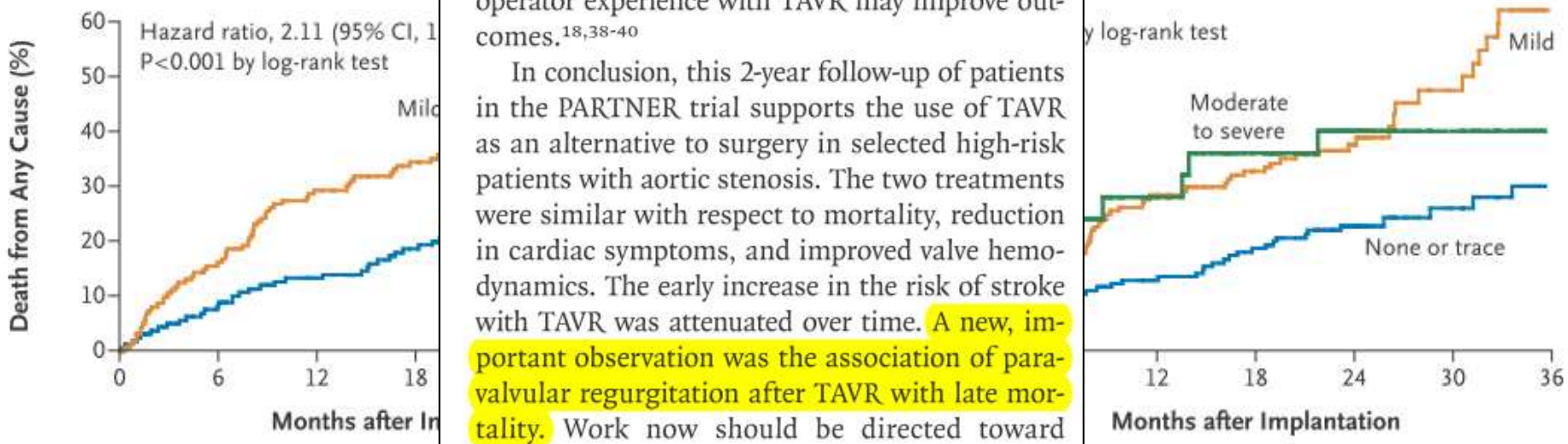
Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement

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*

A **Severity of Paravalvular Leak: None or Tra** … **eak: None or Trace, Mild, or Moderate**



No. at Risk

None or trace	158	142	134	121	134	121	84	39	15
Mild to severe	160	134	112	101	95	86	51	21	10
					17	15	13	5	2

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

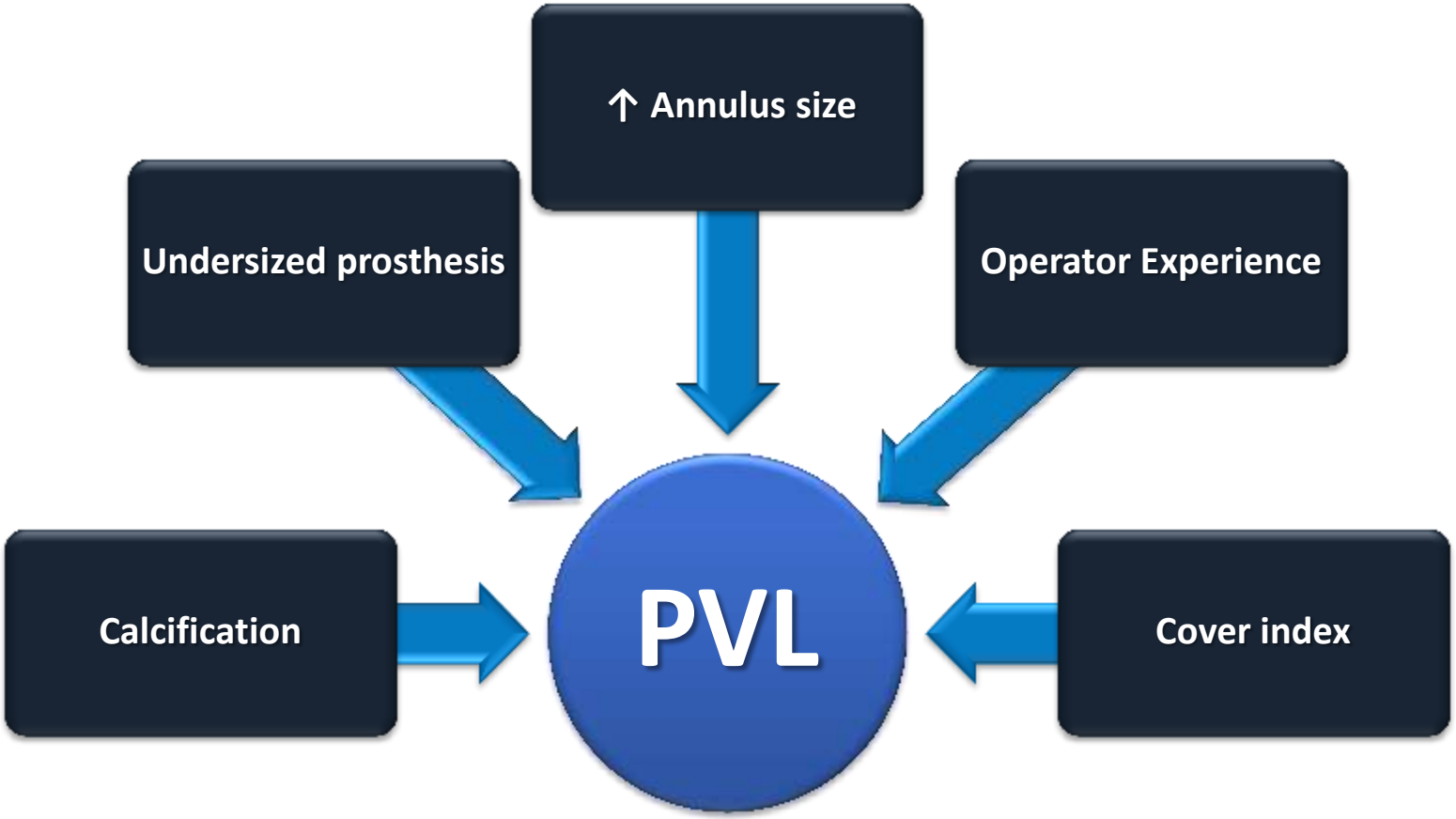
In conclusion, this 2-year follow-up of patients in the PARTNER trial supports the use of TAVR as an alternative to surgery in selected high-risk patients with aortic stenosis. The two treatments were similar with respect to mortality, reduction in cardiac symptoms, and improved valve hemodynamics. The 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

REFERENCES

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

Paravalvular leak
Predisposing factors



Transcatheter Aortic Valve Implantation
PVL prevention

MSCT assessment


The Impact of Integration of a Multidetector Computed Tomography Annulus Area Sizing Algorithm on Outcomes of Transcatheter Aortic Valve Replacement

A Prospective, Multicenter, Controlled Trial

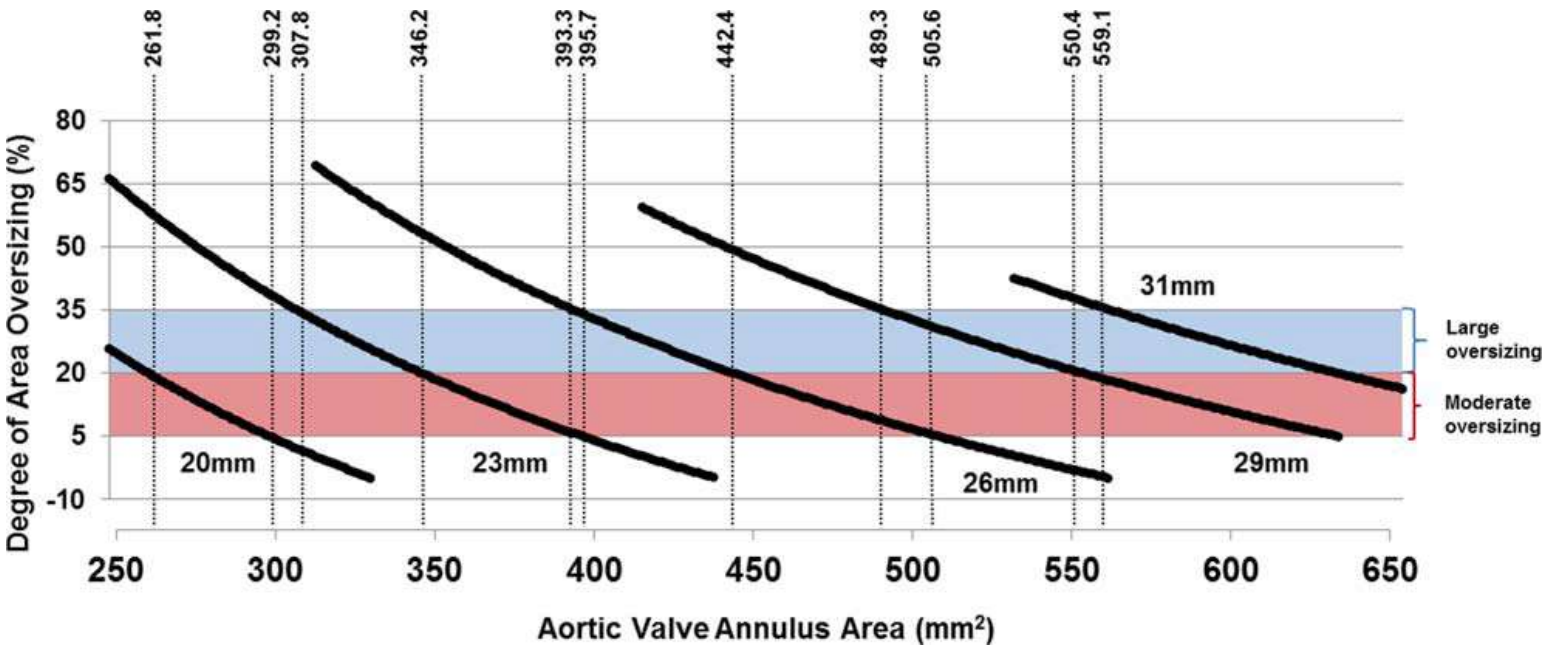
- 266 patients in the trial
- 133 patients underwent TAVR with the MDCT sizing algorithm recommendation and 133 patients without the algorithm
- PVL> mild was present in 5.3% in the MDCT group and in 12.8% in the control group (p=0.032)
- Composite of in-hospital death, aortic annulus rupture and PVL> moderate 3.8% in the MDCT group and in 11.3% in the control group (p=0.020)

Binder RK et al. JACC 2013

Transcatheter Aortic Valve Implantation
PVL prevention

MSCT assessment

Appropriate THV sizing



Dvir D et al. CCI 2015

Transcatheter Aortic Valve Implantation

Paravalvular leak prevention – Calcium is bad!

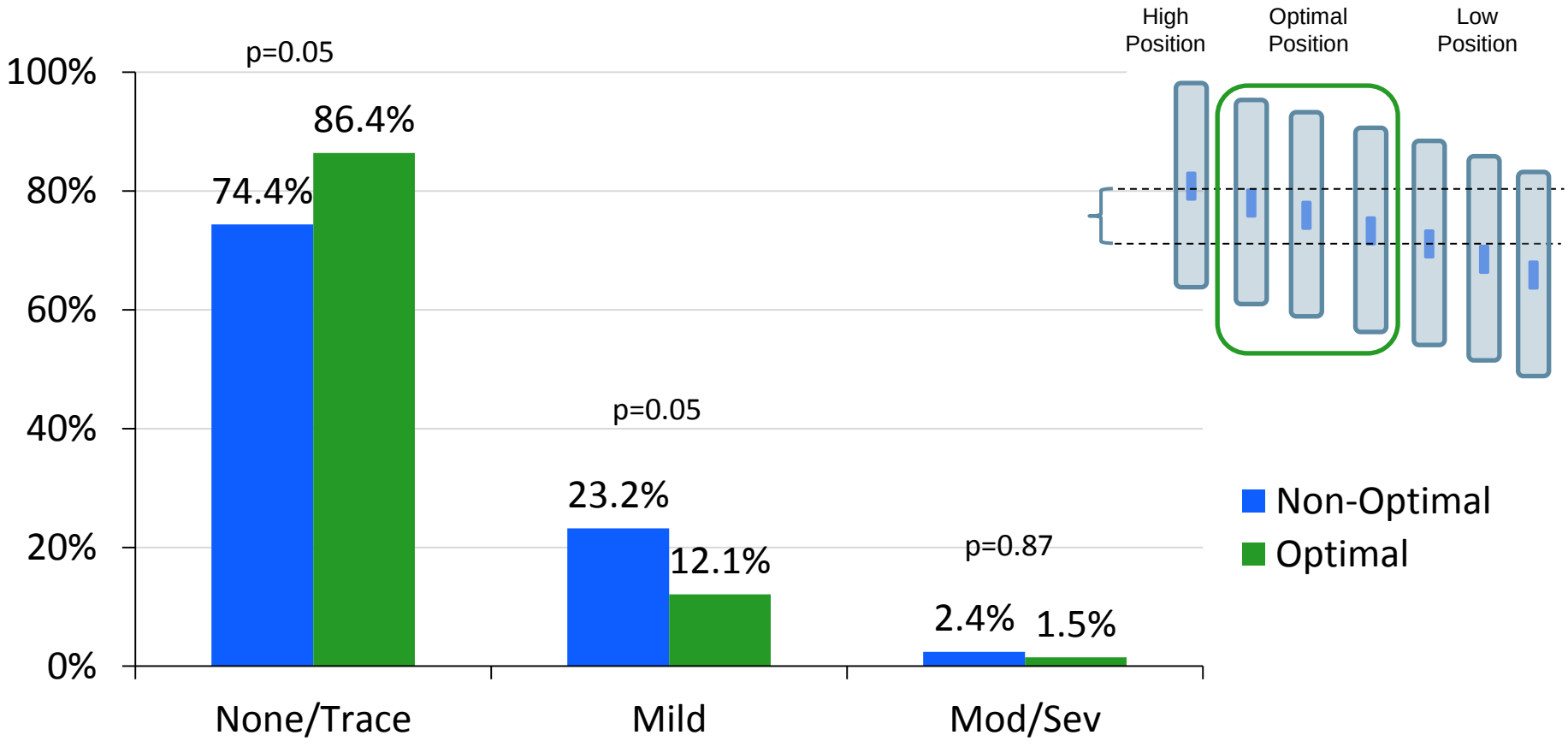
150 patients who received the Sapien or Sapien XT valves at a single institution, Oct 2011 to July 2013; 19% had at least mild leak.

Mean Asymmetry of Calcification	No/Trace PVR	≥ Mild PVR	P Value
LVOT, mm^3	30 ± 69	65 ± 81	0.013
Annulus, mm^3	67 ± 64	125 ± 101	0.002
Leaflet, mm^3	276 ± 209	304 ± 185	0.243

- Study finds that calcification regardless of location predicts mild or greater paravalvular leak after TAVI
- Correlation strongest for asymmetrical calcification of annulus, LVOT regions

Khalique OK, et al. JACC Intv 2014

Edwards SAPIEN 3
OPTIMAL-S3 Outcomes

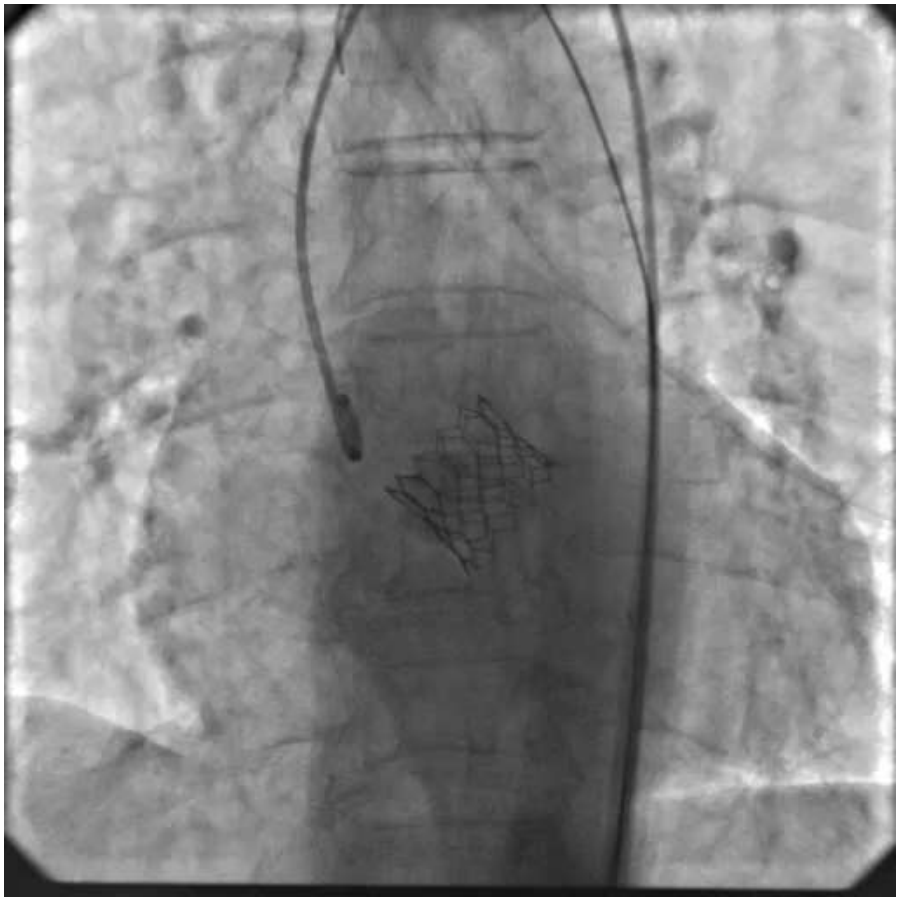


Dvir D. et al., Presented at TCT 2014

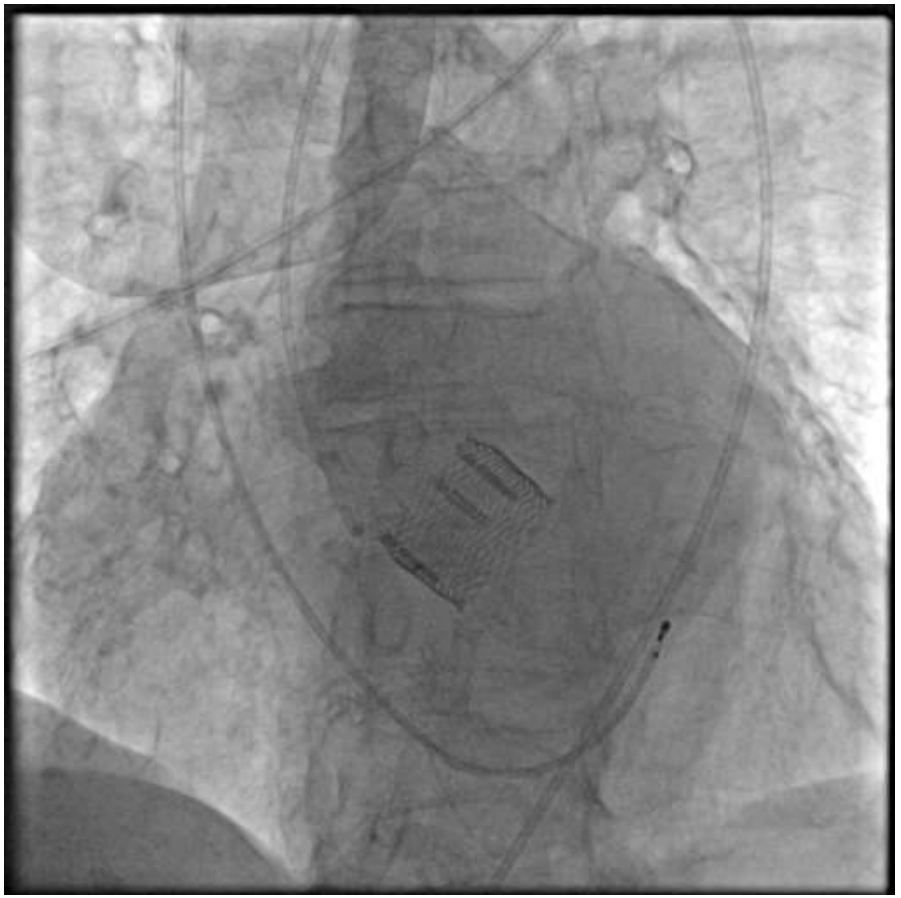
New generation TAVI devices

TAVI & PVL
Second-generation devices

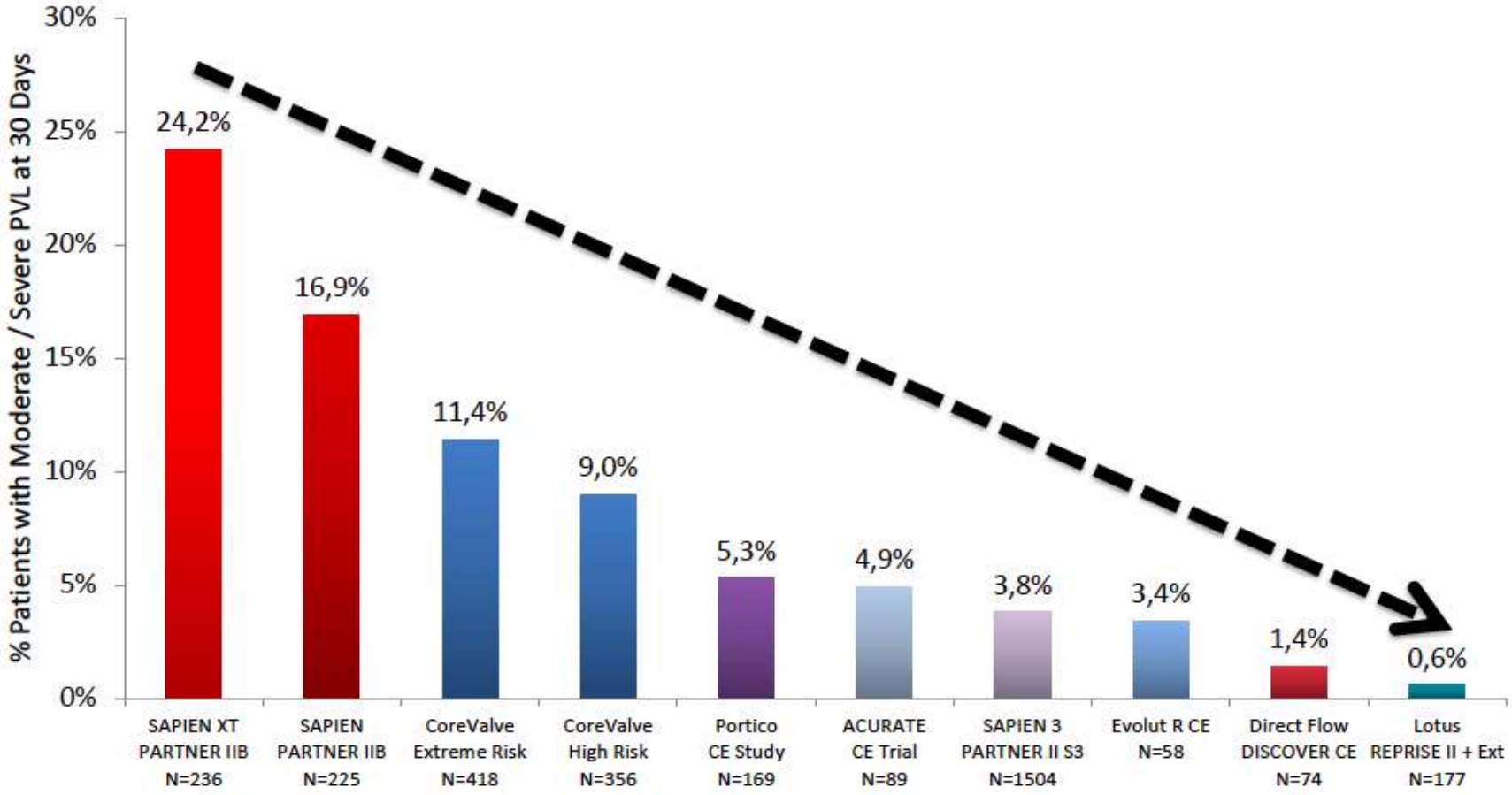
SAPIEN 3 Valve



Lotus Valve



Paravalvular Leak



Transcatheter Aortic Valve Implantation
Potential complications

- Paravalvular regurgitation
- Cerebrovascular events
- Conduction disturbances
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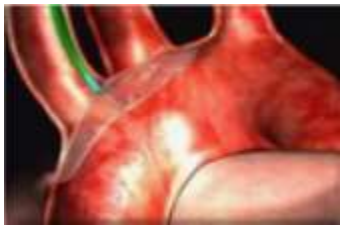
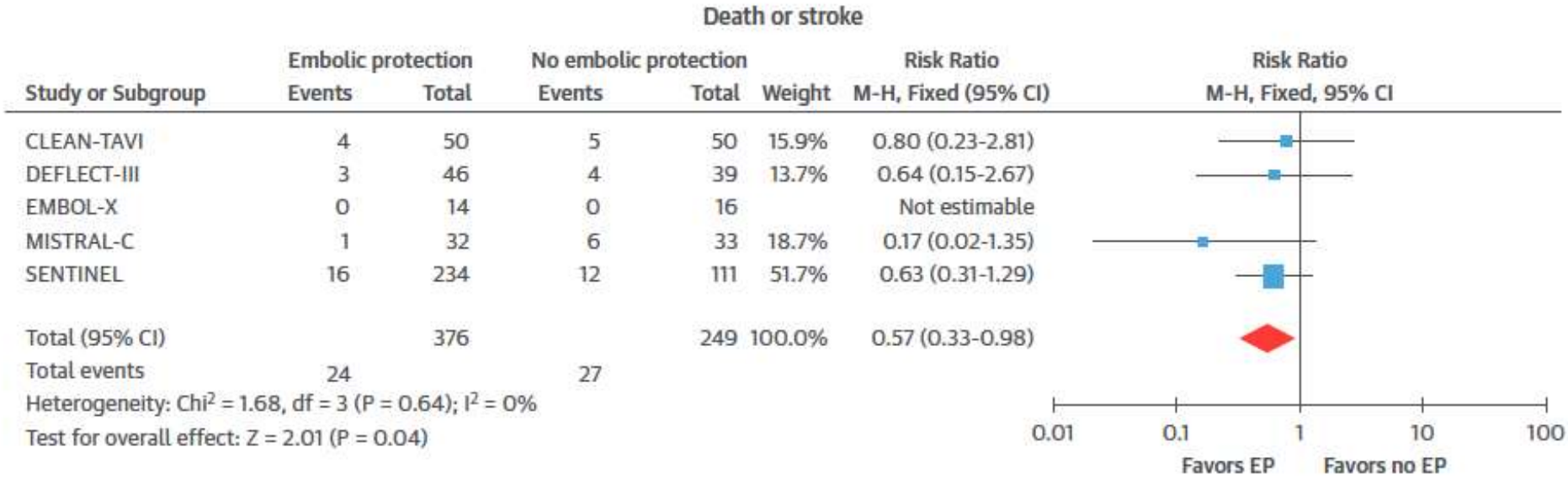
- Annulus rupture and coronary occlusion

Cerebral embolic protection devices

Feature	Embrella Deflector	TriGuard Deflector	Claret Sentinel Filter
			
Access	Radial	Femoral	Radial
Position	Aorta	Aorta	Brachiocephalic Left common carotid
Coverage area	Brachiocephalic & LCC	Brachiocephalic & LCC & LSA	Brachiocephalic & LCC
Mechanism	Deflection	Deflection	Filter
Size	6 Fr	9 Fr	6 Fr
Pore Size	100 microns	~130 microns	140 microns
CE mark	Yes	Yes	Yes

Cerebral embolic protection devices



Pooled effect estimates for the risk of death or stroke according to the use of cerebral embolic protection versus not during TAVR. CI = confidence interval; CLEAN-TAVI = Claret Embolic Protection and TAVI; DEFLECT-III = A Prospective, Randomized Evaluation of the TriGuard HDH Embolic Deflection Device During TAVI; EP = embolic protection; M-H = Mantel-Haenszel; MISTRAL-C = MRI Investigation With Claret; SENTINEL = Cerebral Protection in Transcatheter Aortic Valve Replacement; TAVR = transcatheter aortic valve replacement.

Transcatheter Aortic Valve Implantation
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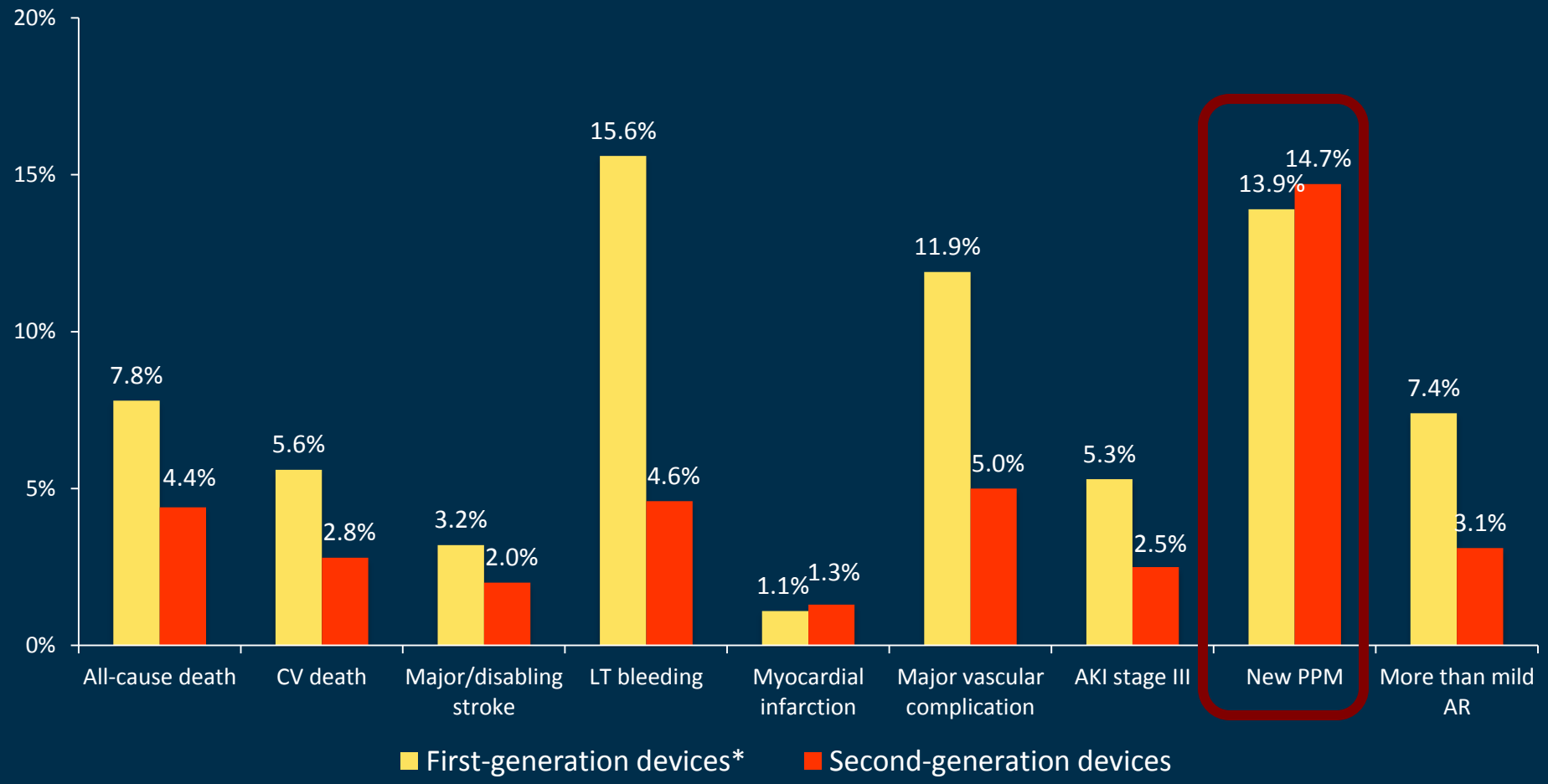
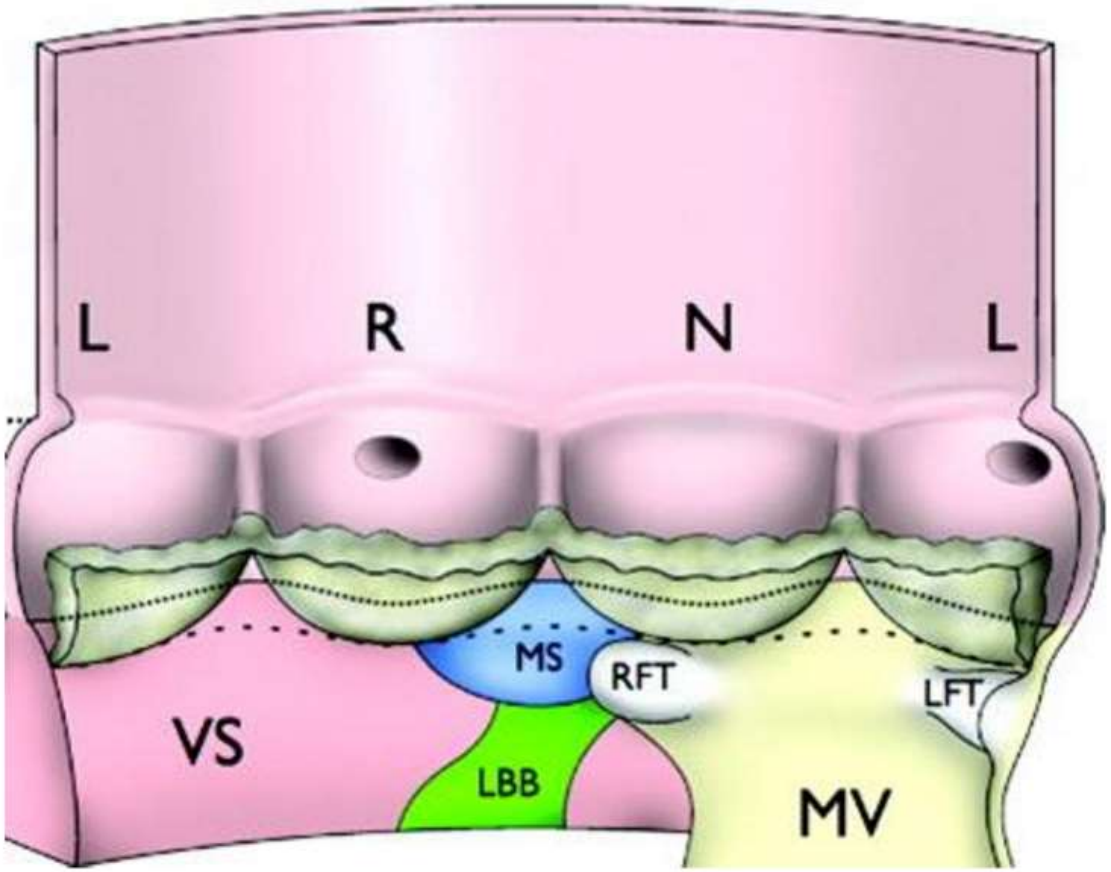
Conduction disturbances and TAVI

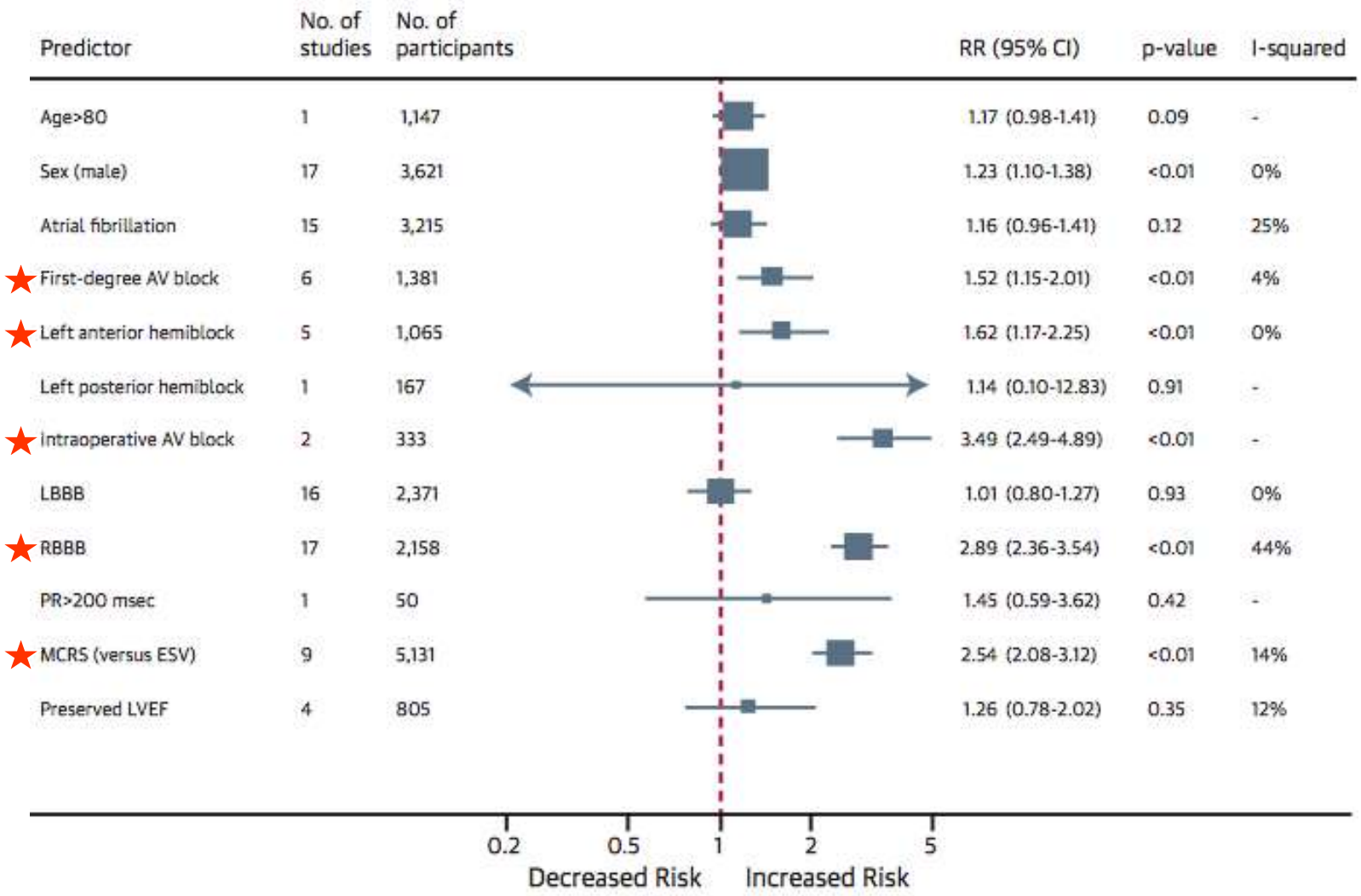
First- vs. Second-generation devices



Conduction disturbances



Conduction disturbances

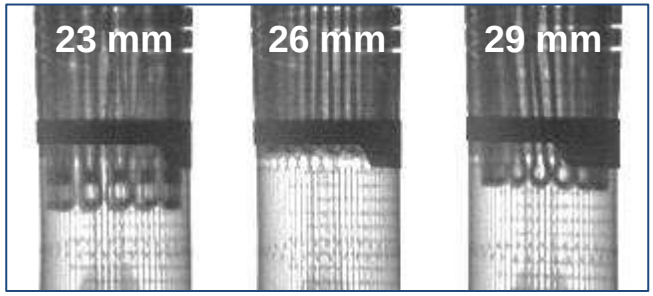


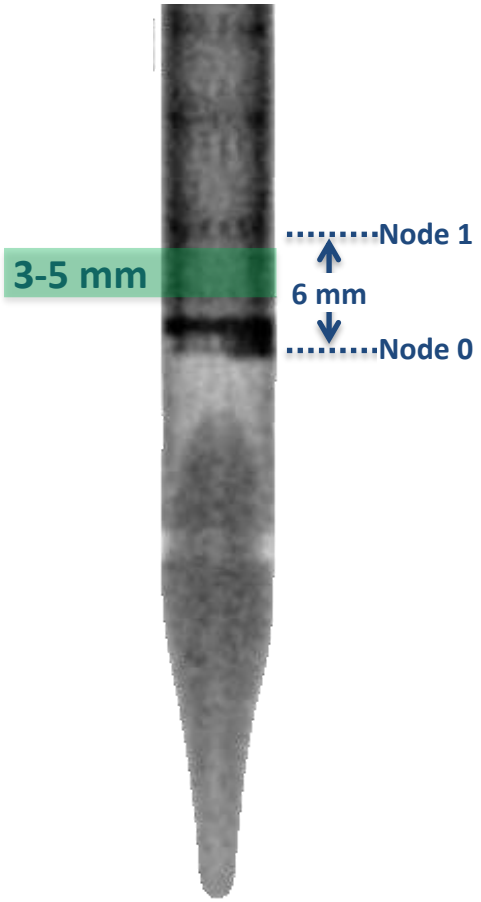
Siontis et al. JACC 2014

Evolut R

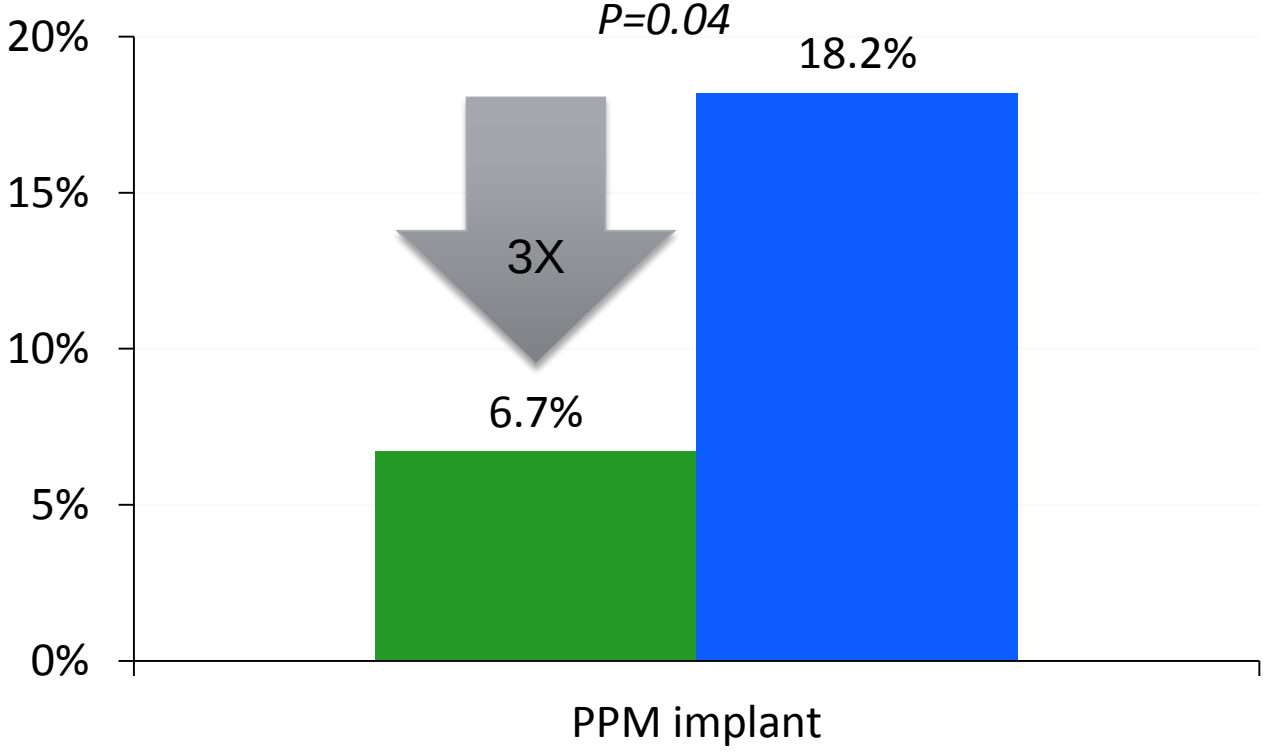
Target implant depth is **3 - 5 mm**

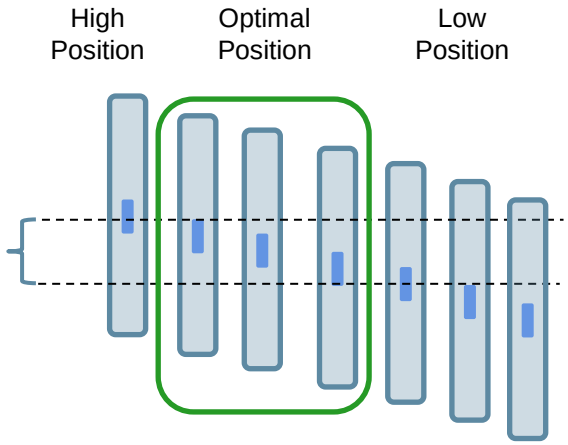
- Midway between node 0 (inflow edge of frame) and node 1 to just below node 1
- Note: due to minor valve frame length differences, ensure to assess valve position from frame inflow (node 0) and not the edge of the marker band:





Edwards SAPIEN 3
OPTIMAL-S3 Outcomes





Optimal Positioning
Non-Optimal Positioning

Dvir D. et al., Presented at TCT 2014

Transcatheter Aortic Valve Implantation
Potential complications

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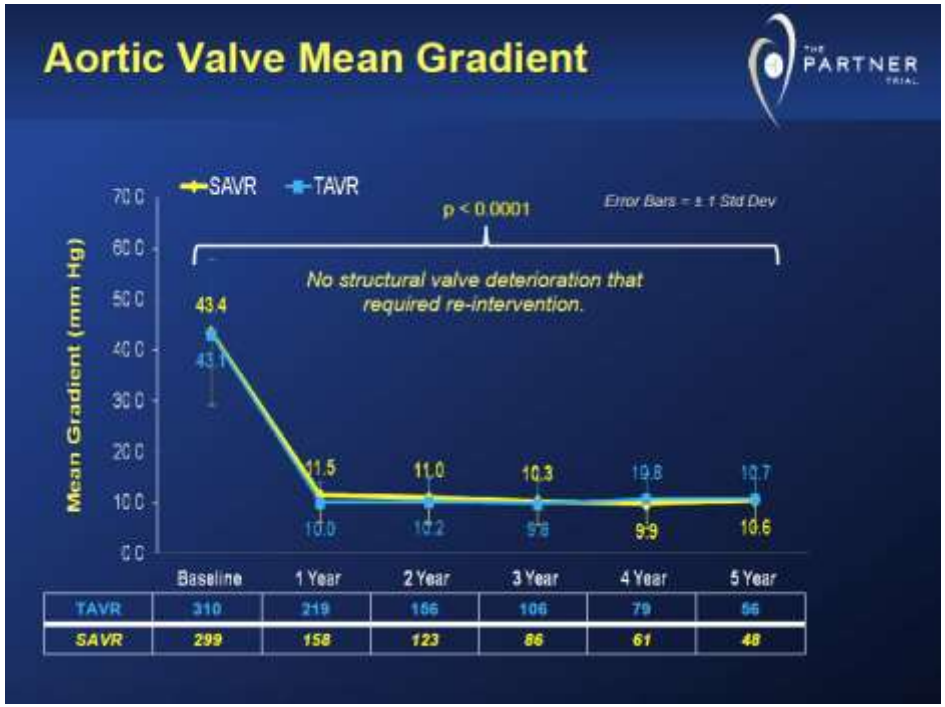
- Annulus rupture and coronary occlusion

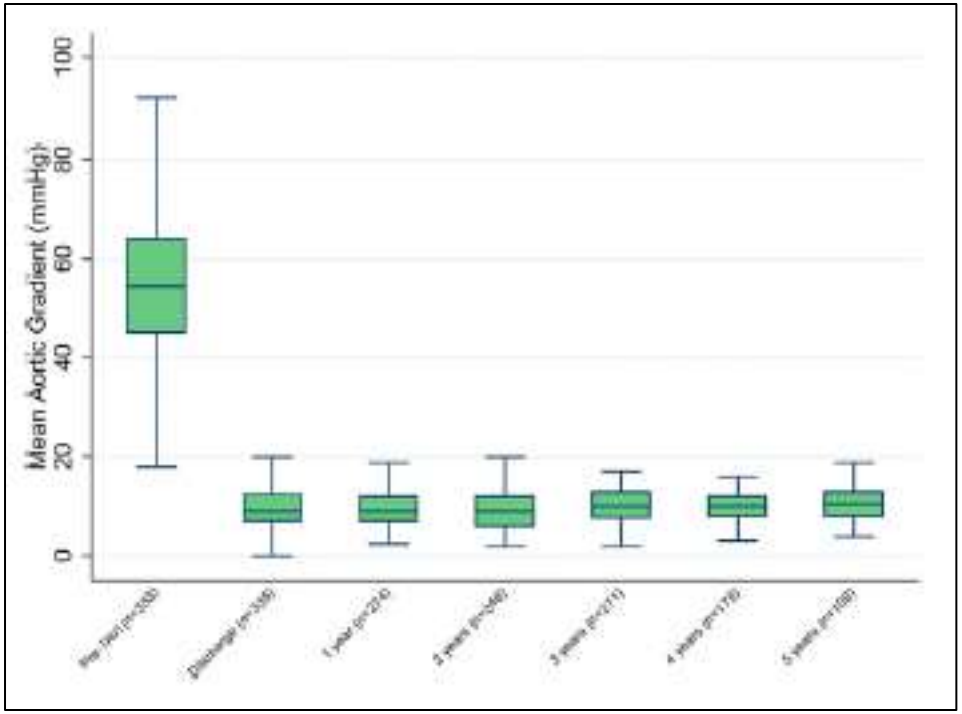
Transcatheter Aortic Valve Implantation
THV durability

PARTNER I



Mack et al. Lancet 2015

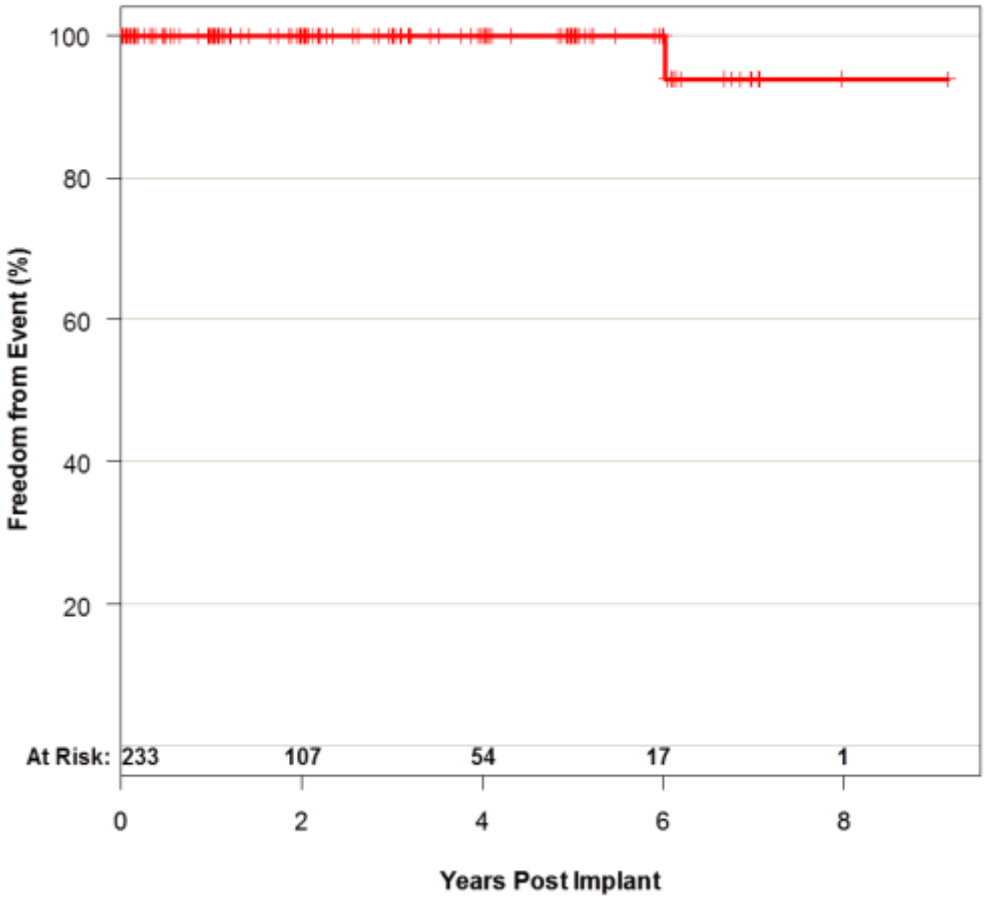
Italian CV Registry



Barbanti et al. JACC Intv 2015

THV Durability
CHU Rouen

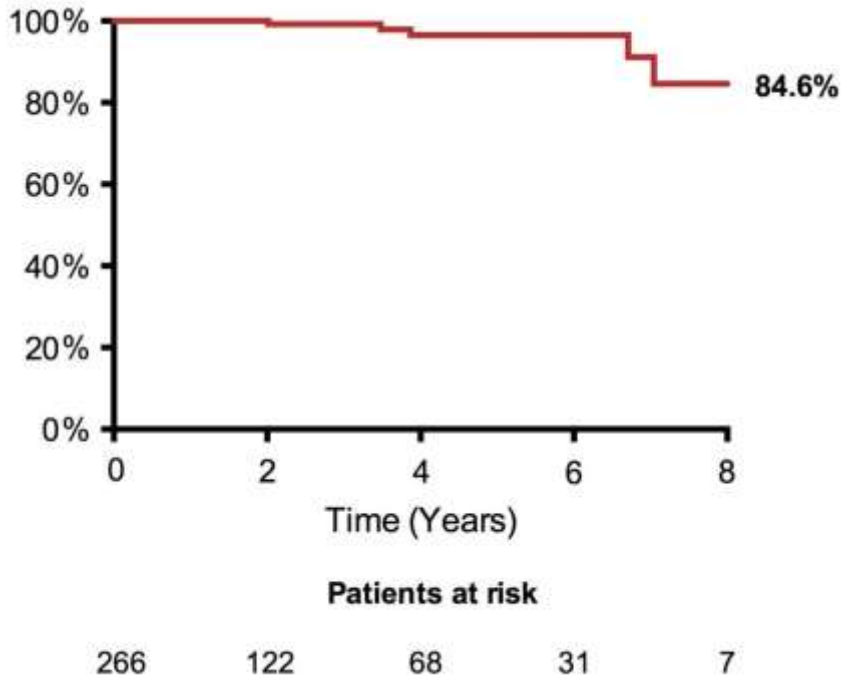
- 239 pts from 2002-2011 (> 5 years FU)
- Freedom from either reoperation, or if asymptomatic, echo mean valve gradient >40 mmHg or severe AR (effective ROA > 0.3cm2)
- *Among survivors, none with MG >40 and only 1 pt with severe AR resulting in ViV procedure*



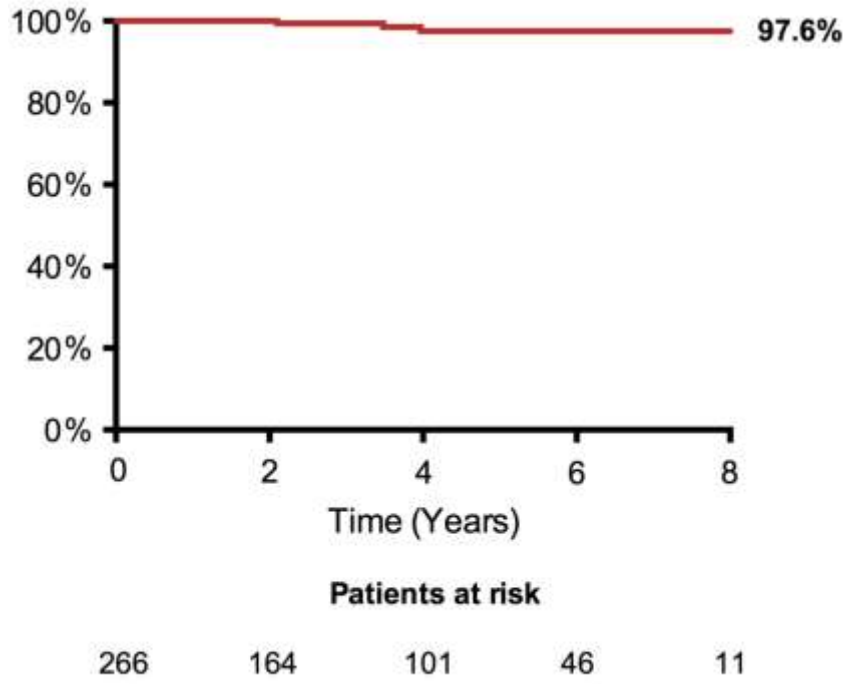
THV Durability
Vancouver

- 266 pts from before 2011 (> 5 years FU)

Freedom from severe failure



Freedom from reintervention



EAPCI-ESC-EACTS consensus 2017

The diagnosis of **SVD** was based on **haemodynamic changes** in valve function assessed by means of echocardiography, with or without evidence of morphological SVD ("isolated haemodynamic dysfunction"). Two degrees of hemodynamic SVD were defined:

1) **Moderate SVD** was defined as **a)** mean gradient ≥20 and <40 mmHg and/or ≥10 and <20 mmHg mmHg change from baseline (before discharge or within 30 days of valve implantation), **and/or b)** moderate new or worsening (>1+/4+) intra-prosthetic aortic regurgitation.
2) **Severe SVD** was defined as **a)** mean gradient ≥40 mmHg and/or ≥20 mmHg change from baseline (before discharge or within 30 days of valve implantation), **and/or b)** severe new or worsening (>2+/4+) intra-prosthetic aortic regurgitation.

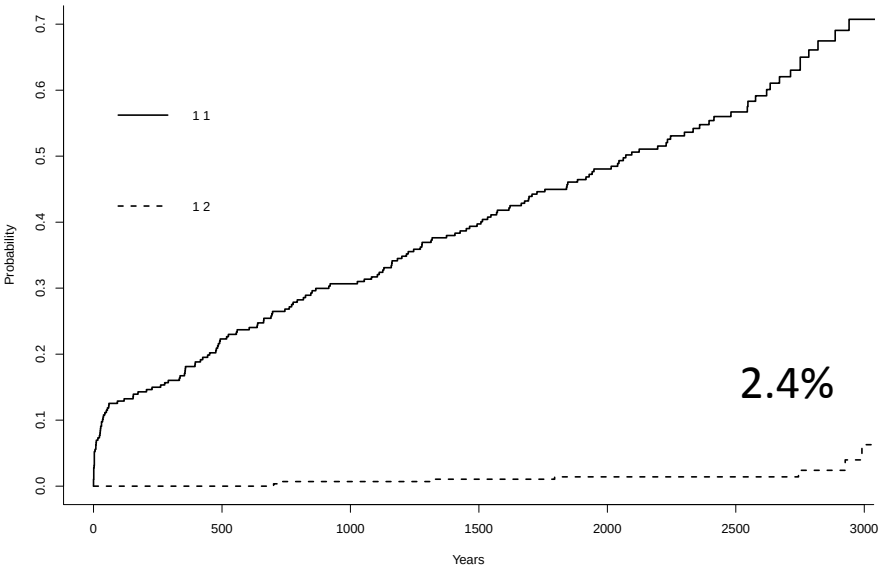
BVF was defined as the composite of:

a) **Severe SVD** at 30 days, 1 year, yearly thereafter or at cardiac-related interim visits,
b) **repeat intervention** for bioprosthetic valve dysfunction, and
c) **valve-related death** or findings of bioprosthetic valve dysfunction at autopsy, likely related to death.

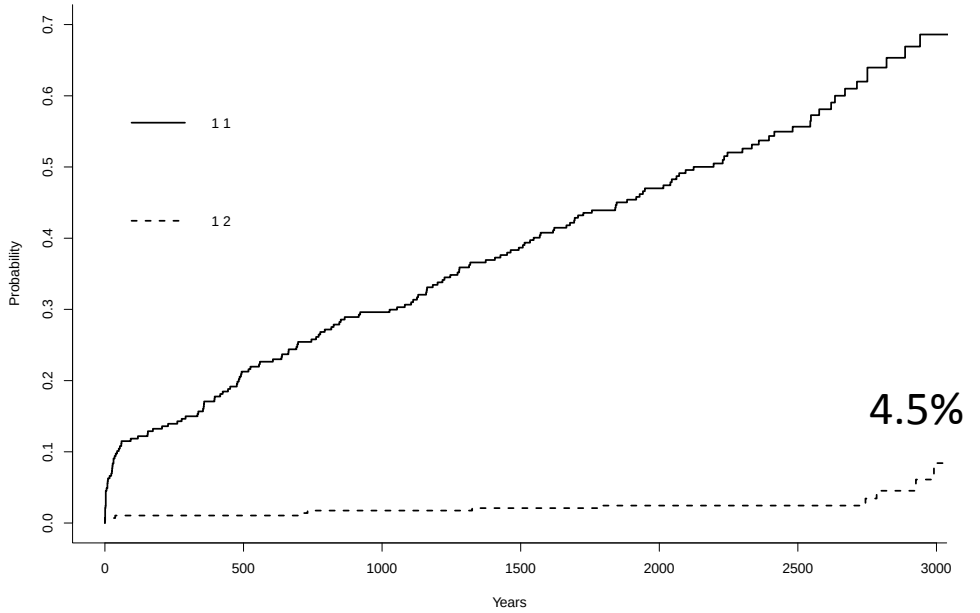
THV Durability
Ferrarotto

- 288 pts before 2012 (> 5 years FU)
- 8-year survival: 29.7%

Severe Structural Valve Dysfunction



Bioprosthesis Valve Failure



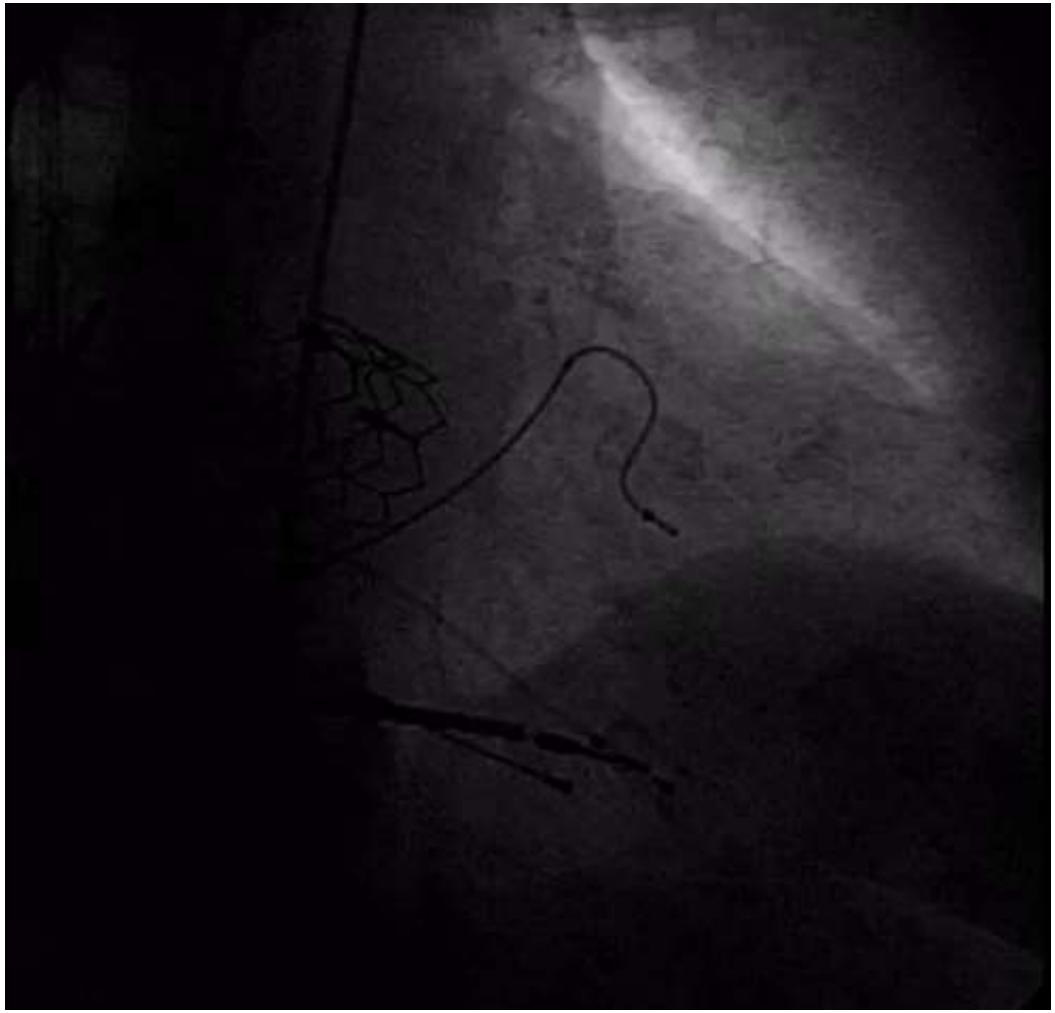
Transcatheter Aortic Valve Implantation

TAVI nightmares

Outcomes	Reported Rate, Min, Max, %	Cumulative Rate	I^2,%	Cochran's Q	p Value Heterogeneity	Pooled Estimate Rate, %	95% CI
Failure to deliver or implantation of the valve in the correct position	0.8, 5.6	79/2,383	53.8	19.5	0.02	3.5	2.2–5.6
Multiple valve implanted	0.6, 4.1	38/2,208	62.1	21.1	0.0069	1.8	1.1–3.1
AVA ≤1.2 cm^2	0.0, 9.7	30/814	98.2	55.0	<0.0001	4.8	3.0–6.6
Mean gradient >20 mm Hg	0.0, 2.9	11/1,064	85.2	20.2	0.0002	1.0	0.0–2.1
Moderate to severe AR	0.0, 30.0	167/2,601	95.3	213.5	<0.0001	7.4	4.6–10.2
Valve embolization	0.0, 5.6	45/2,329	85.9	63.6	<0.0001	1.7	0.2–3.3
Valve in valve	0.0, 9.0	43/2,014	80.9	36.7	<0.0001	2.3	1.3–4.5
Conversion to open surgery	0.0, 5.6	23/2,189	84.1	56.7	<0.0001	1.3	0.0–2.6
Repeat procedure for valve dysfunction	0.0, 4.1	31/1,920	51.7	14.5	0.04	1.8	1.0–3.7
Unplanned CPB	0.0, 1.9	15/1,081	78.0	9.1	0.01	1.3	0.3–2.2
Coronary obstruction	0.0, 3.0	13/1,984	54.1	13.1	0.04	0.7	0.4–1.1
LV perforation	0.2, 0.8	3/702	0.0	0.6	0.43	0.4	0.1–1.5
Tamponade	0.6, 4.6	29/1,097	74.4	19.5	0.0015	2.7	1.7–4.2
Annulus rupture	0.3, 0.8	3/560	0.0	0.5	0.77	0.5	0.2–1.7
Aortic rupture	0.8, 1.0	5/539	0.0	0.1	0.82	0.9	0.4–2.2
Aortic dissection	0.9, 1.7	5/468	0.0	0.7	0.40	1.1	0.4–2.5
Endocarditis	0.3, 1.1	5/832	0.0	1.9	0.39	0.6	0.2–1.4
Valve thrombosis	0.0, 2.7	2/380	93.5	15.3	<0.0001	1.2	0.3–2.2
LVOT rupture	0.6	1/165	—	—	—	0.6	0.1–4.3
VSD	0.6	1/165	—	—	—	0.6	0.1–4.3

Généreux P et al. JACC 2012

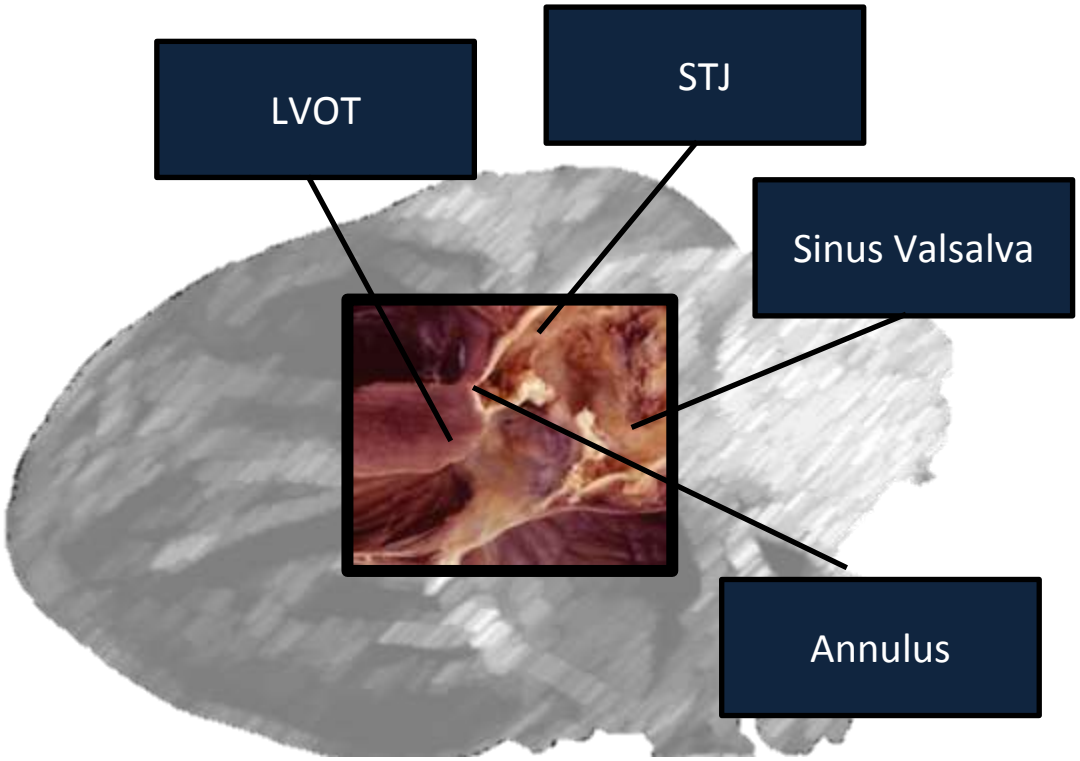
TAVI nightmares
Aortic rupture



Courtesy of Azeem Latib

TAVI nightmares
Aortic rupture

Where aortic rupture might occur?



TAVI nightmares
Aortic rupture

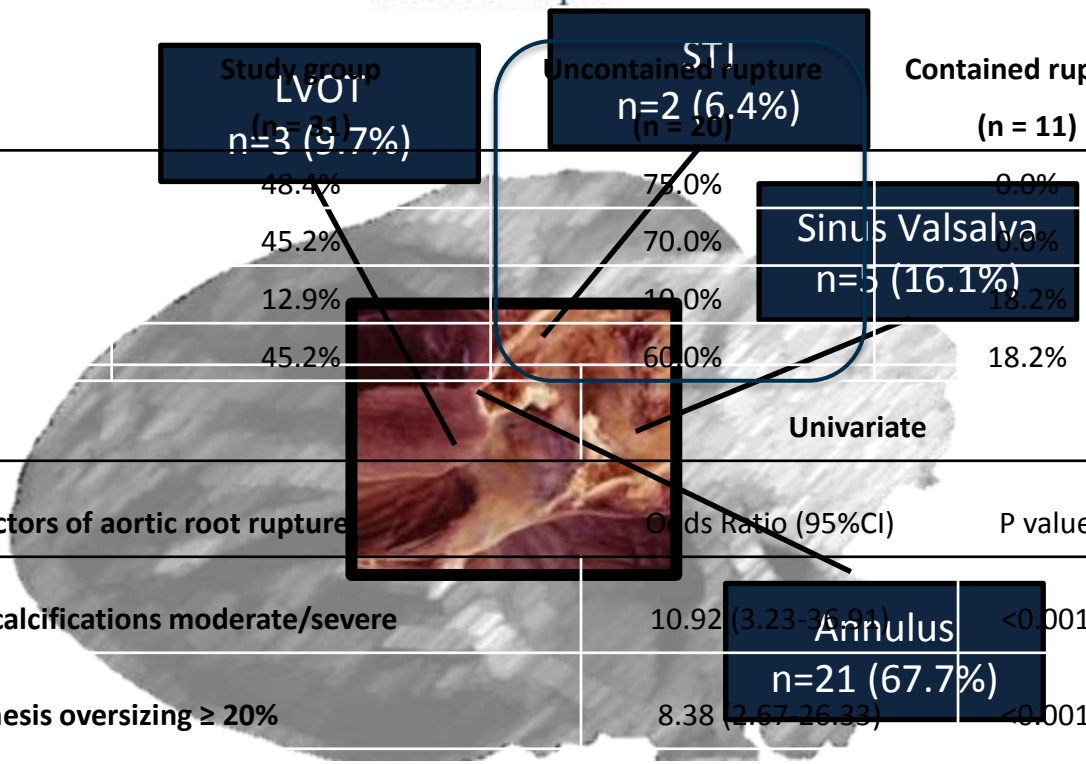
Anatomical and Procedural Features Associated with Aortic Root Rupture During Balloon-Expandable Transcatheter Aortic Valve Replacement

Marco Barbanti, Tae-Hyun Yang, Josep Rodés-Cabau, Corrado Tamburino, David A. Wood, Hasan Jilaihawi, Philipp Blanke, Raj R. Makkar, Azeem Latib, Antonio Colombo, Giuseppe Tarantini, Rekha Raju, Ronald K. Binder, Giang Nguyen, Melanie Freeman, Henrique B. Ribeiro, Samir Kapadia, James Min, Gudrun Feuchtner, Ronen Gurtvich, Faisal Alqoofi, Marc Pelletier, Gian Paolo Ussia, Massimo Napodano, Fabio Sandoli de Brito, Jr., Susheel Kodali, Bjarne L. Norgaard, Nicolaj C. Hansson, Gregor Pache, Sergio J. Canovas, Hongbin Zhang, Martin B. Leon, John G. Webb and Jonathon Leipsic

Study group	Uncontained rupture (n = 20)	Contained rupture (n = 11)	P value
Mortality	75.0%	0.0%	<0.001
Cardiovascular mortality	70.0%	0.0%	<0.001
Disabling stroke	10.0%	18.2%	0.447
Life-threatening bleeding	60.0%	18.2%	0.049

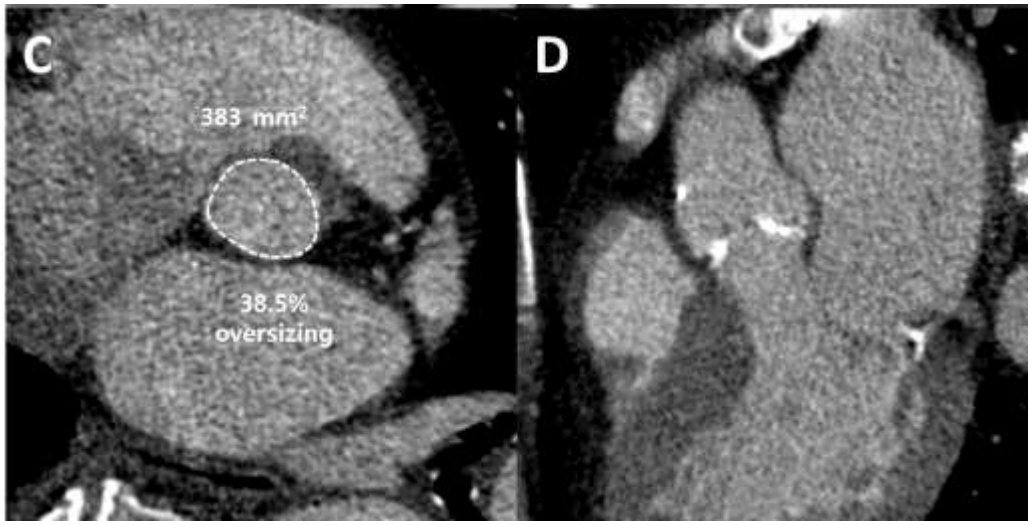
Univariate

Predictors of aortic root rupture	Odds Ratio (95%CI)	P value
LVOT calcifications moderate/severe	10.92 (3.23-36.91)	<0.001
Prosthesis oversizing ≥ 20%	8.38 (2.67-26.33)	<0.001



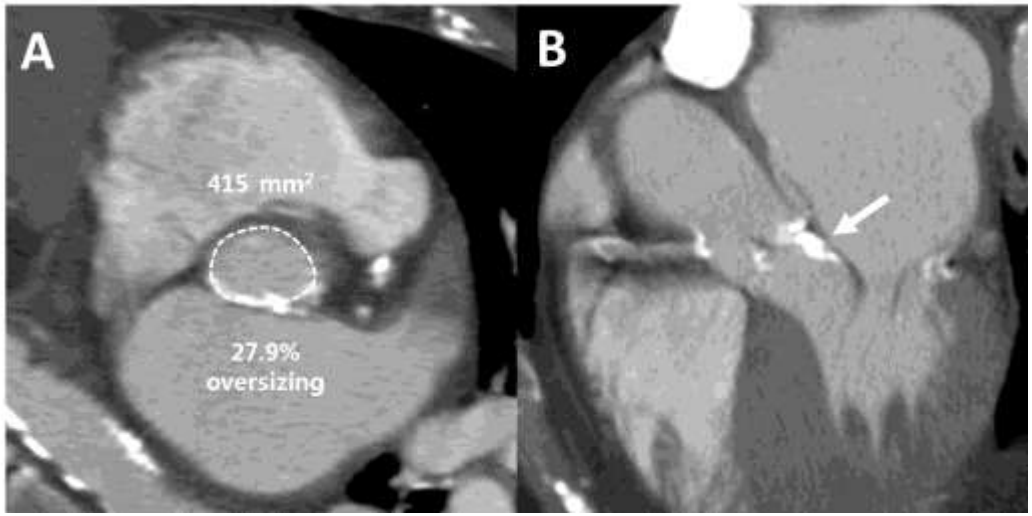
Barbanti M et al. Circulation 2013

Significant oversizing (>20%) is possible… Just not in the wrong patient!



Case example #1

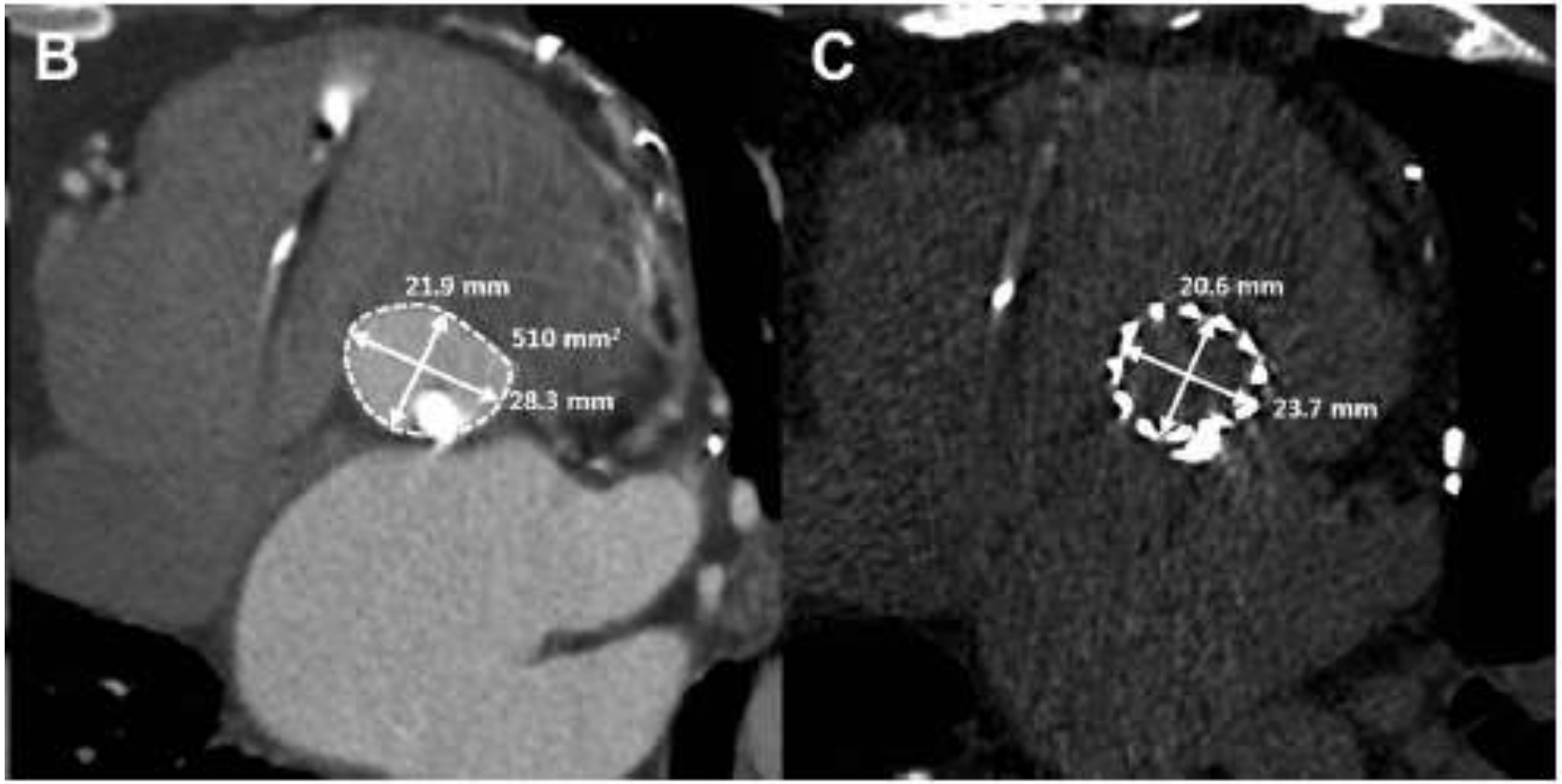
- ❑ 26-mm SAPIEN XT
- ❑ 38.5% oversizing
- ❑ No LVOT calcification
- ❑ Uneventful TAVR!



Case example #2

- ❑ 26-mm SAPIEN XT
- ❑ 27.9% oversizing
- ❑ Severe LVOT calcification
- ❑ Annular rupture!

How to prevent aortic rupture
Balloon-expandable THV intentional underexpansion

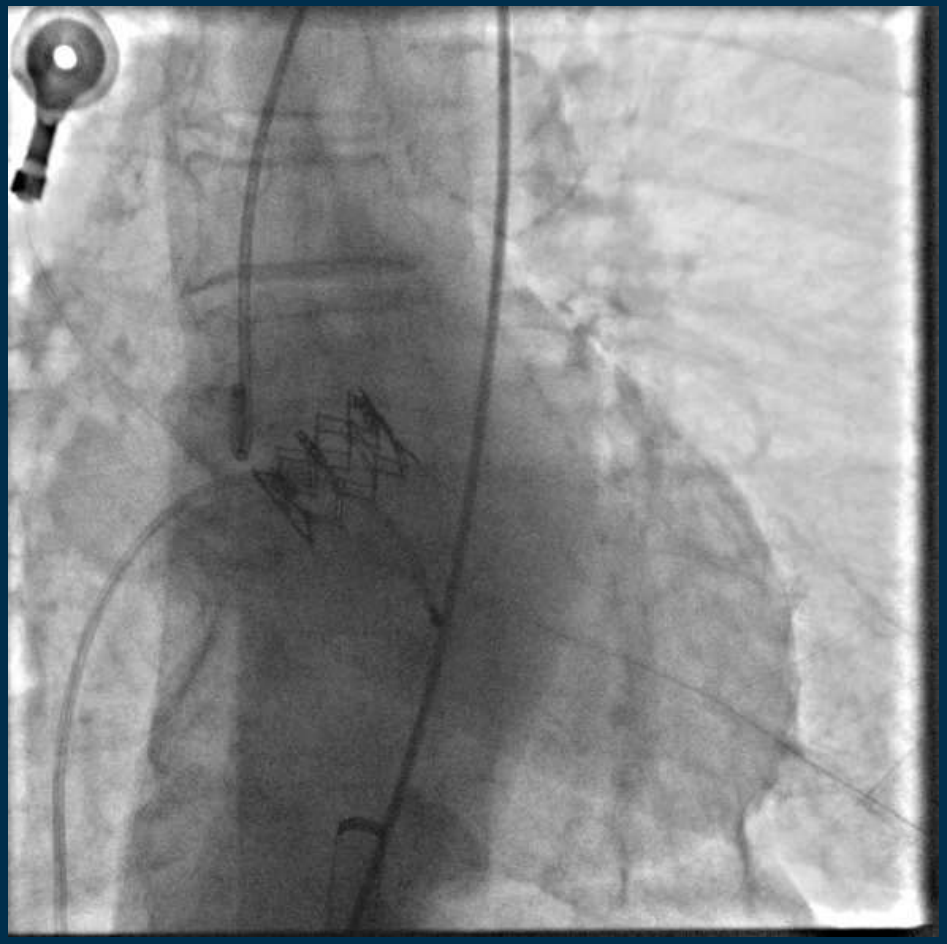


26-mm SAPIEN XT 2 ml underfilled

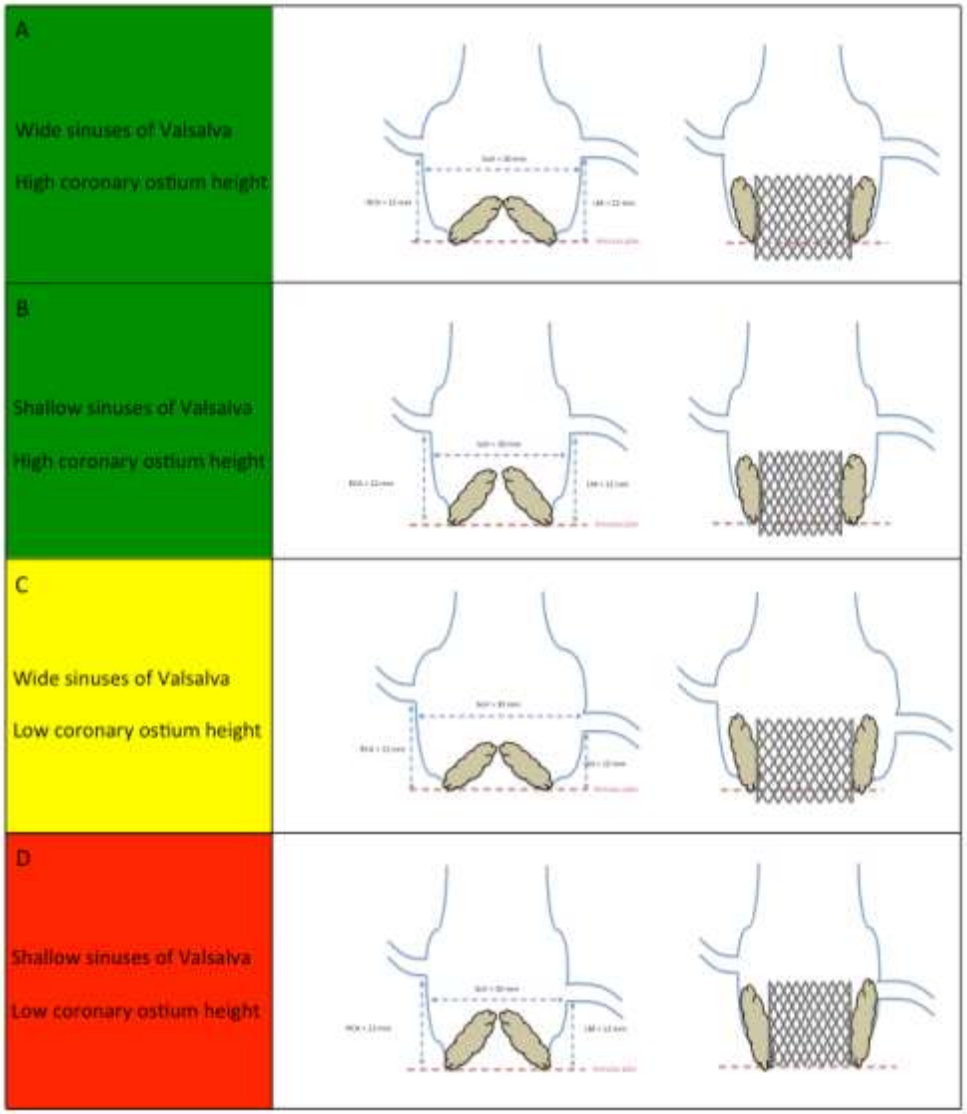
Barbanti M et al. JACC 2014

TAVI nightmares

Coronary occlusion

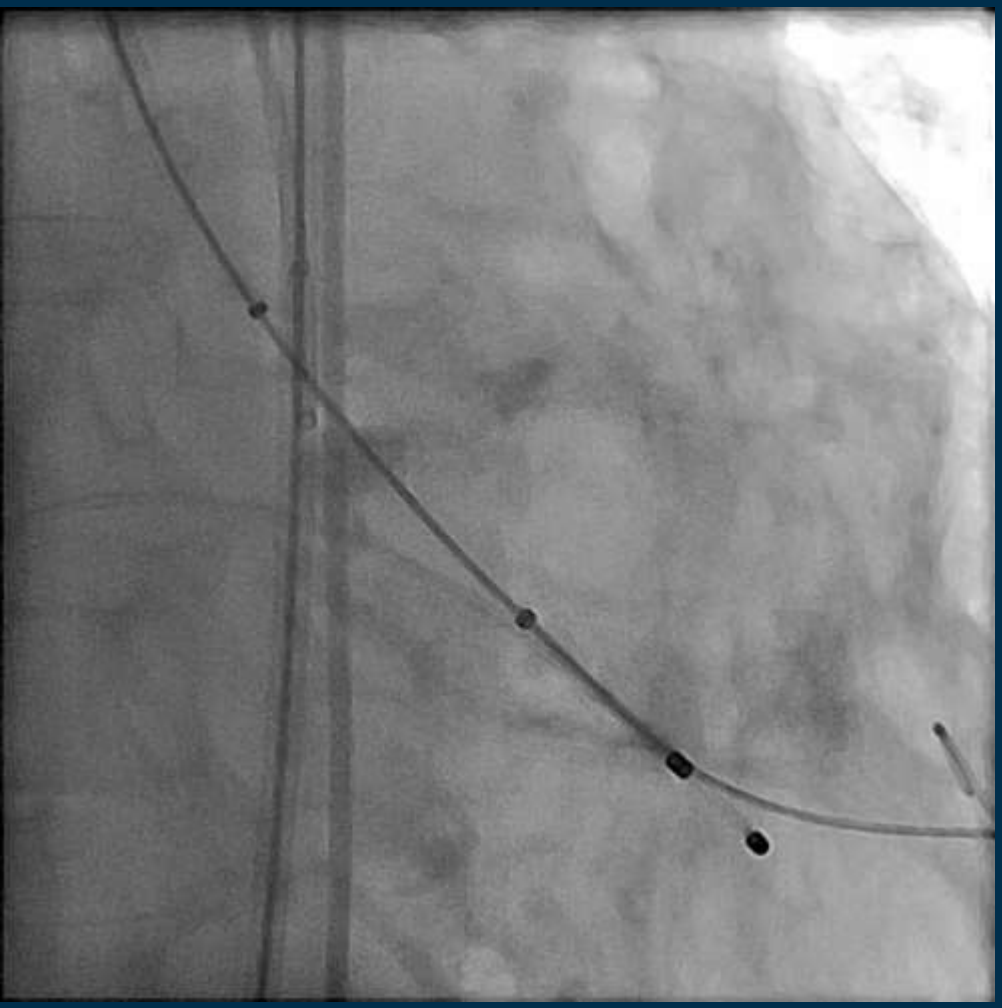


Coronary occlusion



TAVI nightmares

Coronary occlusion – How to prevent it?



- Both coronaries well perfused
- Very low risk of ostia occlusion

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Conclusions

- Aortic rupture and coronary occlusion are rare, but life-threatening TAVI complications
- The best way to "deal" with such complications is to AVOID THEM - Optimal aortic root assessment:
  - Annular, SoV and STJ dimensions
  - Coronary ostia height
  - LVOT and aortic valve calcium distribution
- Optimal positioning technique
- Develop pre-specified plans and techniques to deal with these complications when they happen
- Recognize the potential complications of TAVI early on
- Bailout equipment and expertise