Conoscere e Curare il Cuore 2019

VENERDI' 1 MARZO

TAVI: COME RIDURRE LE COMPLICANZE POST-INTERVENTO

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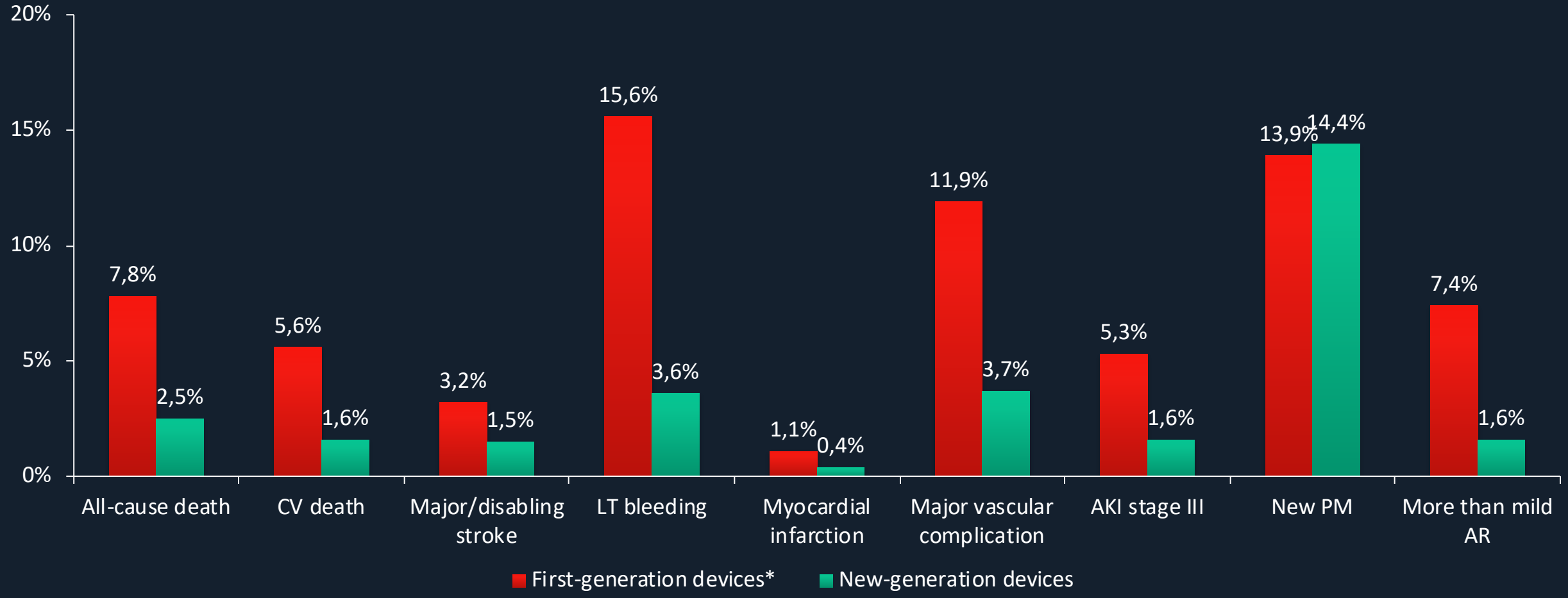
Ospedale Policlinico, Catania
Università degli Studi di Catania

Aortic Stenosis: Recommendations for the choice of intervention mode

	COR	LOE
Aortic valve interventions should only be performed in centres with both departments of cardiology and cardiac surgery on site and with structured collaboration between the two, including a Heart Team (heart valve centres)	I	C
TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team	I	B
In patients who are at increased surgical risk (STS or EuroSCORE II ≥ 4% or logistic EuroSCORE I ≥ 10% or other risk factors not included in these scores such as frailty, porcelain aorta, sequelae of chest radiation), the decision between SAVR and TAVI should be made by the Heart Team according to the individual patient characteristics, with TAVI being favoured in elderly patients suitable for transfemoral access	I	B

Baumgartner H, et al. Eur Heart J 2017

Transcatheter Aortic Valve Implantation
First- vs. Second-generation devices



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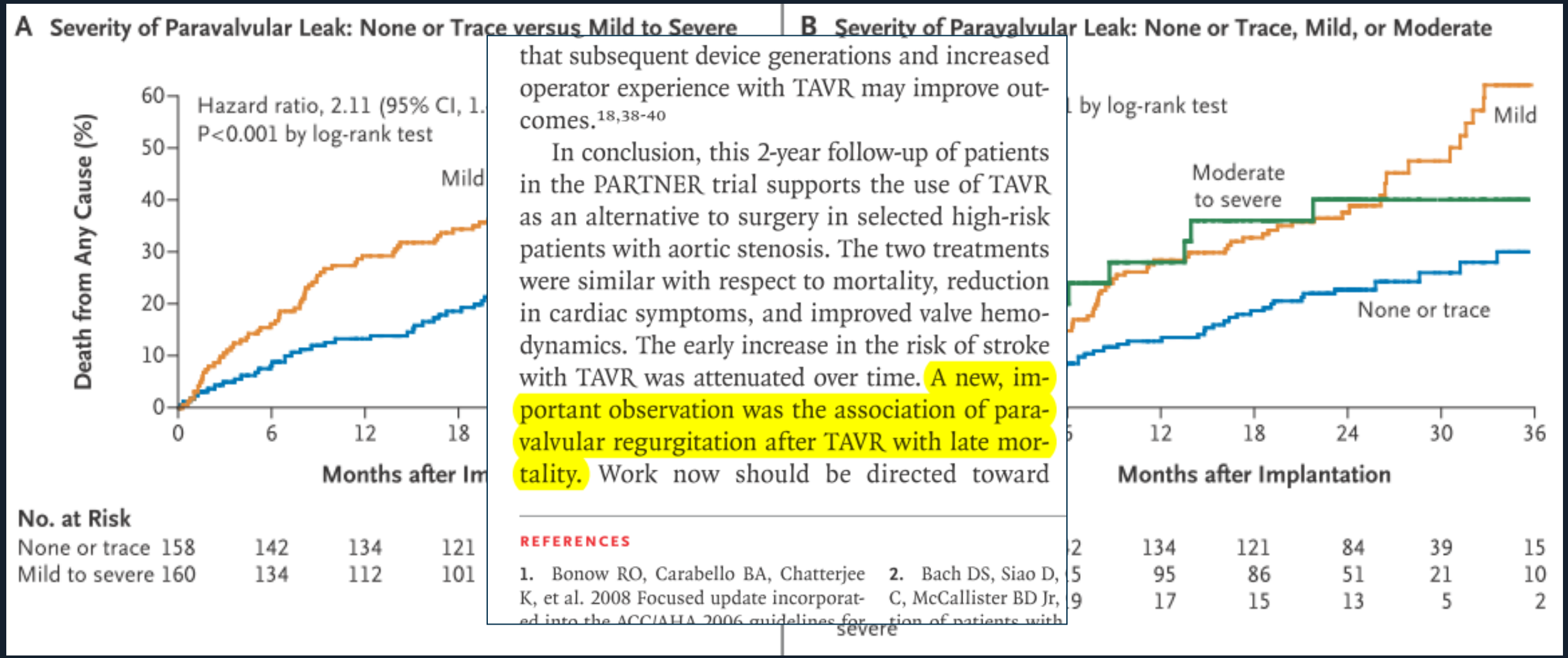
Barbanti et al. Eurointervention 2017

TAVI potential complications

- **Paravalvular regurgitation**
- Cerebrovascular events
- Conduction disturbances
- Vascular complications
- Renal complications
- Annulus rupture and coronary occlusion

Impact of PVL after TAVI



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

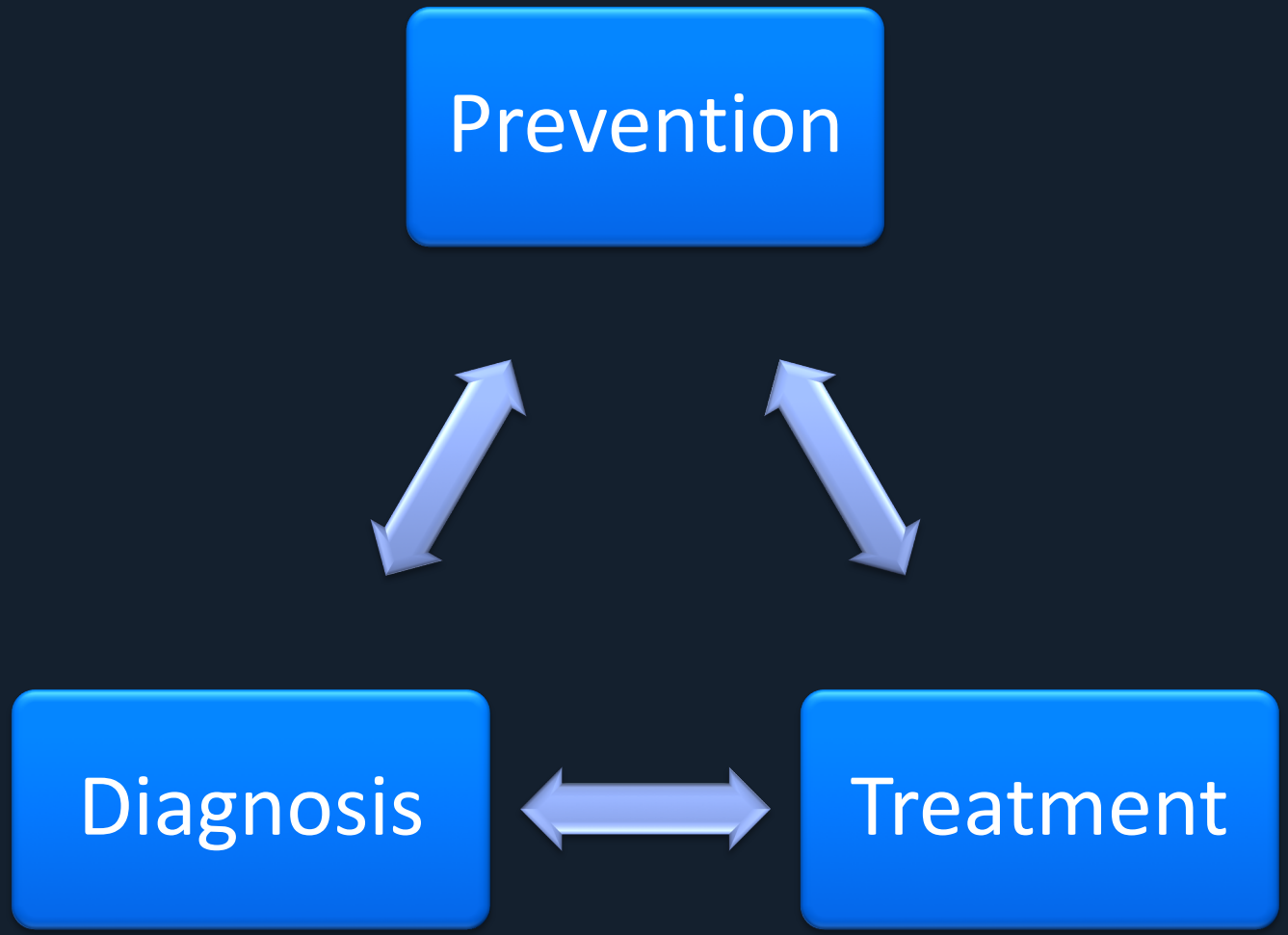
REFERENCES

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

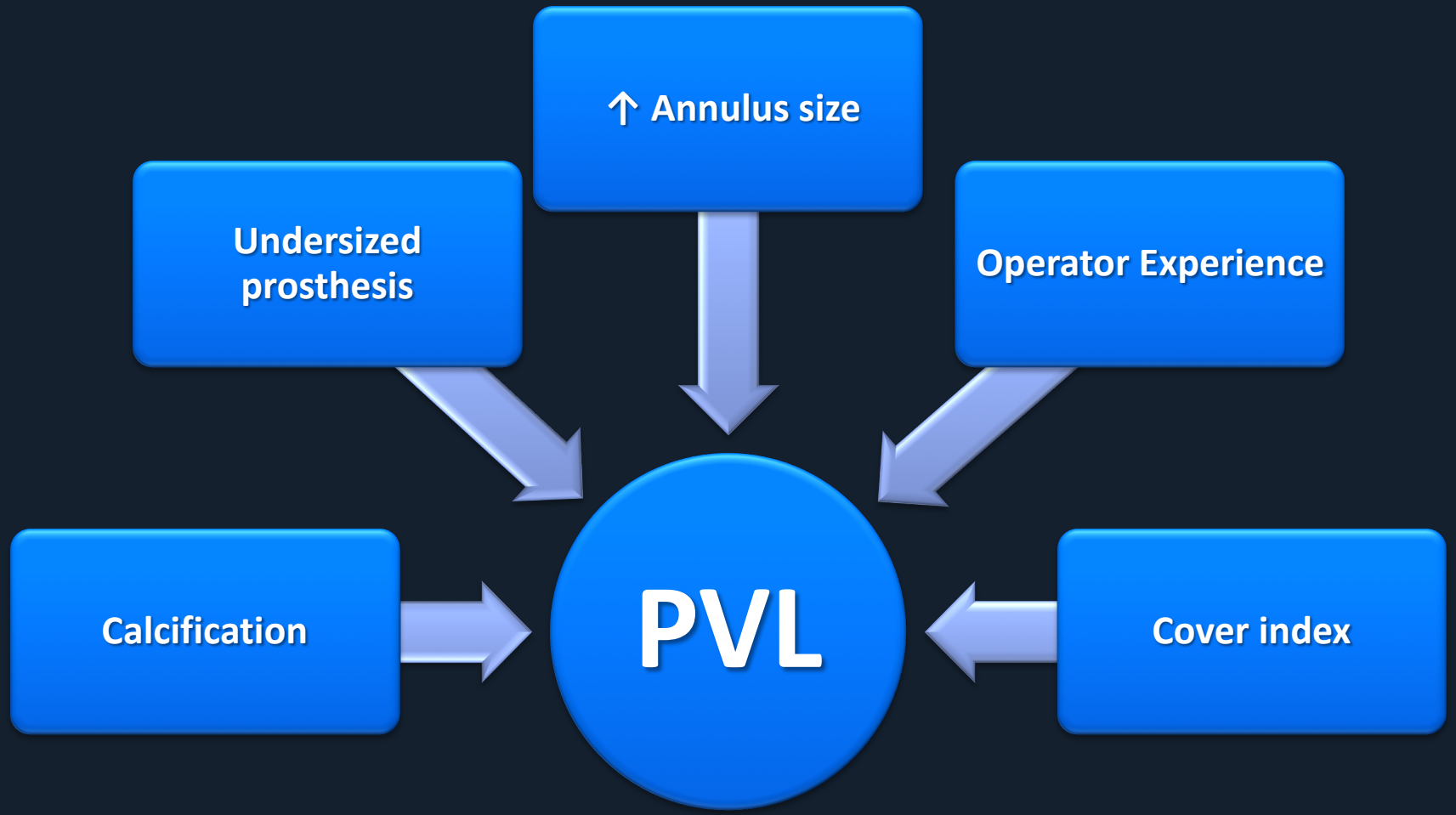
2. Bach DS, Siao D, C, McCallister BD Jr, tion of patients with

Kodali et al., NEJM 2012

PVL after TAVI

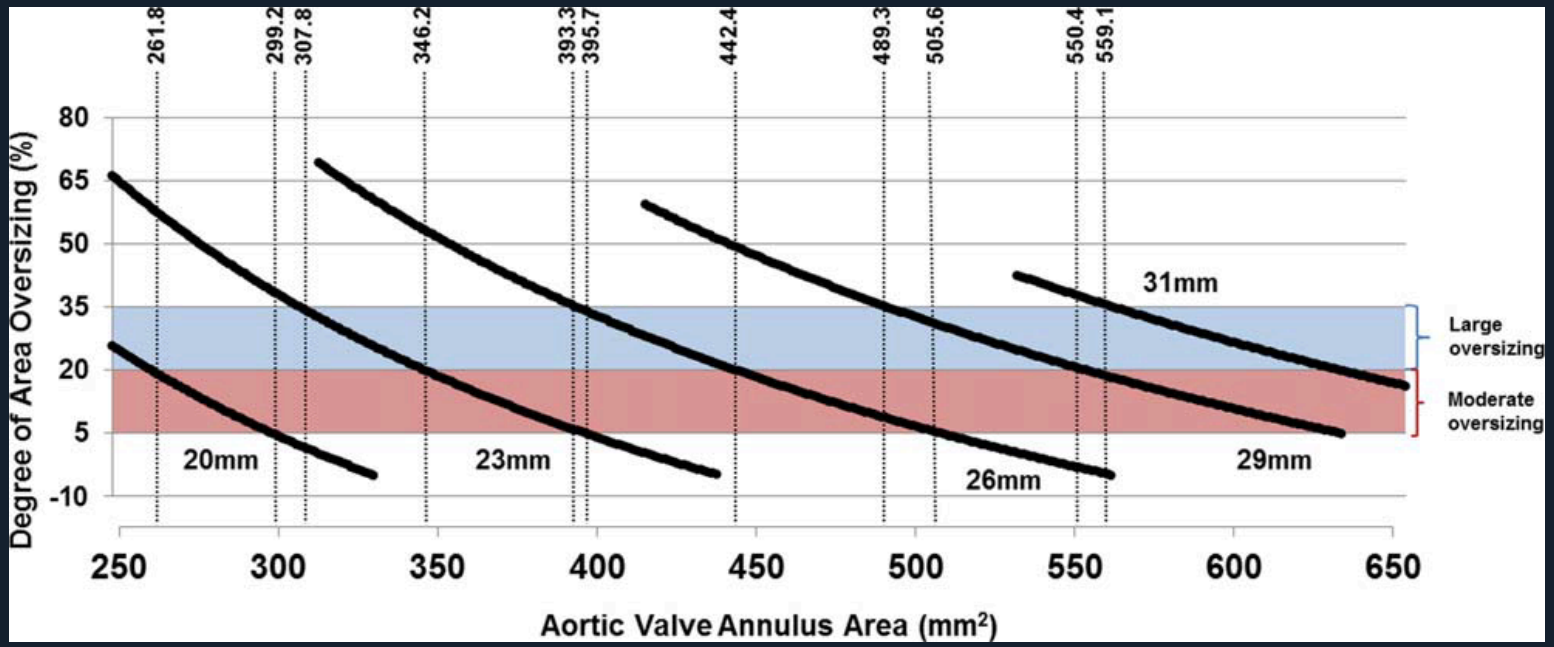


Predisposing factors of PVL after TAVI



Prevention of PVL after TAVI

- MSCT assessment
- Appropriate THV sizing



Dvir D et al. CCI 2015

Prevention of PVL after TAVI: Calcium is bad!

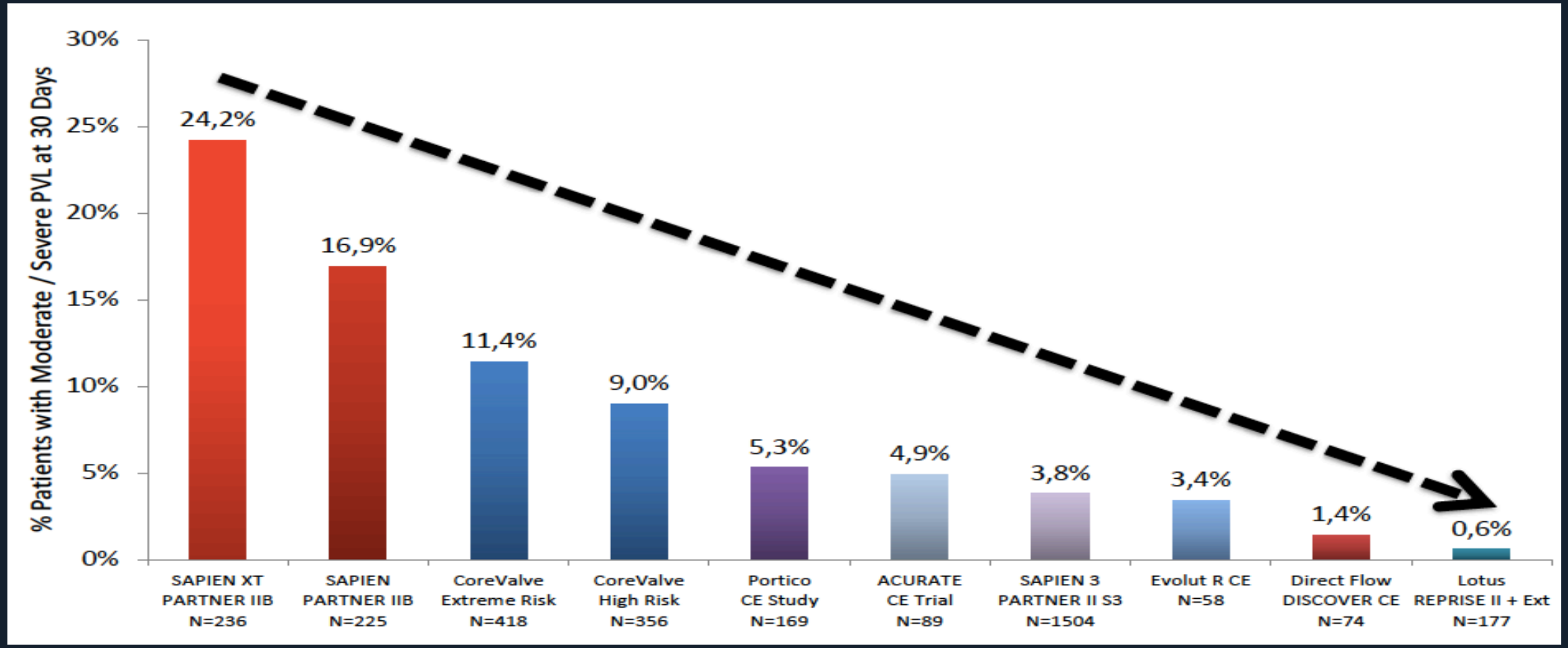
150 patients who received the Sapien or Sapien XT valves at a single institution, Oct 2011 to July 2013; 19% had at least mild leak.

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

Paravalvular Leak



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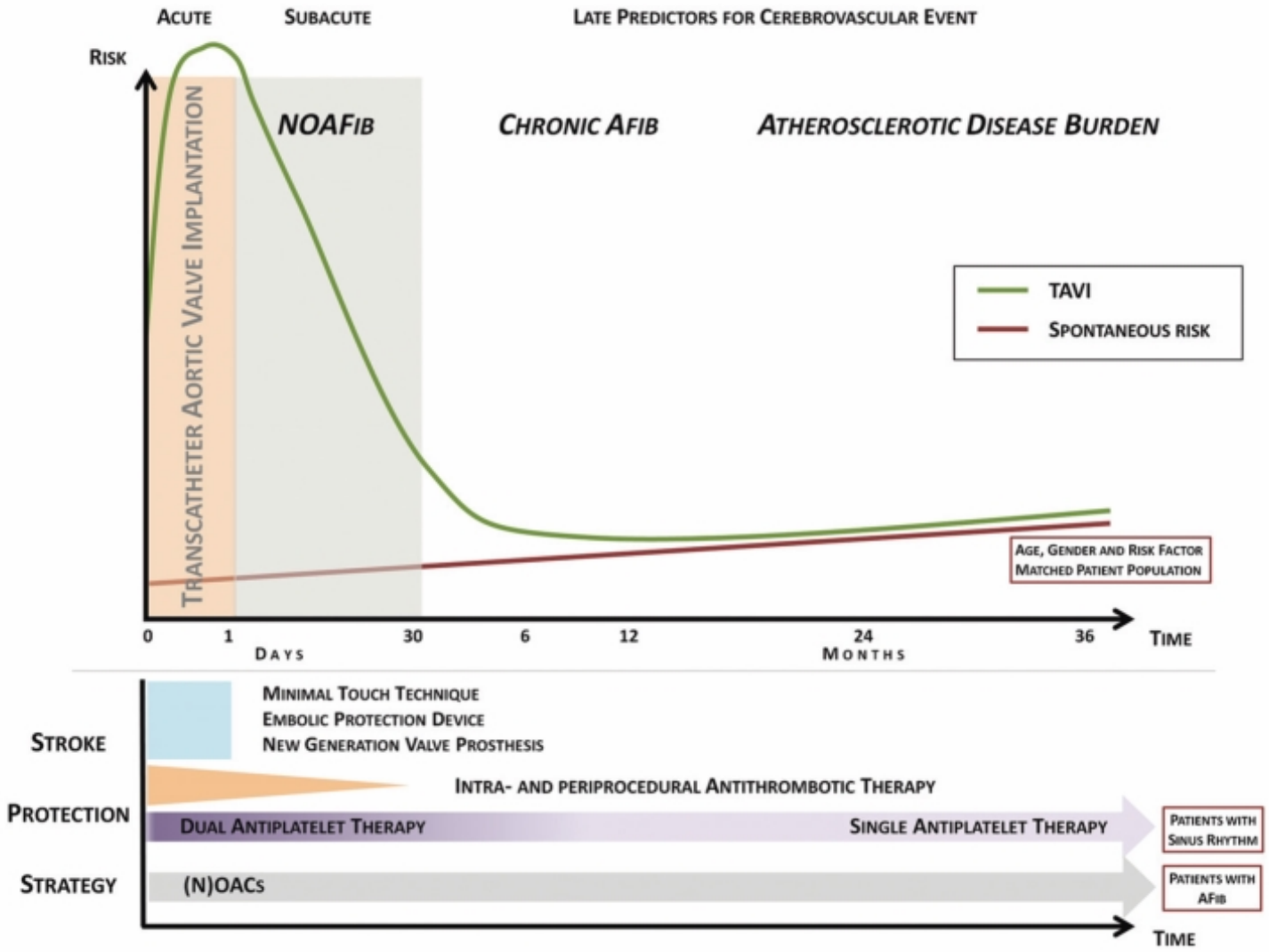
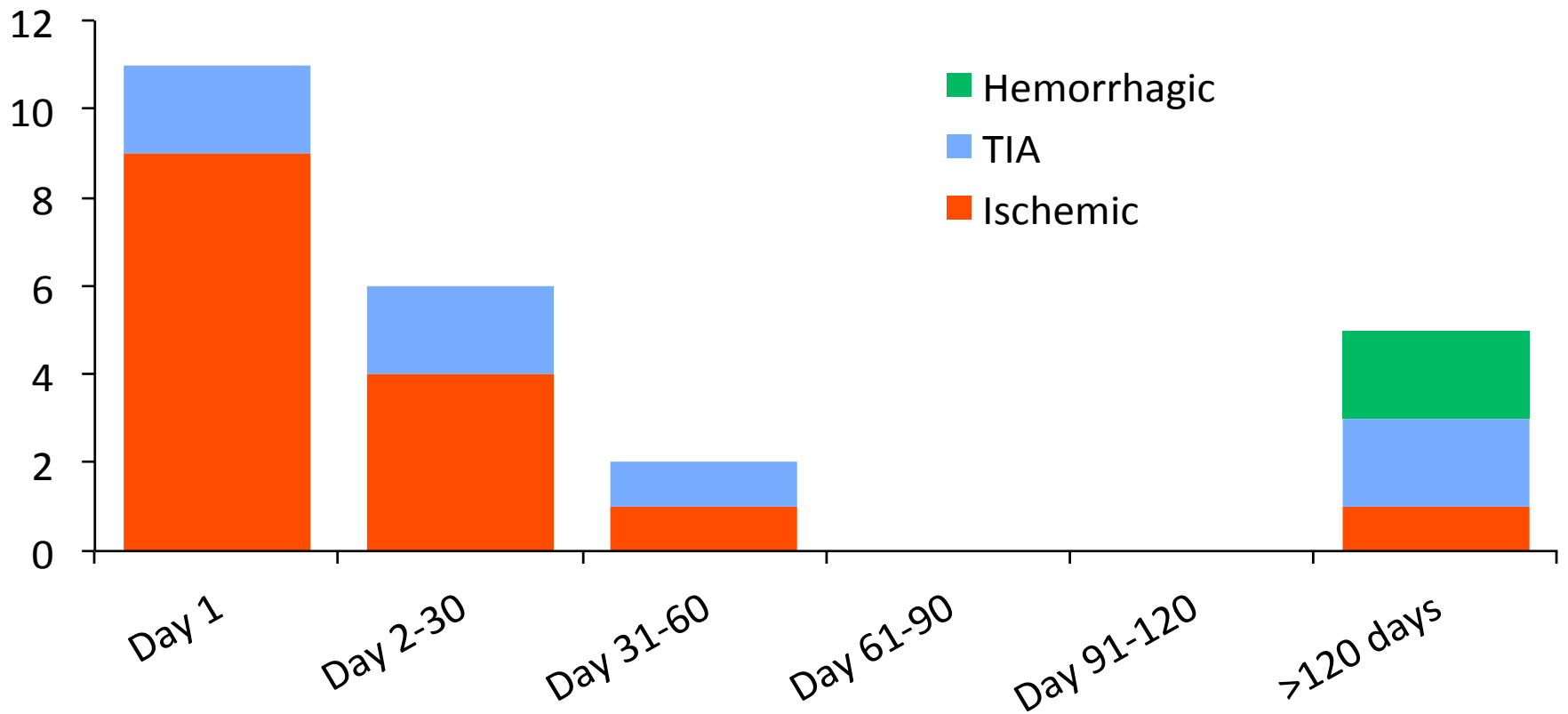
Cerebrovascular events and TAVI

- Stroke is a potential major complication of SAVR, TAVI, and balloon aortic valvuloplasty
- Although it is rare, stroke significantly affects survival and quality of life
- Stroke aetiology is still under debate, particularly when it occurs far from the procedure
- Procedural expedients and optimization of antithormbotic medical therapy are key to reduce cerebrovascular complications



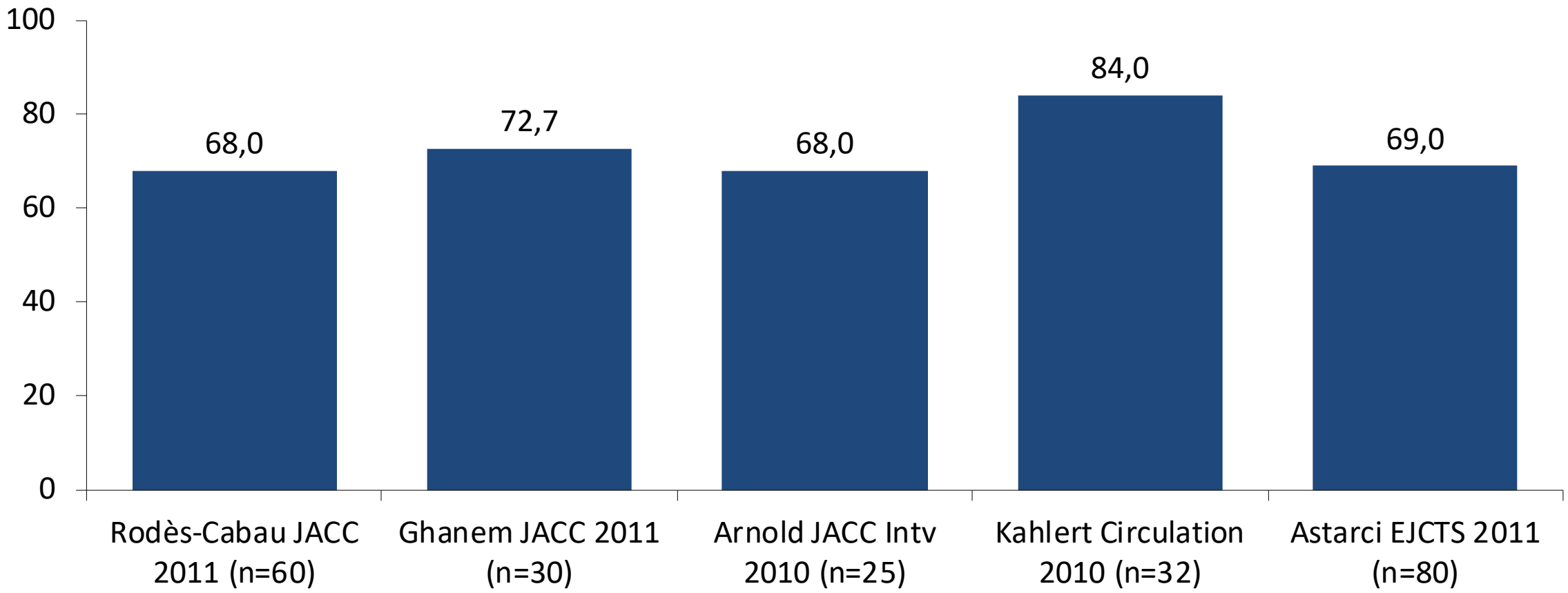
Stortecky et al., Circulation, 2012

Timing of cerebrovascular events after TAVI

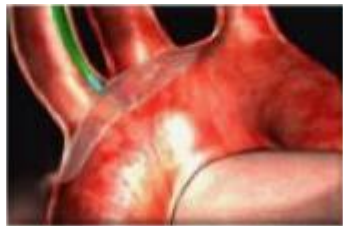
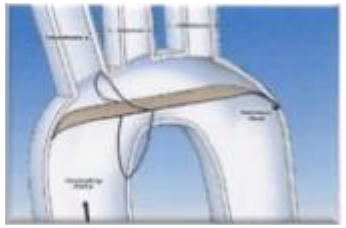


Tay et al, JACC Cardiovasc Interv 2011

MRI cerebral ischemic lesions



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

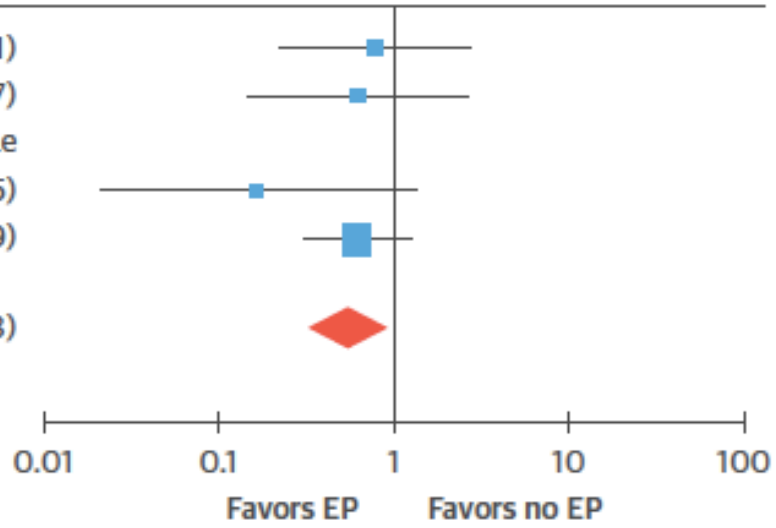
Cerebral embolic protection devices

Death or stroke

Study or Subgroup	Embolic protection Events	Total	No embolic protection Events	Total	Weight	Risk Ratio M-H, Fixed (95% CI)
CLEAN-TAVI	4	50	5	50	15.9%	0.80 (0.23-2.81)
DEFLECT-III	3	46	4	39	13.7%	0.64 (0.15-2.67)
EMBOL-X	0	14	0	16		Not estimable
MISTRAL-C	1	32	6	33	18.7%	0.17 (0.02-1.35)
SENTINEL	16	234	12	111	51.7%	0.63 (0.31-1.29)
Total (95% CI)		376		249	100.0%	0.57 (0.33-0.98)
Total events	24		27			

Heterogeneity: $Chi^2 = 1.68$, $df = 3$ ($P = 0.64$); $I^2 = 0\%$

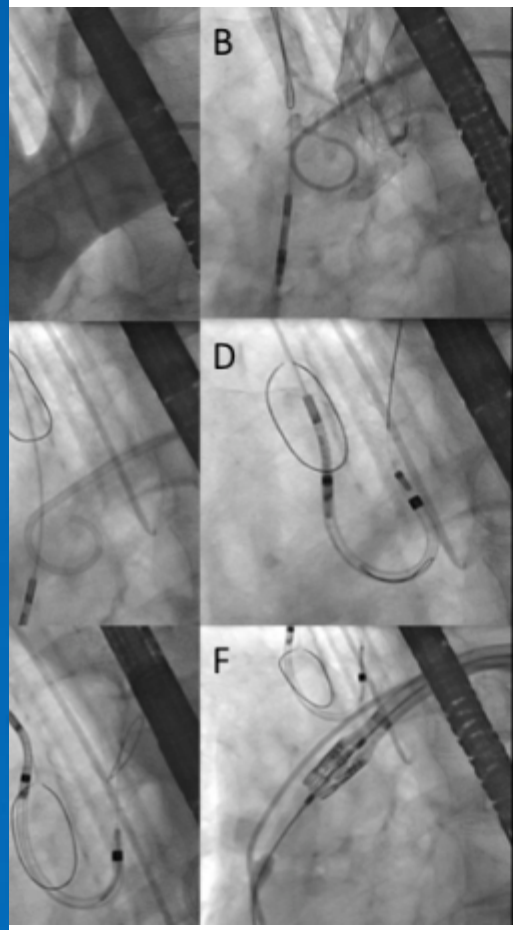
Test for overall effect: $Z = 2.01$ ($P = 0.04$)

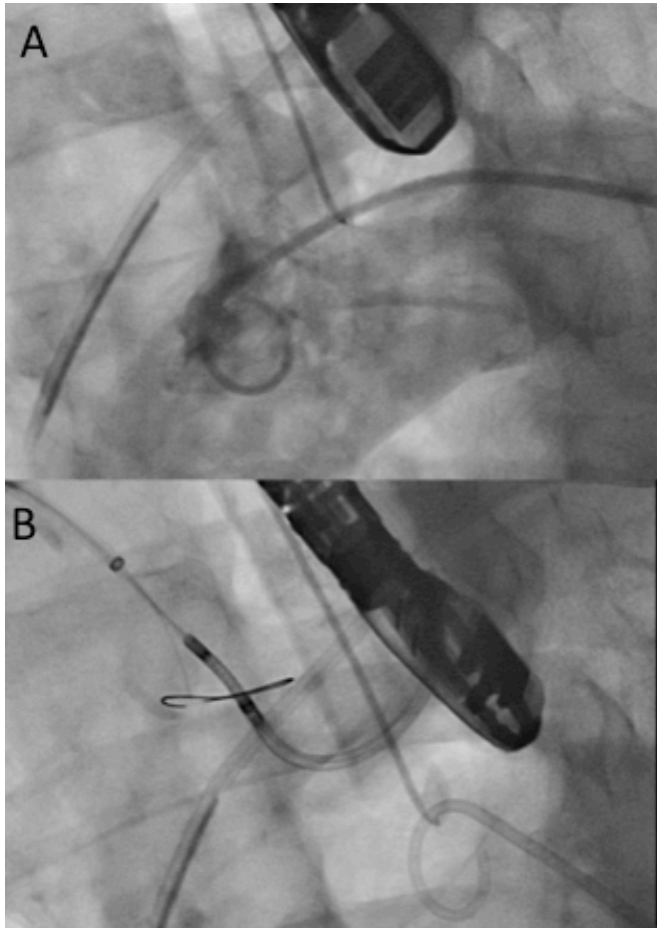


Pooled effect estimates for the risk of death or stroke according to the use of cerebral embolic protection versus not during TAVR. CI = confidence interval; CLEAN-TAVI = Claret Embolic Protection and TAVI; DEFLECT-III = A Prospective, Randomized Evaluation of the TriGuard HDH Embolic Deflection Device 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.

Giustino G, et al. JACC 2016

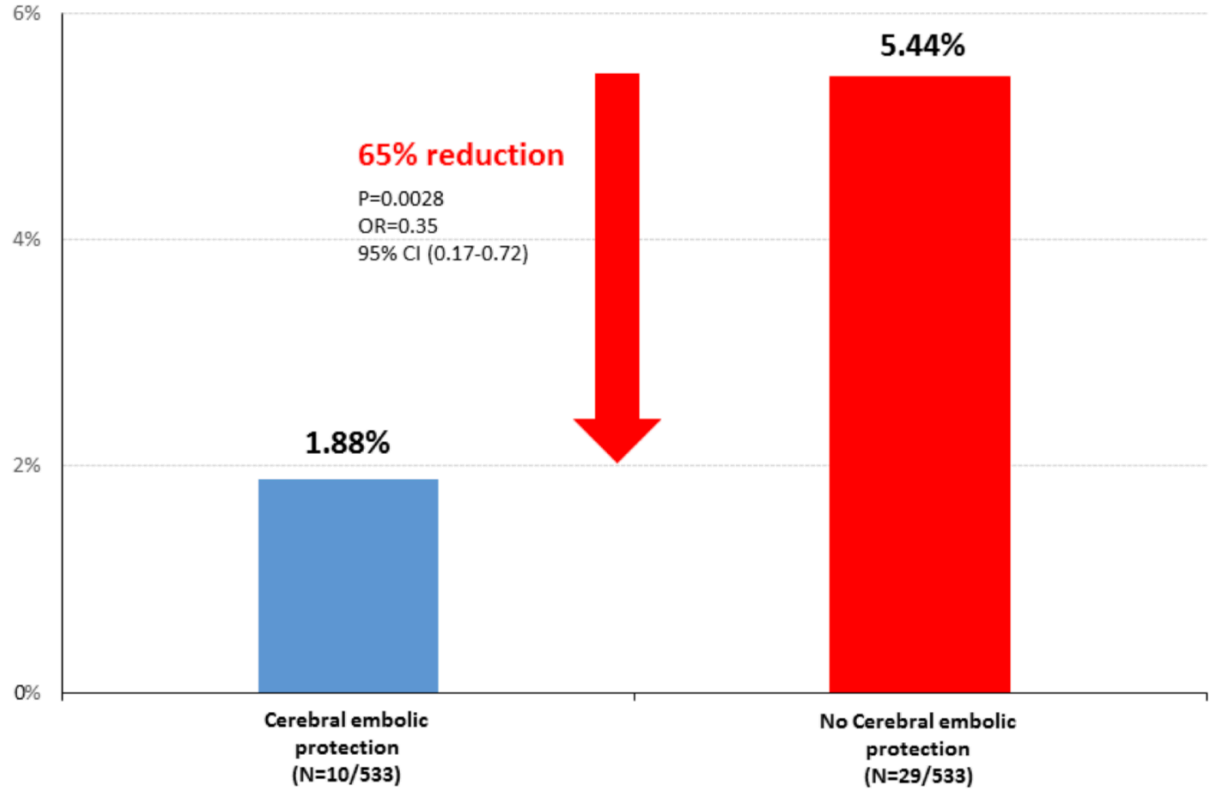
mbolic protection device

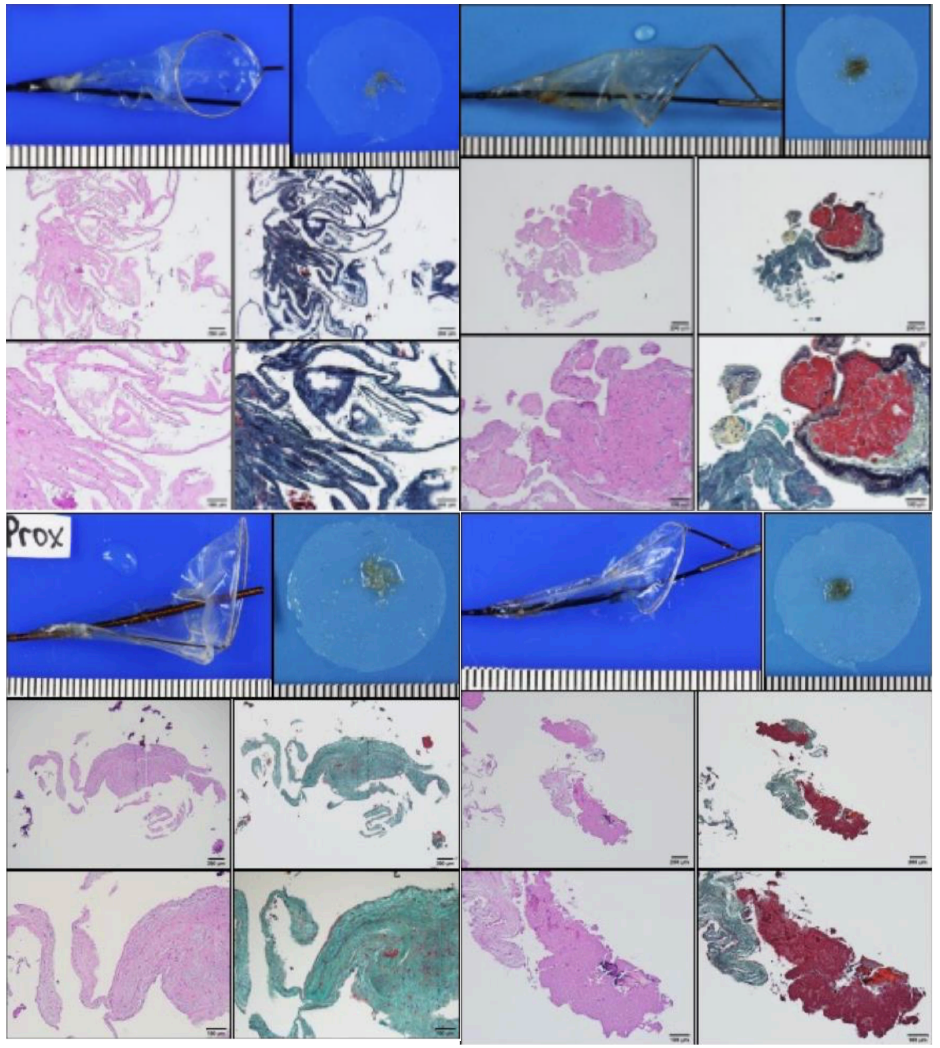




Patient level meta-analysis of 1306 patients enrolled in SENTINEL, CLEAN-TAVI, SENTINEL-ULM

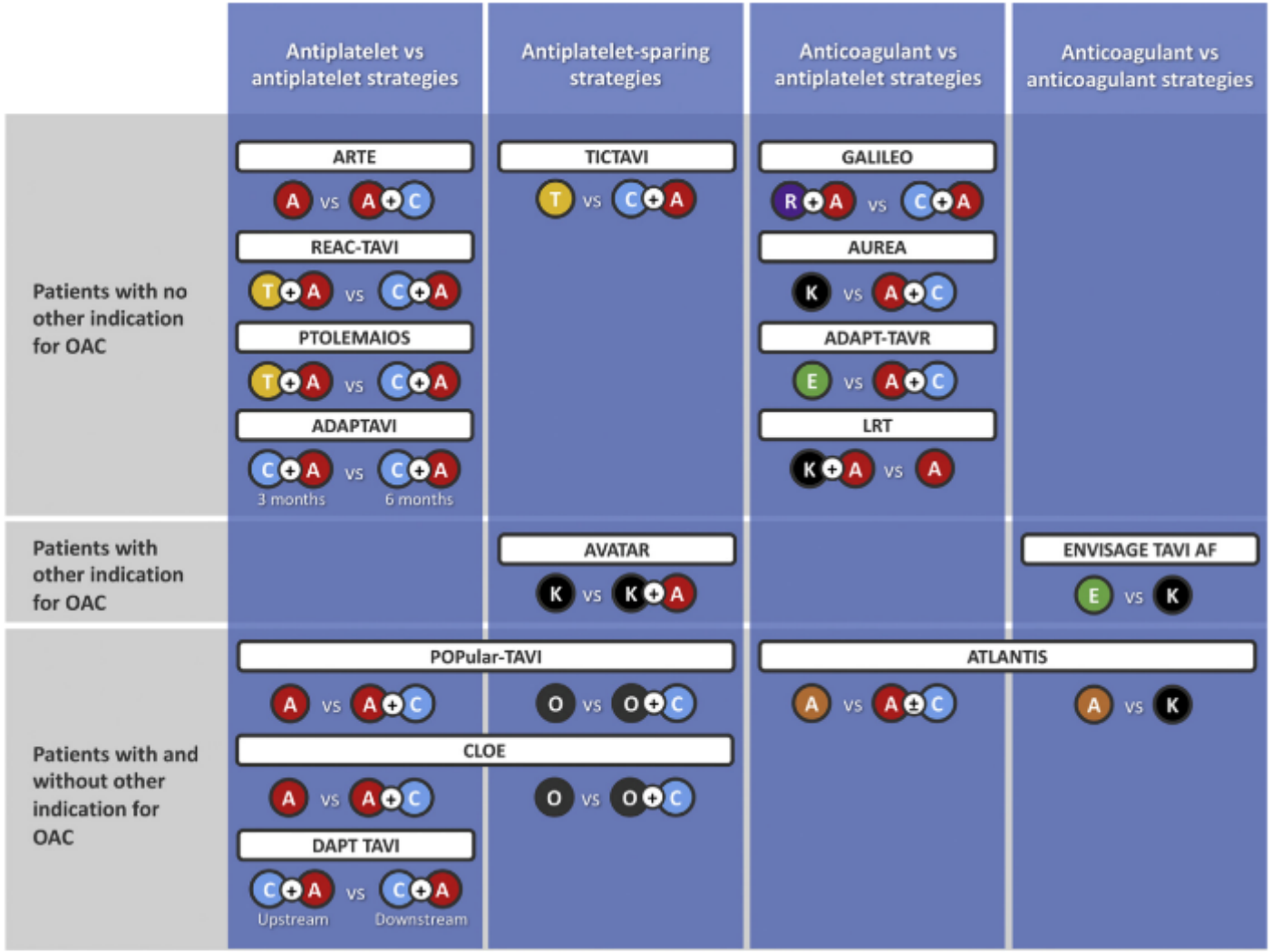
- Propensity score matching: 533 pairs
- primary endpoint was all procedural stroke within 72 hrs post TAVR
- No ViV procedures





Seeger, Eur Heart J, 2019

Trials of Antithrombotic Pharmacotherapy in Patients Undergoing Transcatheter Aortic Valve Replacement



A Aspirin
C Clopidogrel
T Ticagrelor
R Rivaroxaban
A Apixaban
E Edoxaban
K Vitamin K antagonists
O Oral anticoagulation

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Capodanno D, JACC Intv 2019

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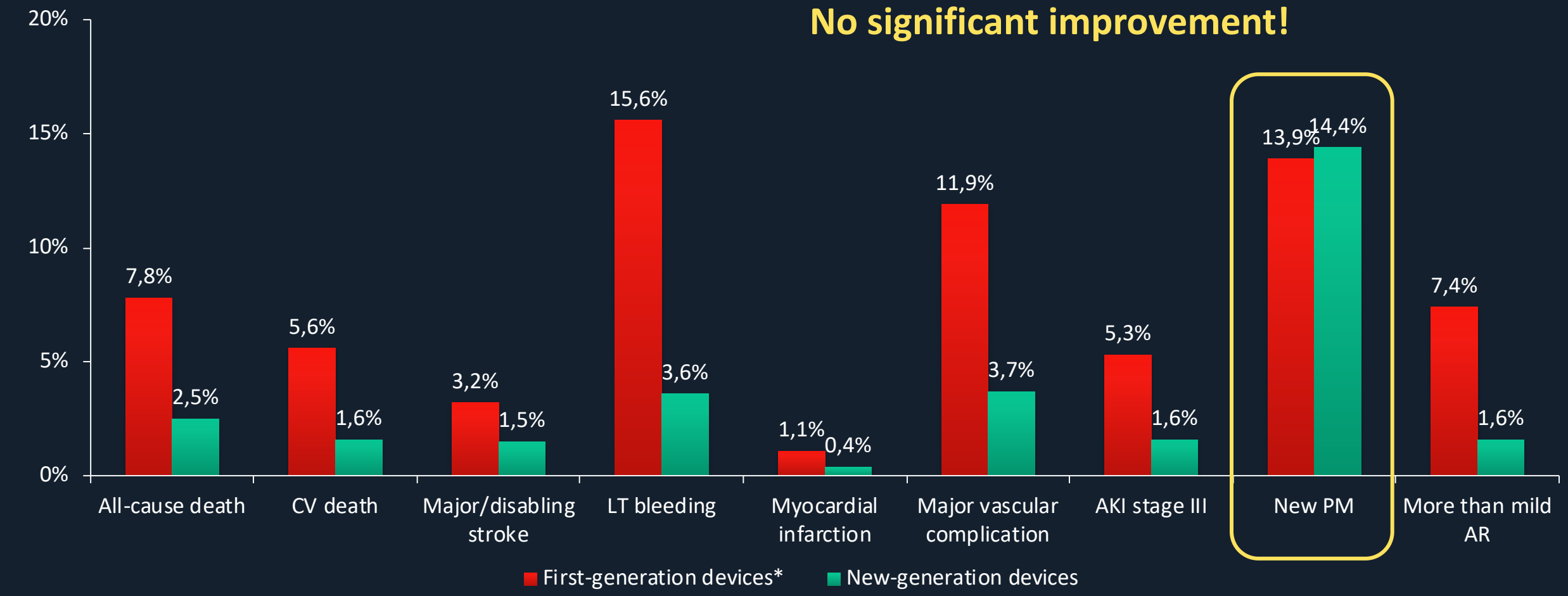
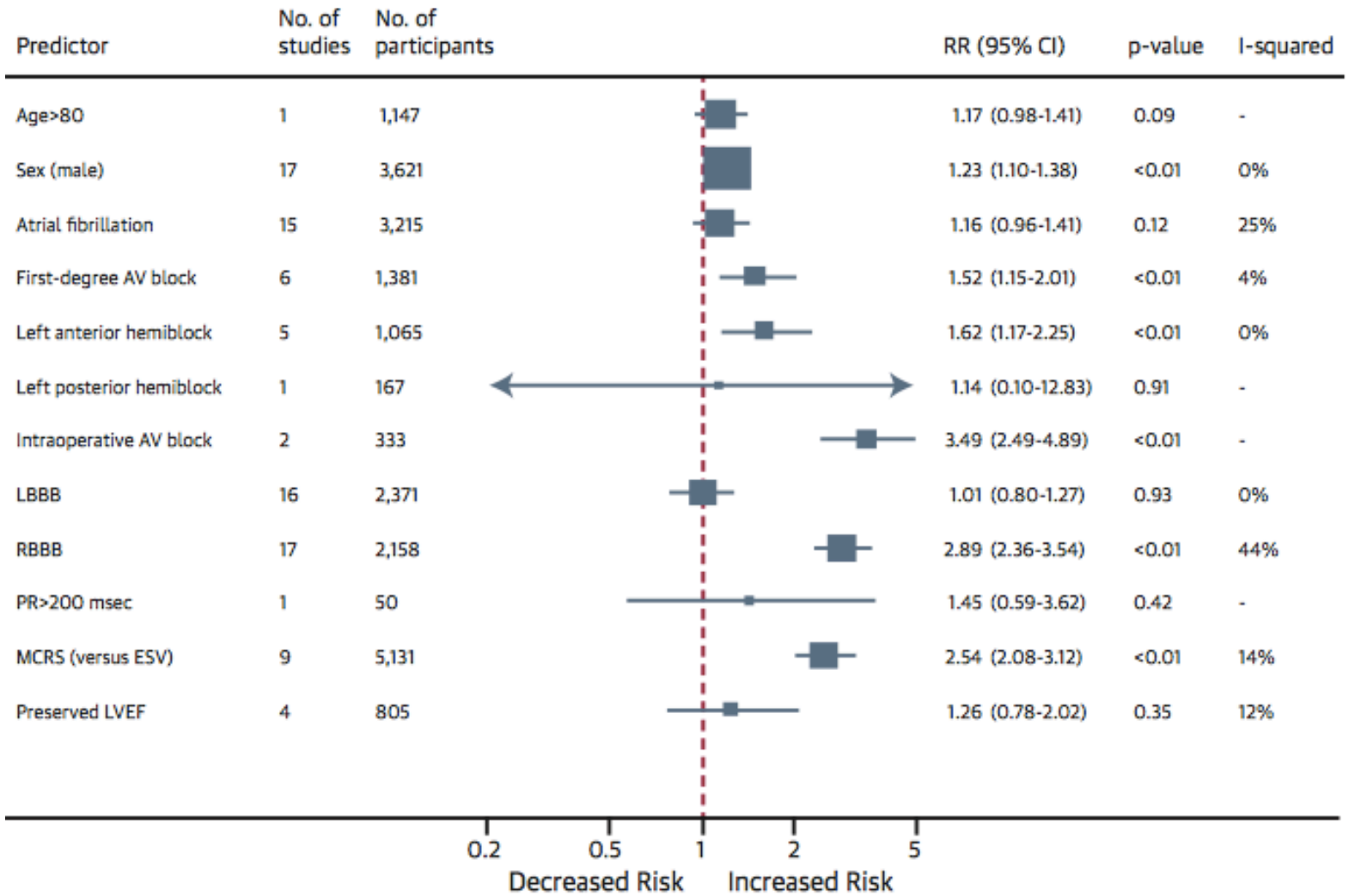
Conduction disturbances and TAVI
First- vs. Second-generation devices



Barbanti et al. Eurointervention 2017

Conduction disturbances after TAVI

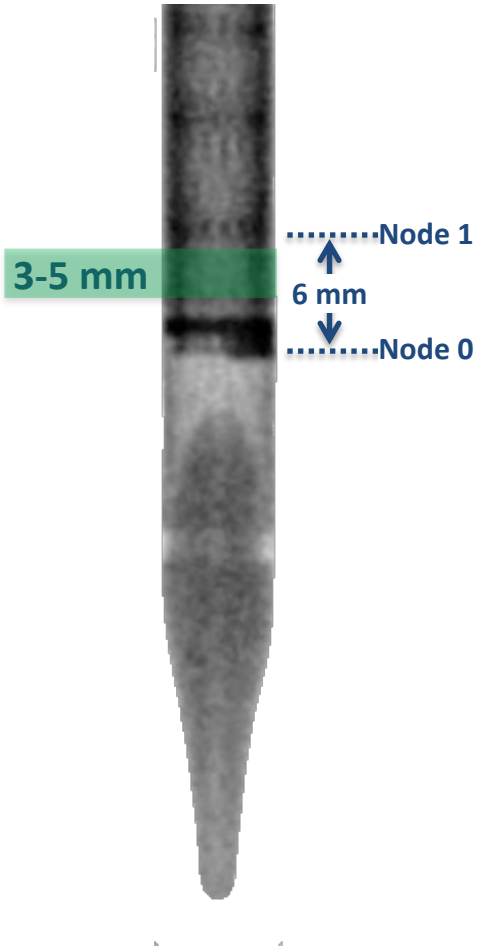


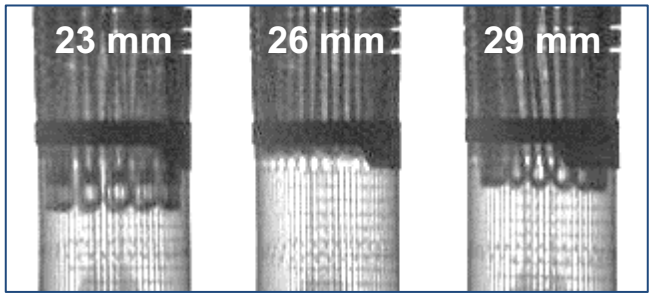
Siontis et al. JACC 2014

Prevention of conduction disturbances after TAVI

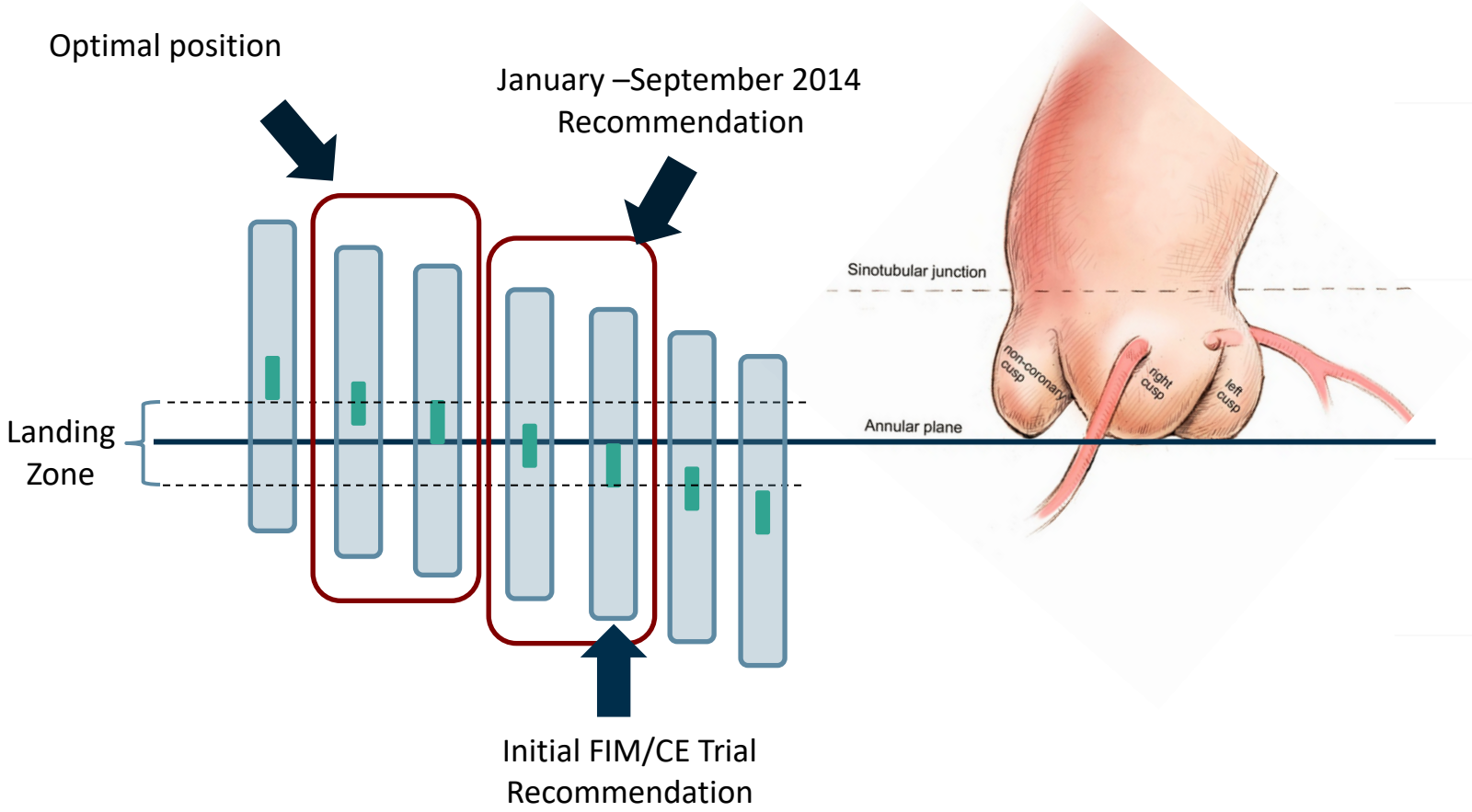
Target implant depth (3-5 mm) easier to achieve thanks to enhanced deliverability

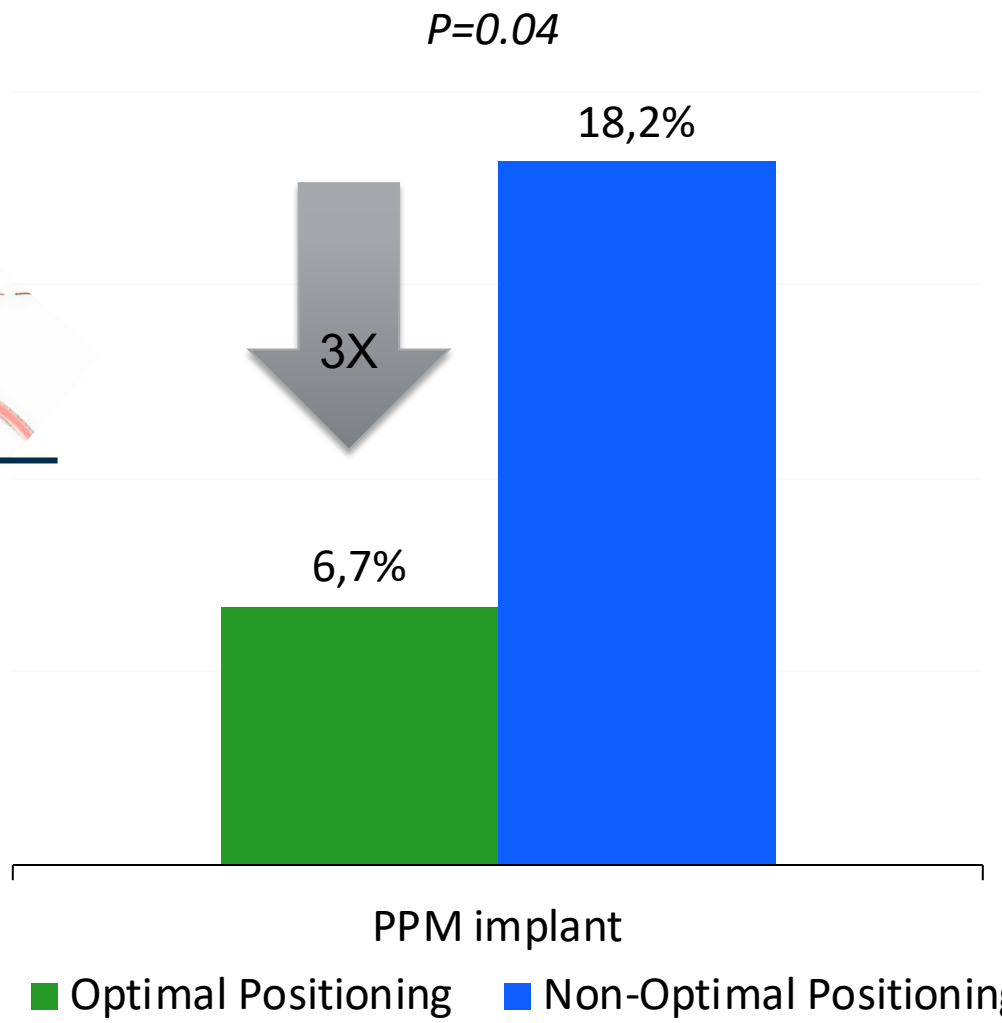
- Midway between node 0 (inflow edge of frame) and node 1 to just below node 1
- Note: due to minor valve frame length differences, ensure to assess valve position from frame inflow (node 0) and not the edge of the marker band:





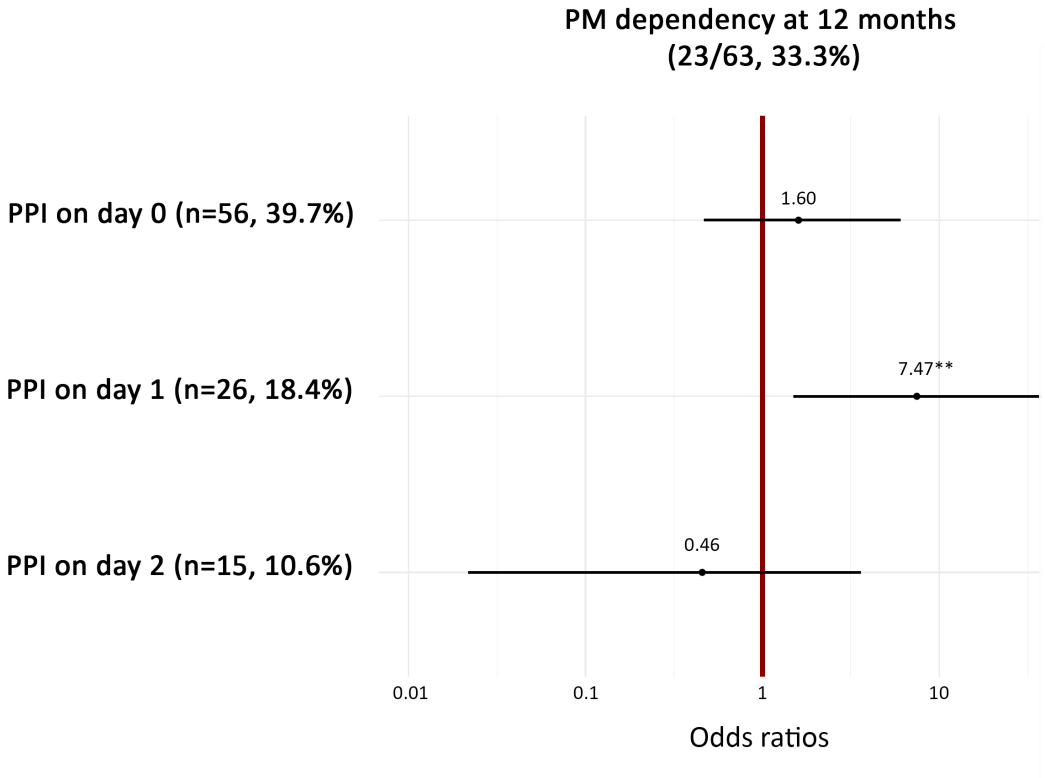
Prevention of conduction disturbances after TAVI



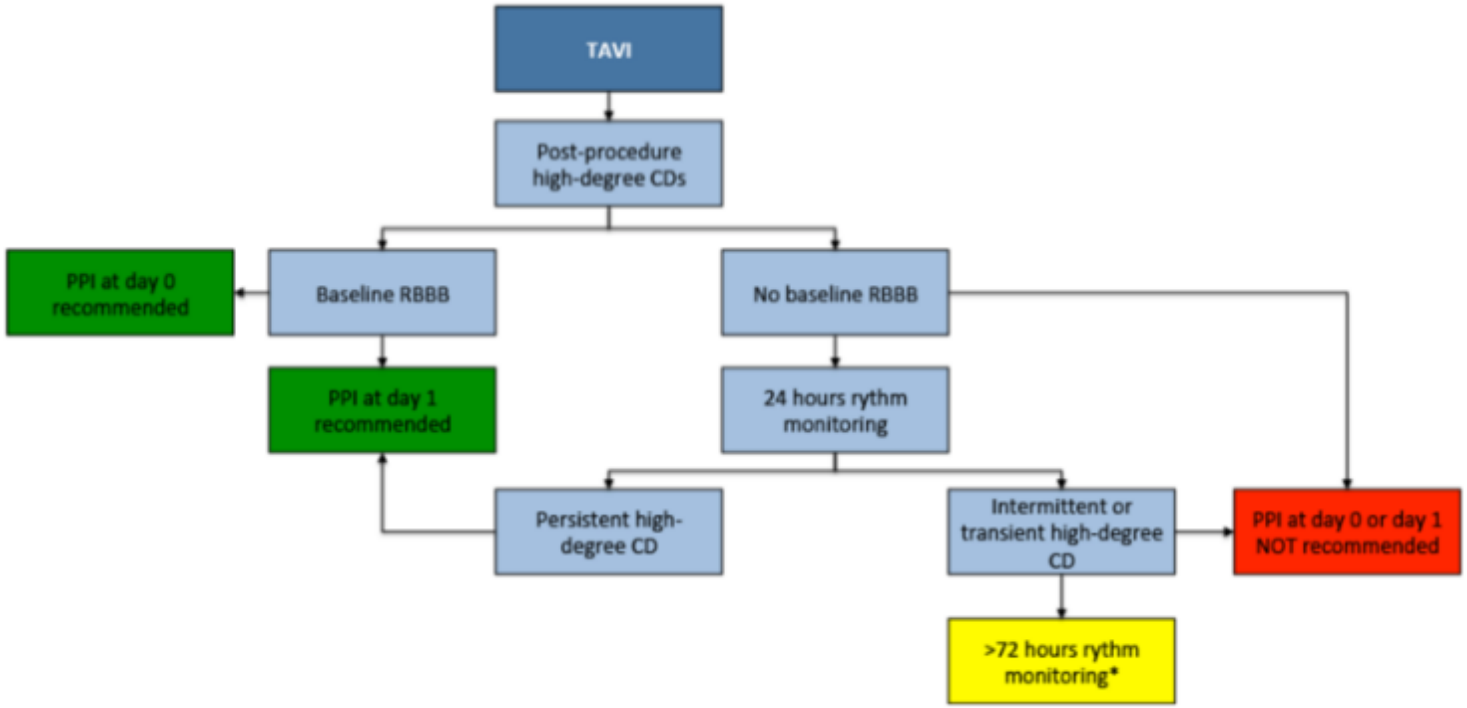


- The initial positioning guidance used in FIM & CE trial was based on XT experience
- After an ad-hoc internal analysis of CE trial and partial IDE data the guidance was expanded to include a larger zone in January, 2014

PM implantation after TAVI: The importance of preventing inappropriate implants



**p<0.05



Costa G. et al. Eurointervention, in press

TAVI potential complications

- Paravalvular regurgitation
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- **Vascular complications**
- Renal complications
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Vascular complications

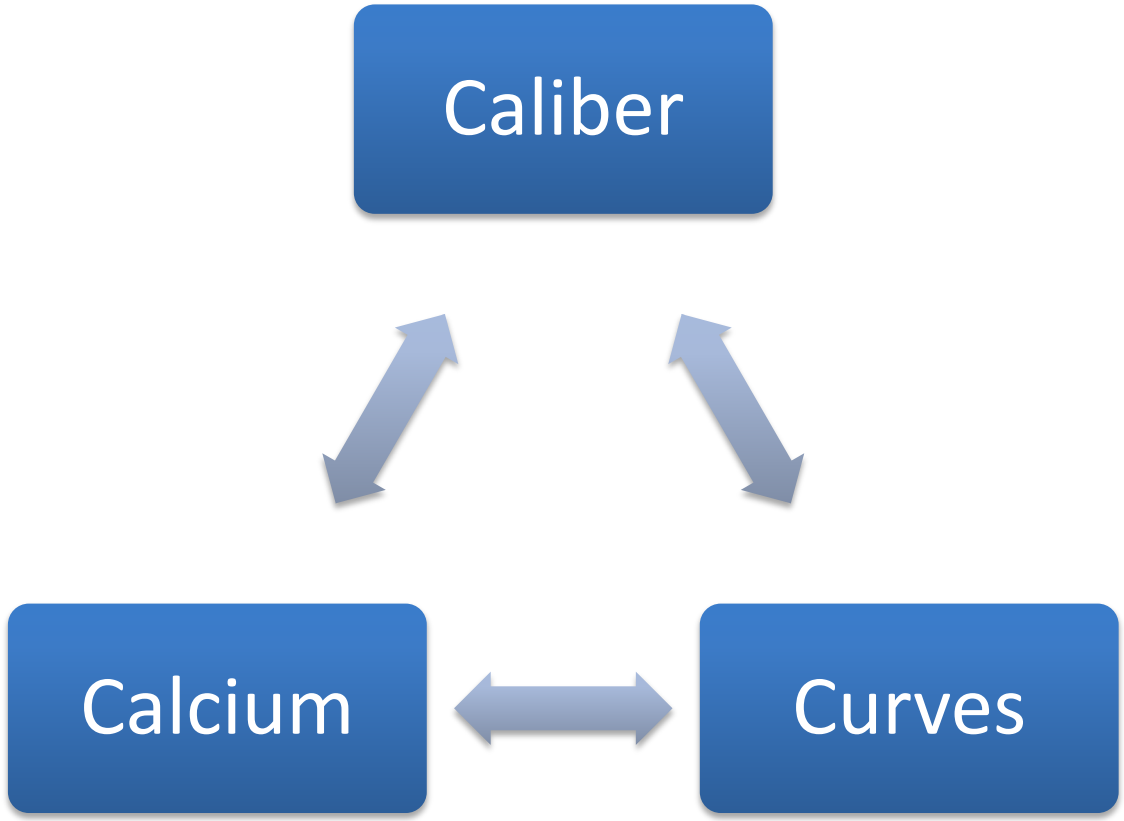
How to prevent vascular complications

- Vascular access screening phase

- Vascular access management
  - Arterial puncture
  - Closure devices placement
  - Sheath and wire management

How to prevent vascular complications

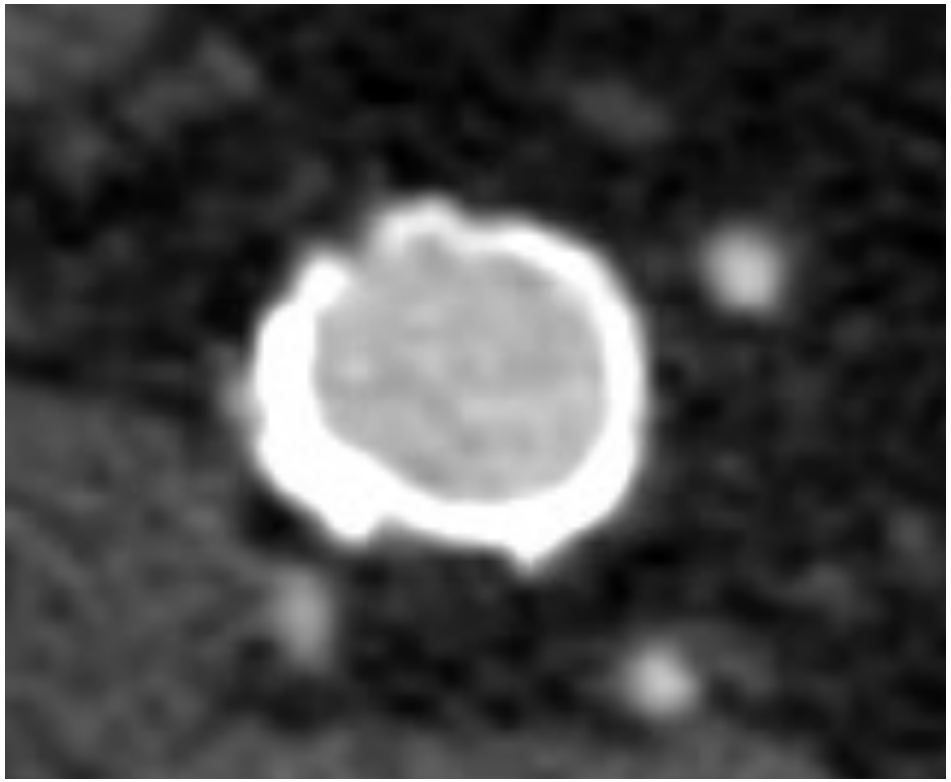
- **Vascular access screening phase**



How to prevent vascular complications

How to prevent vascular complications

Circumferential or horseshoe calcification



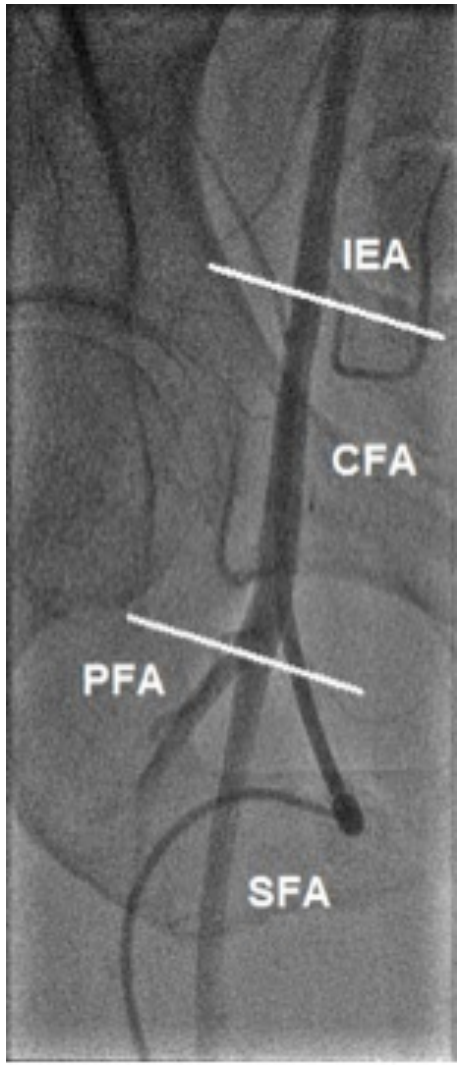
This won’t dilate!

How to prevent vascular complications

- Vascular access screening phase

- **Vascular access management**
  - **Arterial puncture**
  - **Closure devices placement**
  - **Sheath and wire management**

How to prevent vascular complications



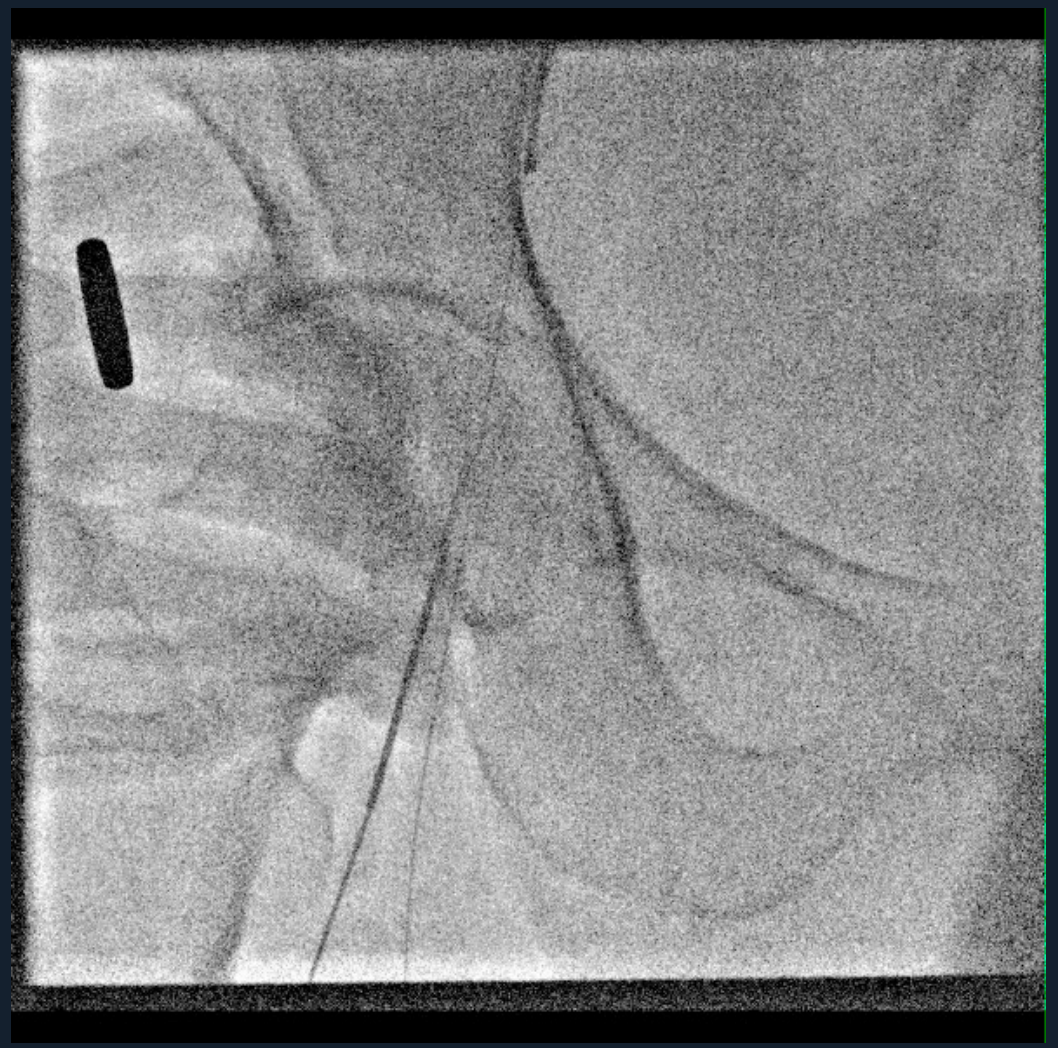
Appropriate Iliac and Femoral anatomy

- Size≥**5.5 mm (14 Fr) SFAR<1.05**
- No major **tortuosity + calcium**
- No **calcification** at puncture site

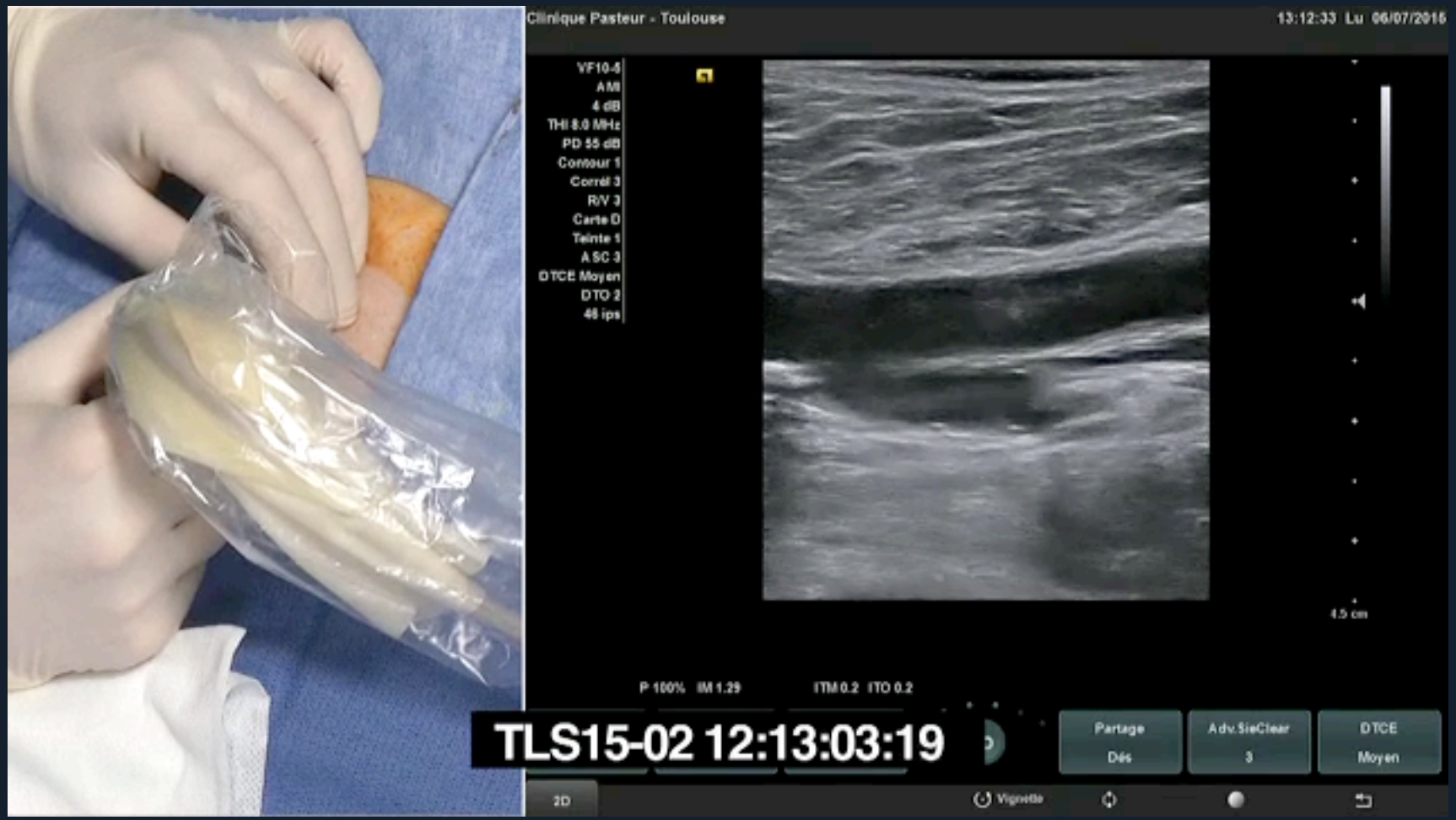
Puncture of Common Femoral Artery

- Below the Inguinal Ligament
- At least **10 mm** above the Femoral bifurcation
- In the centre of the anterior wall
- Back-up cross-over wire

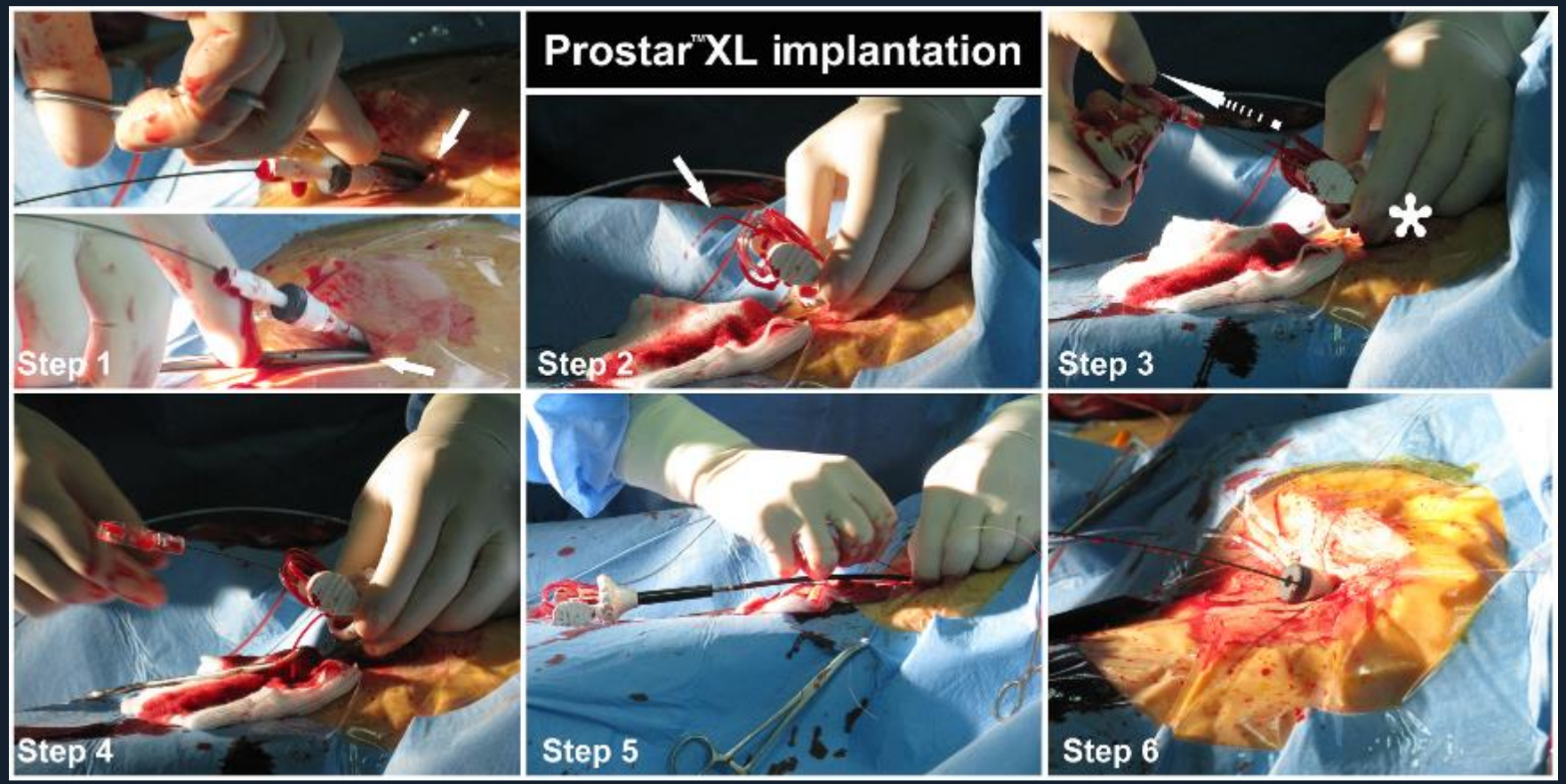
How to prevent vascular complications: The importance of accurate puncture

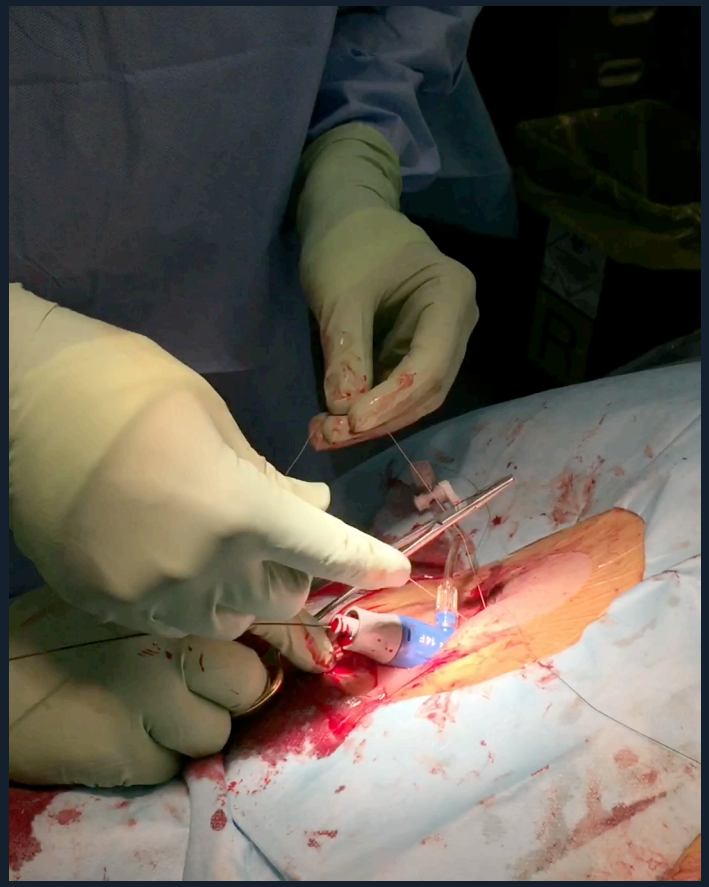


How to prevent vascular complications: The importance of accurate puncture



How to prevent vascular complications: The importance of vascular closure devices





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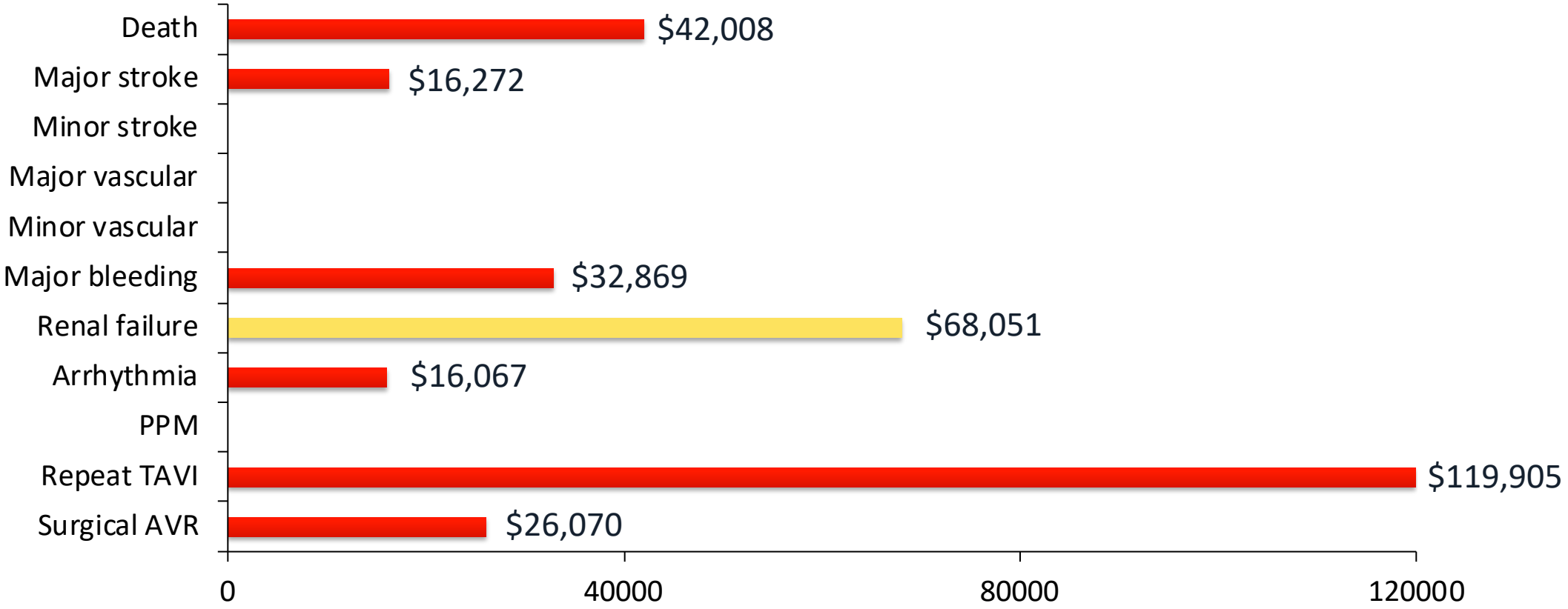
Acute kidney injury after TAVI

Adjusted Incremental Costs of TAVI from PARTNER trial

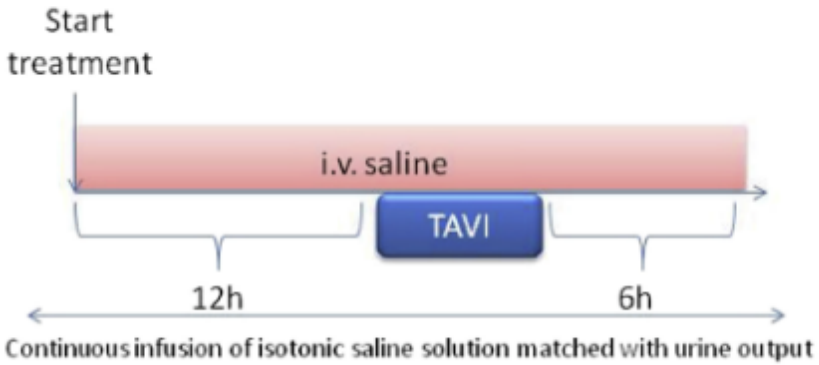
*Adjusted for age, sex, prior bypass surgery, peripheral vascular disease, diabetes, and STS mortality risk score; R2=0.41



Arnold SV, et al. Circ Cardiovasc Interv 2014

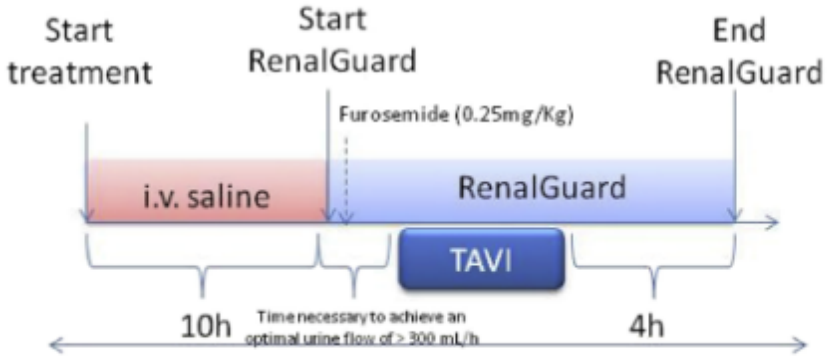
Prevention of AKI after TAVI

Control Group



Continuous infusion of isotonic saline solution matched with urine output

Renalguard Group



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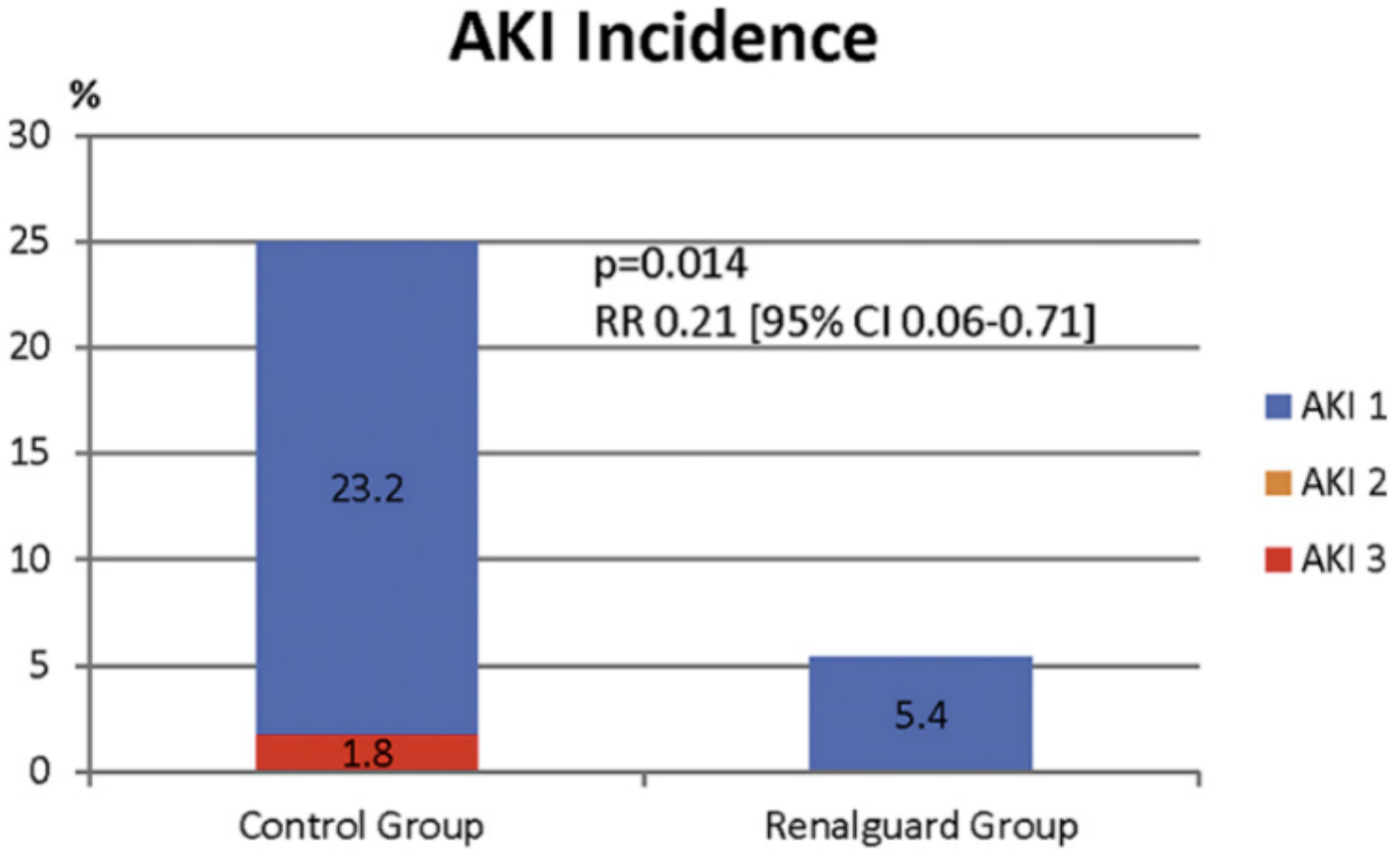

Barbanti M et al. JACC Intv 2015

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- Renal complications
- **Annulus rupture and coronary occlusion**

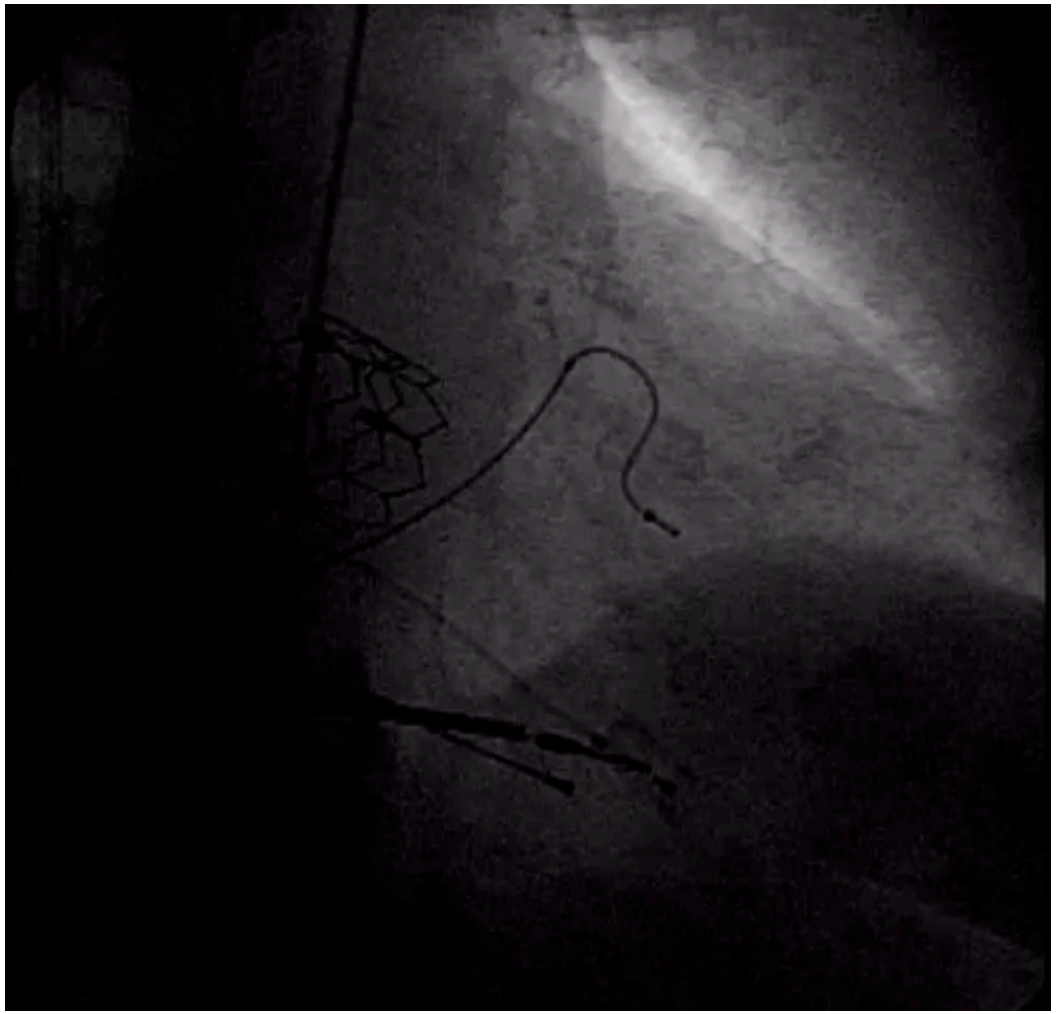
Annulus rupture and coronary occlusion: Impact on operator's well-being

Uncomplicated TAVI

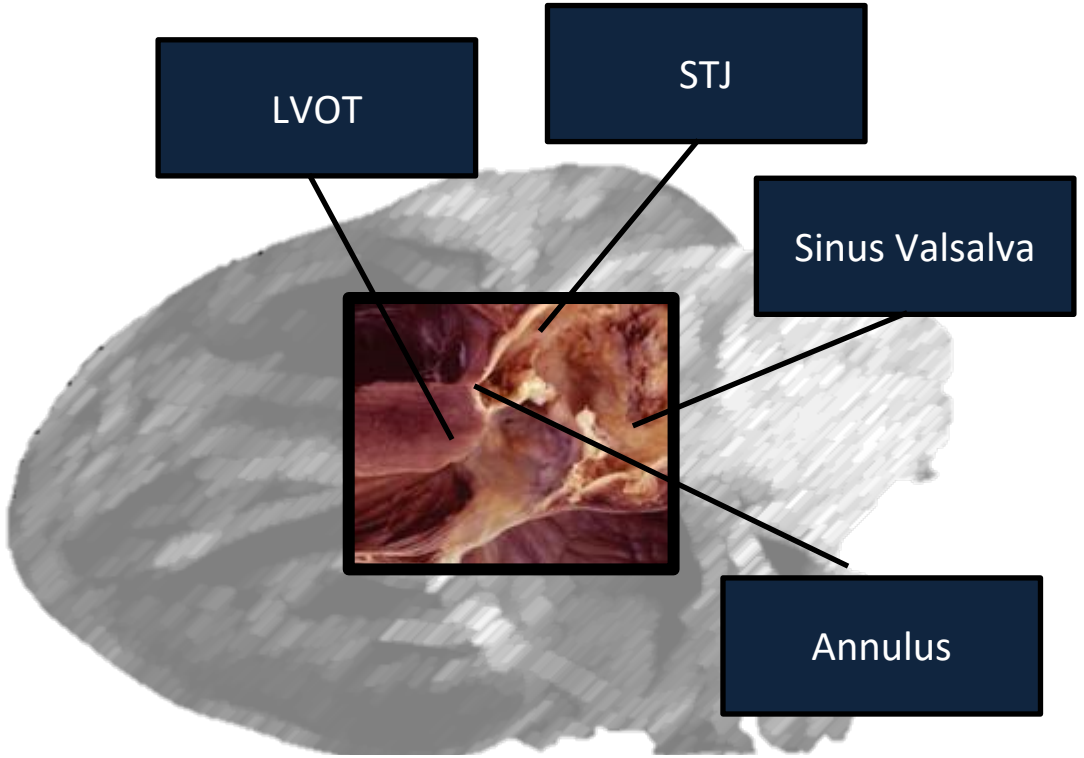
Moderate PVR
Conduction disturbaces
Vascular complication

Aortic rupture
Coronary occlusion

Aortic rupture after TAVI



Where aortic rupture might occur?



Aortic rupture after TAVI

	Study group (n = 31)	Uncontained rupture (n = 20)	Contained rupture (n = 11)	P value
Mortality	48.4%	75.0%	0.0%	<0.001
Cardiovascular mortality	45.2%	70.0%	0.0%	<0.001
Disabling stroke	12.9%	10.0%	18.2%	0.447
Life-threatening bleeding	45.2%	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

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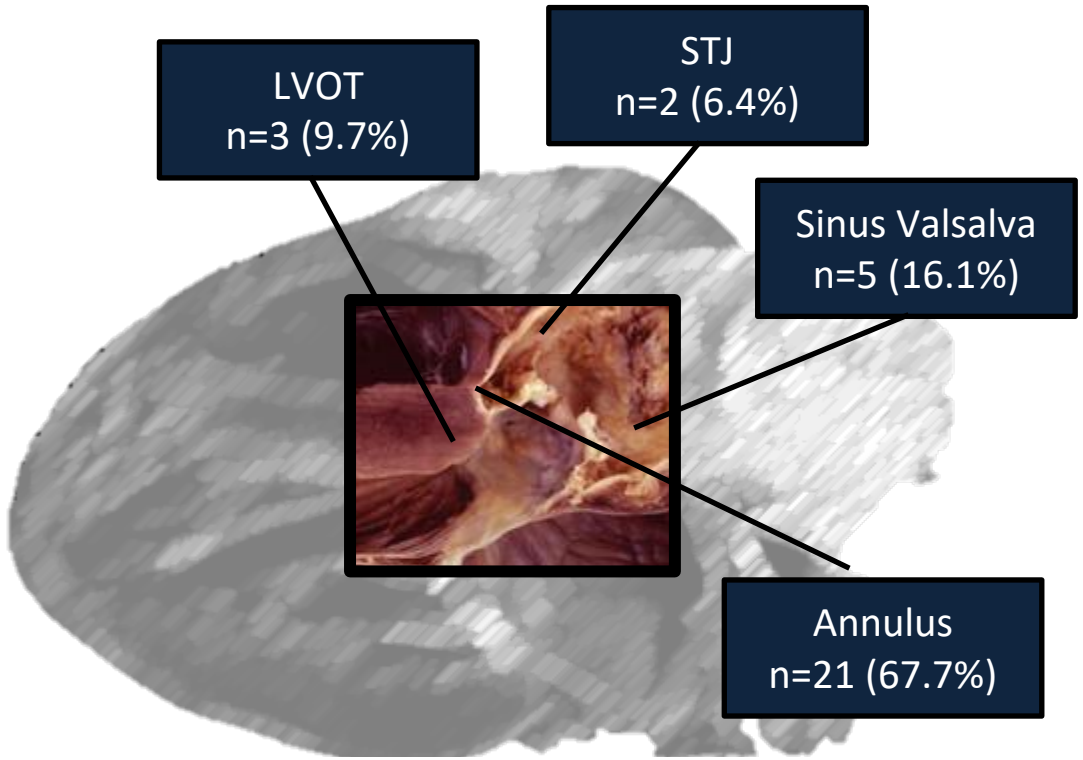
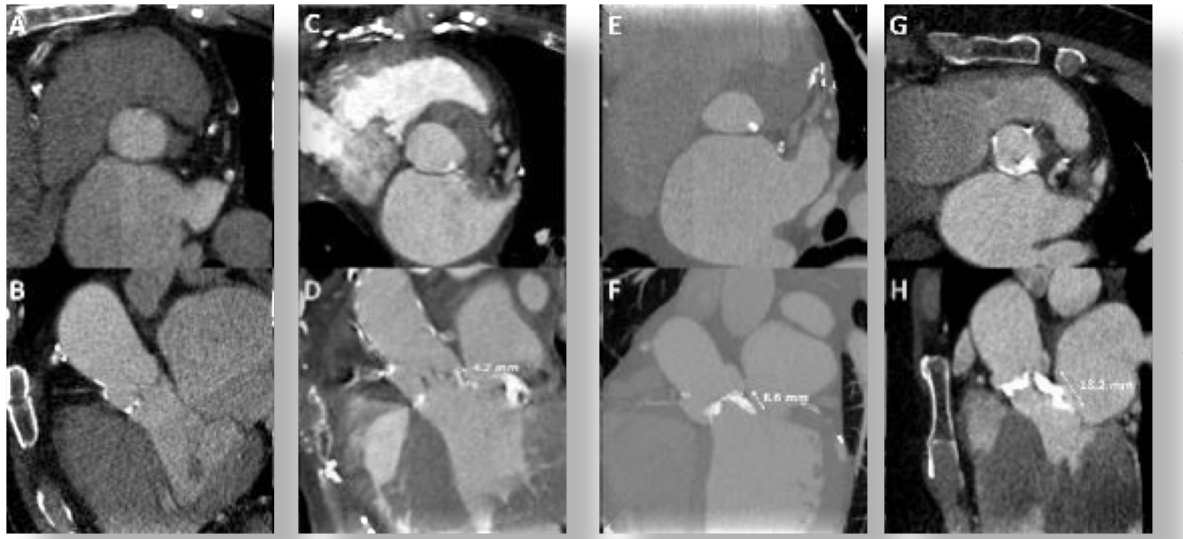


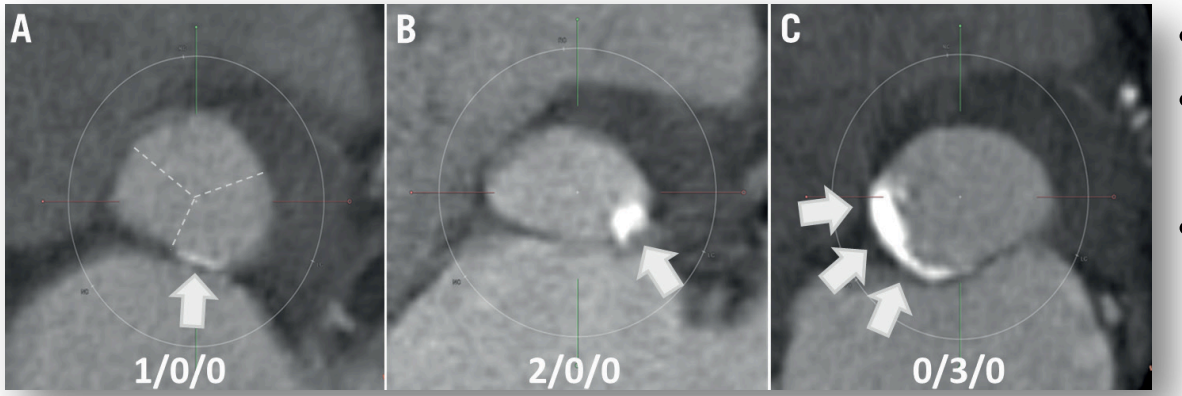
Barbanti M et al. Circulation 2013

Aortic rupture after TAVI: LVOT Calcium classification



Barbanti et al. Circulation 2013

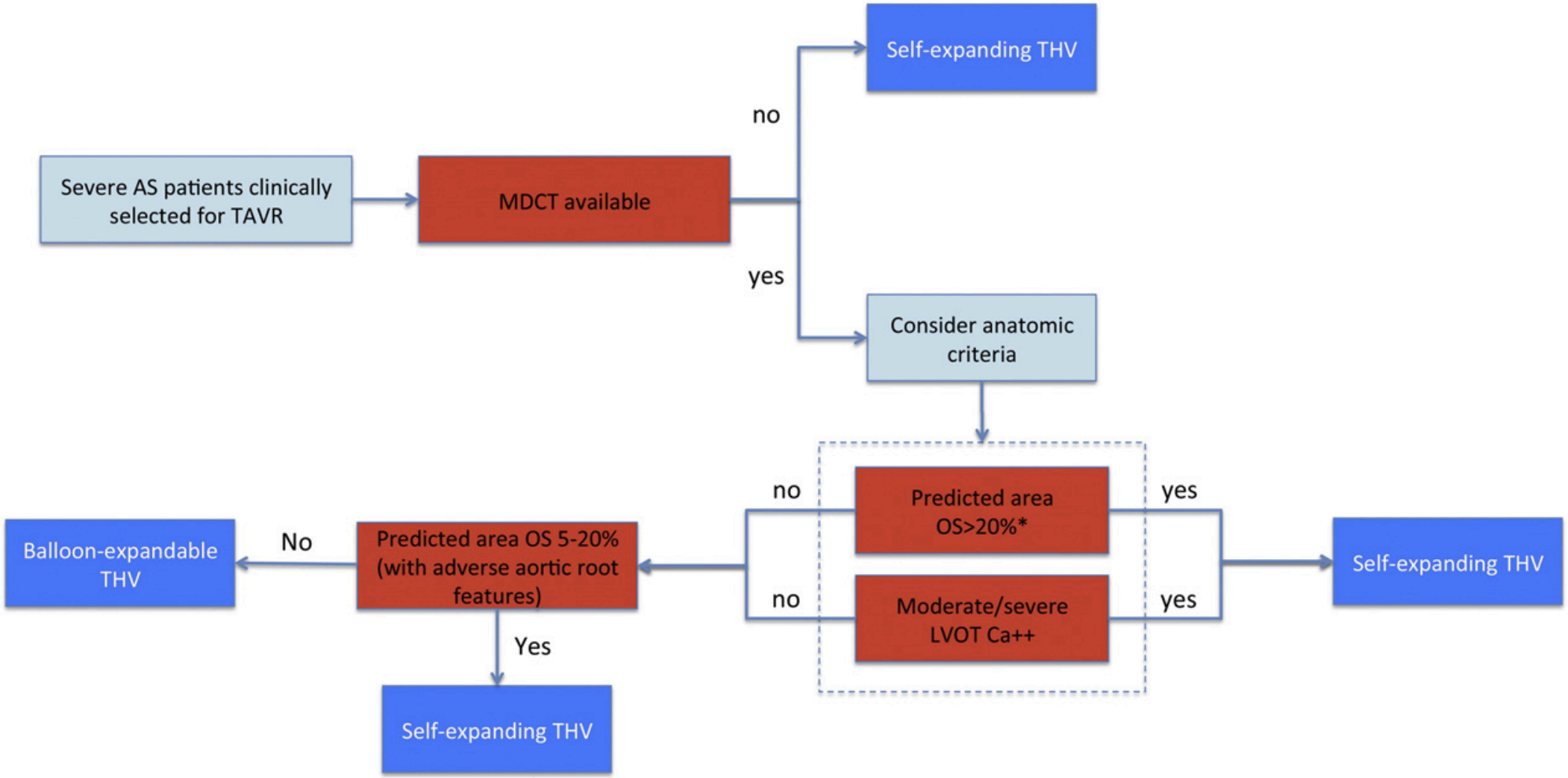
- **Mild:** 1 nodule of calcium extending <5 mm in any dimension and covering <10% of the perimeter of the LVOT
- **Moderate:** 2 nodules of calcification or 1 extending >5 mm in any direction or covering >10% of the perimeter of the LVOT
- **Severe:** multiple nodules of calcification of single focus extending >1 cm in length or covering >20% of the perimeter of the LVOT



Buellesfeld et al. Eurointervention 2014

- **Grade 1 (mild):** Small, non-protruding calcification
- **Grade 2 (moderate):** Protruding (>1 mm) or extensive (>50% of cusp sector) calcification
- **Grade (severe):** Protruding (>1 mm) and extensive (>50% of cusp sector) calcification

Preventing aortic rupture after TAVI: The importance of THV type choice



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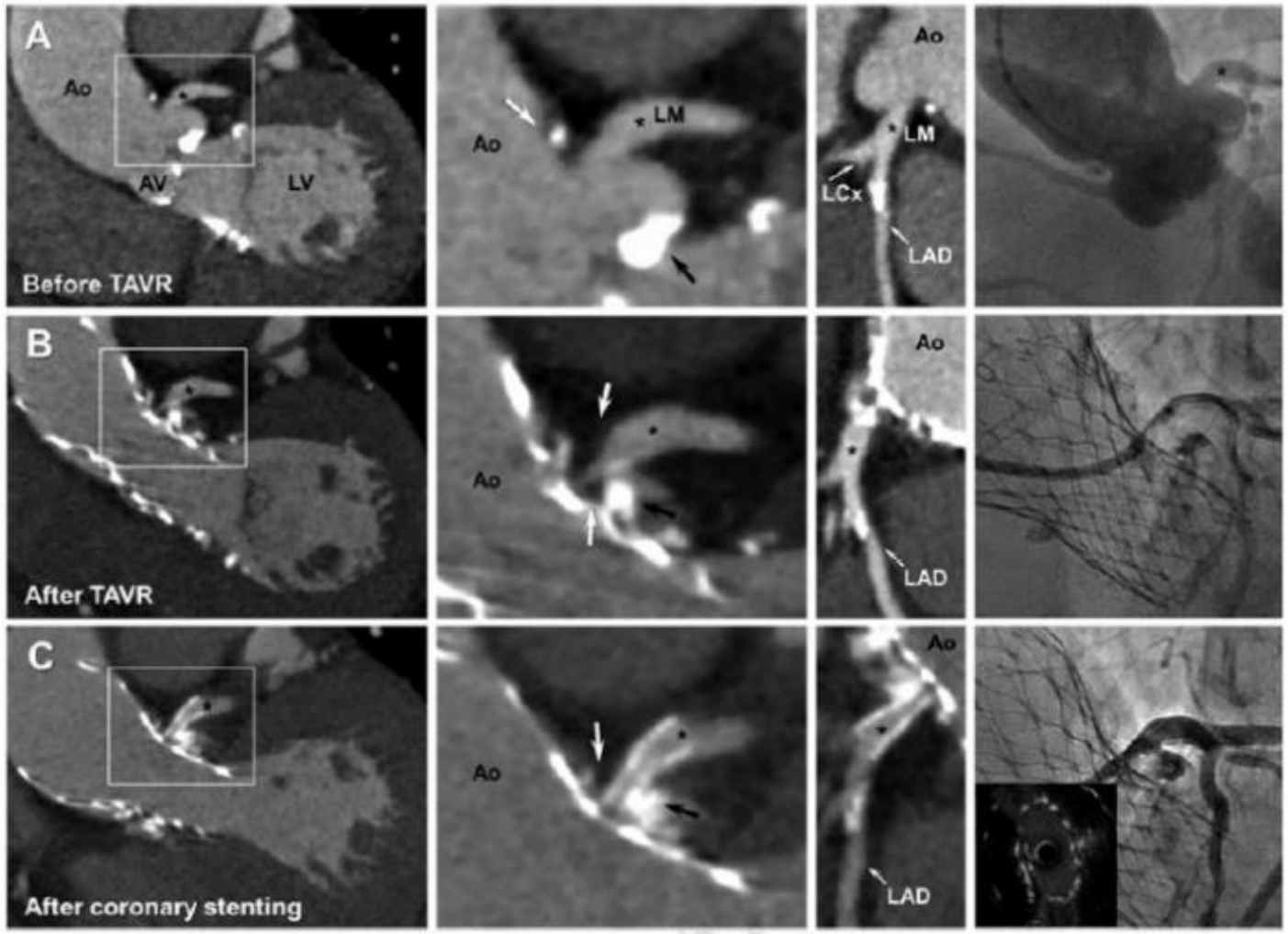
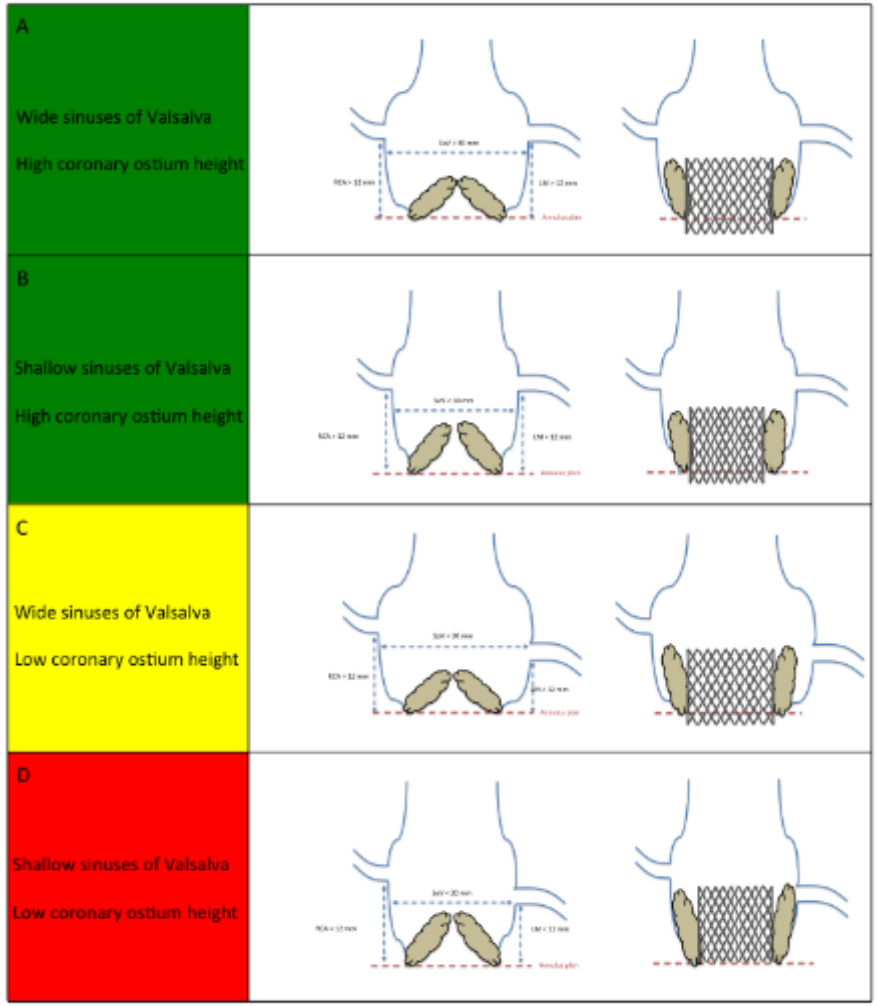
Barbanti M et al. Int J Cardiol 2015

Preventing coronary occlusion after TAVI: The importance of CTA screening





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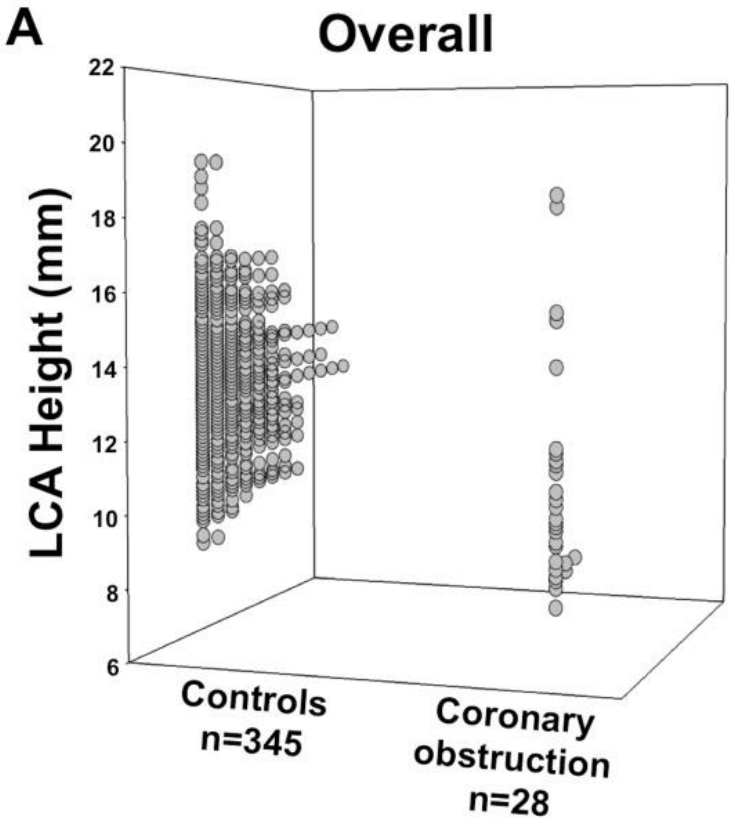
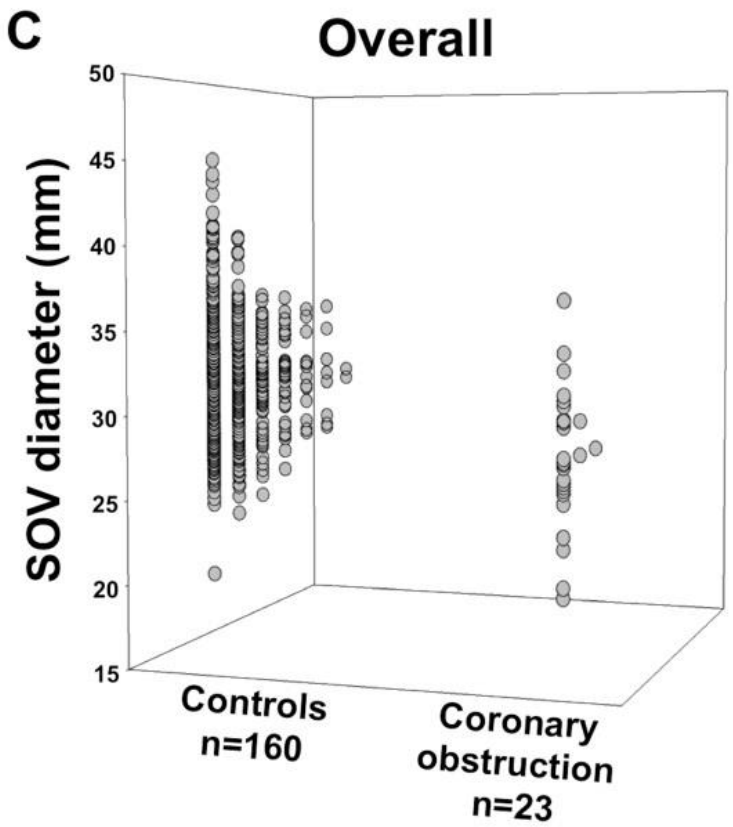
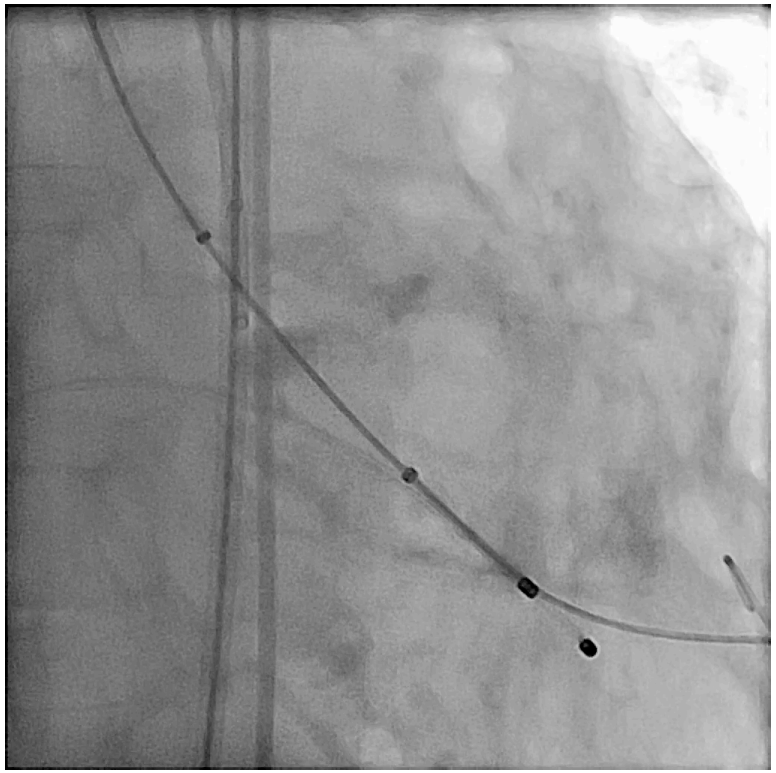
Preventing coronary occlusion after TAVI: The importance of CTA screening and procedural tips & trics



LCA height<12mm



SoV diameter<27mm



Preventing TAVI complications: Optimized TAVI patients pathway

Pre procedure

- Outpatient baseline TTE
- Outpatient baseline MDCT
- Admission for TAVI 24 hours before the procedure
- Patient and family preparation for possible early discharge after TAVI

Procedure

- Local anesthesia
- Back-up TTE
- Fully percutaneous access
- No urinary catheter
- CAD screening and ad hoc PCI
- All sheaths removed in procedure room
- Temporary pacemaker removed in procedure room[1]

Post procedure

- Review of TTE
- Reduce CICU stay
- Early return to baseline mobilization (6-8 hours)
- Early return to baseline hydration (6-8 hours)
- Criteria-driven discharge

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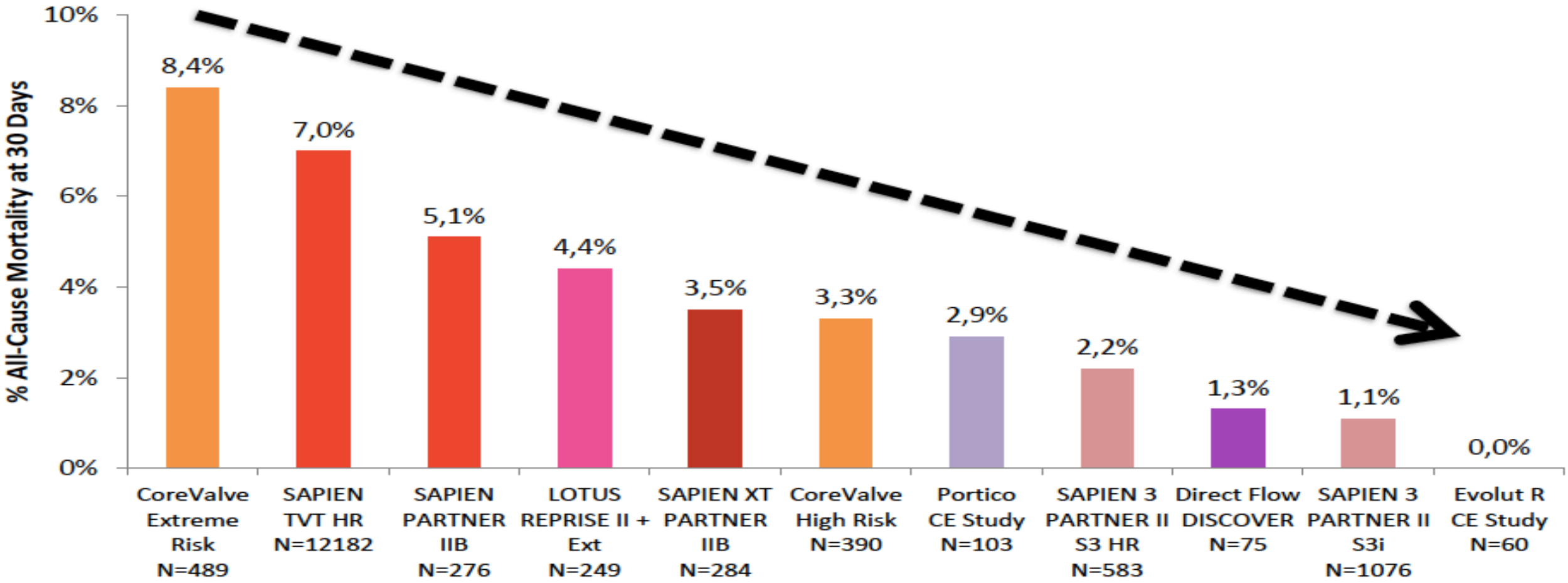
TAVI: 30-day All-cause Mortality



CONCLUSIONI

Le complicanze durante TAVI sono sempre in agguato

alcune sono quasi sempre imprevedibili (stroke, TIA, perforazione ventricolare da giuda o da PM);

tutte le altre (insufficienza aortica, pace-maker, rottura di anulus, occlusione coronarica, danno arterioso femorale, insufficienza renale) sono quasi sempre prevedibili e prevenibili con una accurata selezione della strategia di procedura e del dispositivo da utilizzare