TAVI Devices: Major Complications

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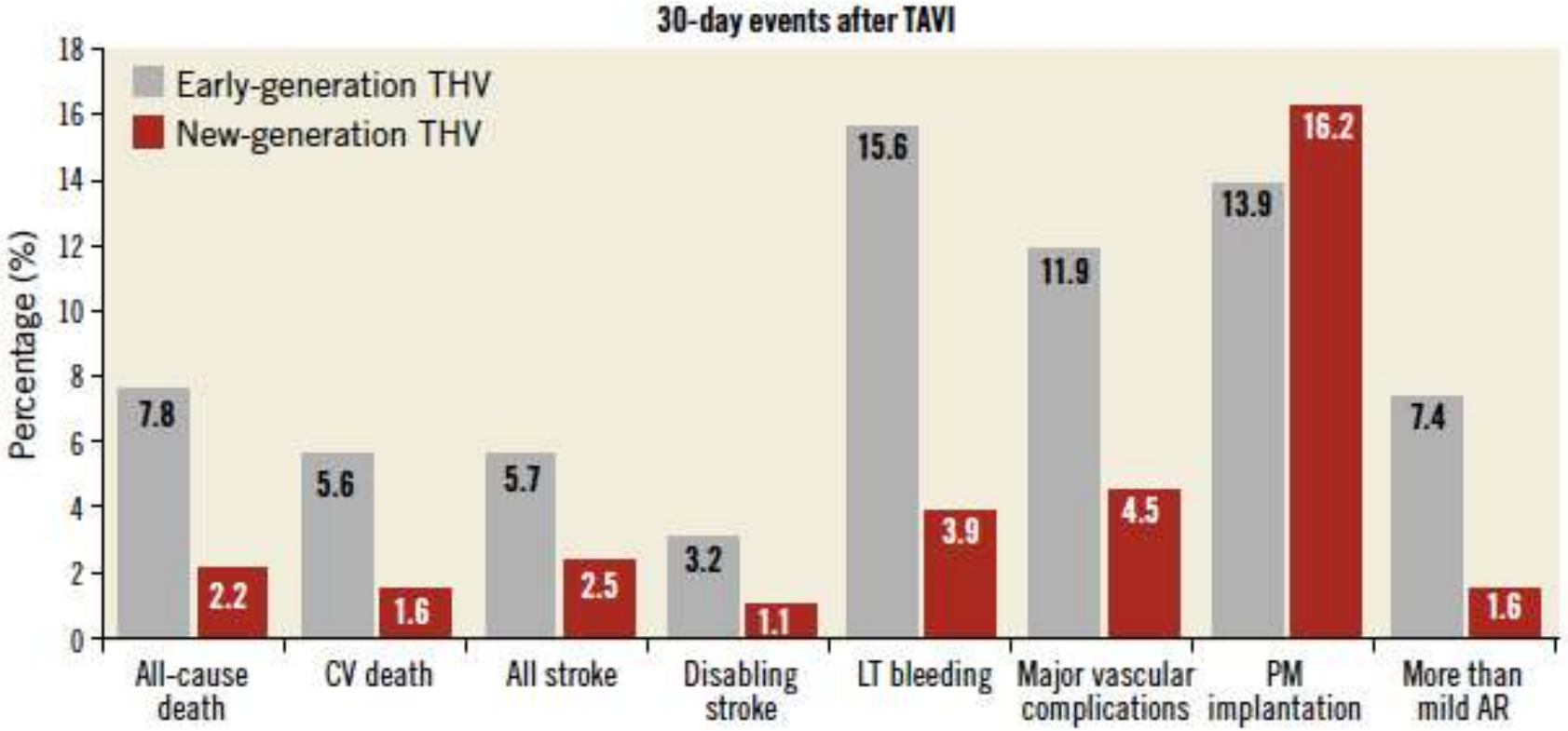


Barbanti et al, Eurointervention, 2017

TAVI Complications

Periprocedural

- Vascular Issues
- Valve Deployment
- Valve Function
- Organ Injury
- Arrhythmia

Long-Term

- PVR
- Valve Thrombosis
- Endocarditis

Vascular Issues

Periprocedural Complications

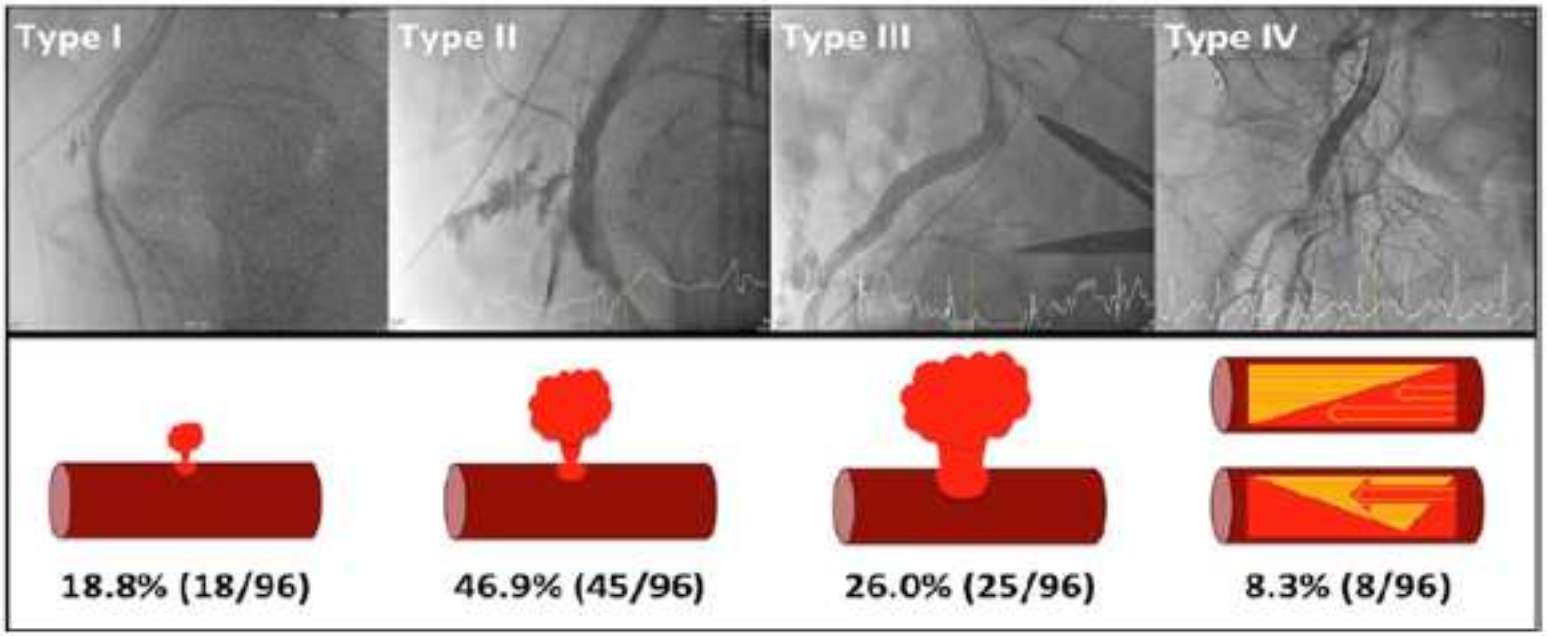
1a. Vascular Issues-Access Site

- Bleeding
- Dissection
- Occlusion

} 4-6%

Risk Factors

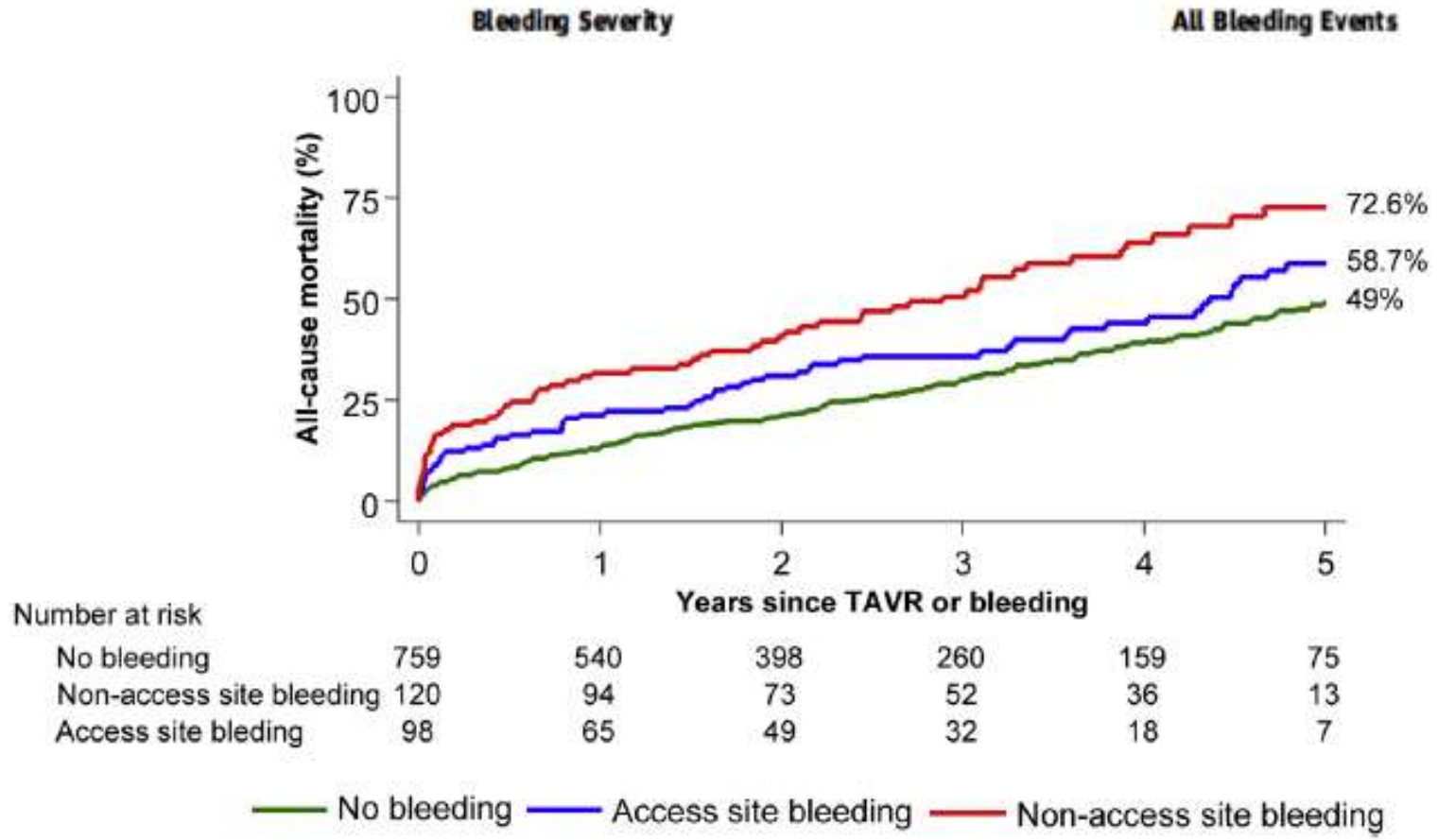
- Sheath-to-artery ratio
- Calcification
- Tortuosity
- Closure Device



Sharma et al, J Thromb.Thrombolysis, 2013

Periprocedural Complications

1b. Access Site Bleeding-Mortality



Piccolo et al, JACC Cardiol Intv, 2017

Periprocedural Complications

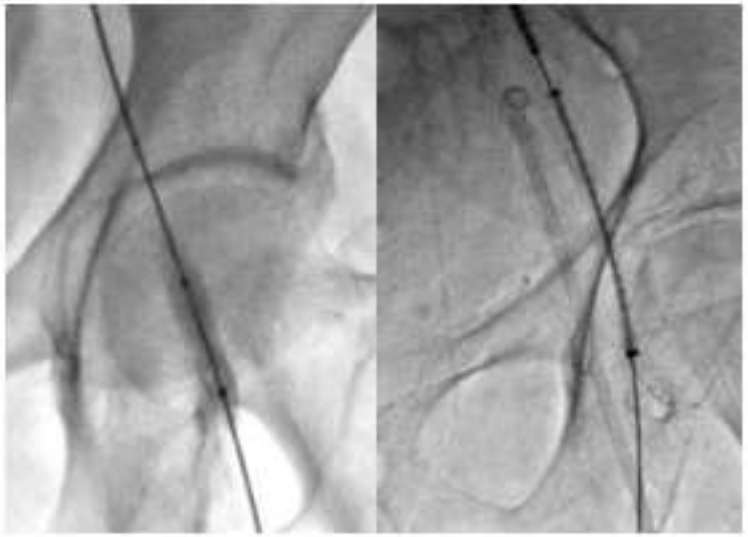
1c. Vascular Issues- Prevention and Management

Prevention

- Suitable Anatomy
- Closure Device
- Continuous Access to Punctured Artery (Cross-over)

Management

- Occlusion Balloon
- Covered Stent
- Surgery



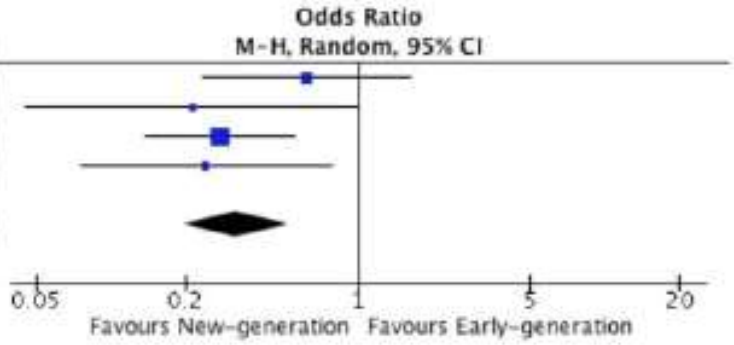
Periprocedural Complications

1d. Vascular Issues- NG Devices

Major and life threatening bleeding

Study or Subgroup	New-generation Events	Total	Early-generation Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
Levi 2017	7	175	11	175	24.8%	0.62 [0.24, 1.64]
Nijhoff 2015	2	44	12	66	9.8%	0.21 [0.05, 1.01]
Ruparelia 2016	12	154	36	154	48.2%	0.28 [0.14, 0.56]
Schaefer 2016	4	69	14	69	17.2%	0.24 [0.08, 0.78]
Total (95% CI)		**442**		**464**	**100.0%**	**0.32 [0.20, 0.52]**
Total events	25		73			

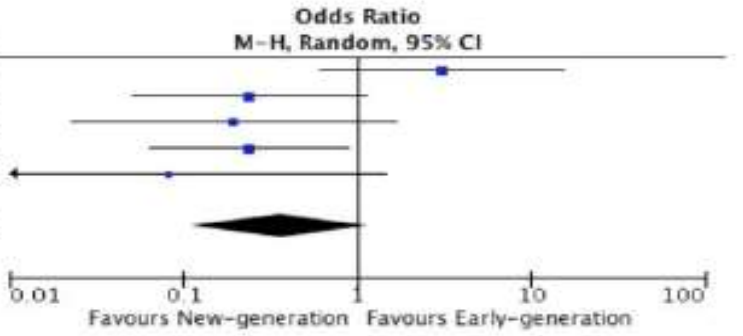
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 2.44$, df = 3 (P = 0.49); $I^2 = 0\%$
Test for overall effect: Z = 4.58 (P < 0.00001)



Major vascular complication

Study or Subgroup	New-generation Events	Total	Early-generation Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
Levi 2017	6	175	2	175	22.4%	3.07 [0.61, 15.43]
Nijhoff 2015	2	44	11	66	23.0%	0.24 [0.05, 1.13]
Ruparelia 2016	1	154	5	154	16.9%	0.19 [0.02, 1.69]
Schaefer 2016	3	69	11	69	25.9%	0.24 [0.06, 0.90]
Zhang 2015	0	40	10	80	11.8%	0.08 [0.00, 1.45]
Total (95% CI)		**482**		**544**	**100.0%**	**0.36 [0.11, 1.18]**
Total events	12		39			

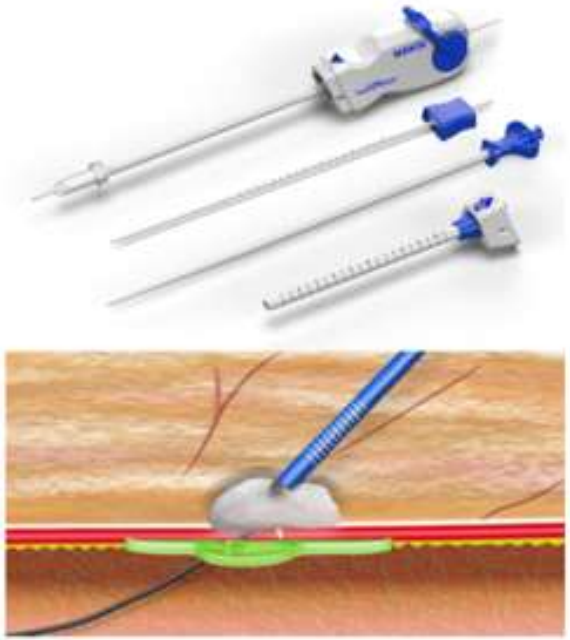
Heterogeneity: $Tau^2 = 0.95$; $Chi^2 = 8.72$, df = 4 (P = 0.07); $I^2 = 54\%$
Test for overall effect: Z = 1.69 (P = 0.09)



Ando et al, Cardiovasc Revasc Medicine, 2017

Periprocedural Complications

1e.Vascular Issues- NG Closure Devices



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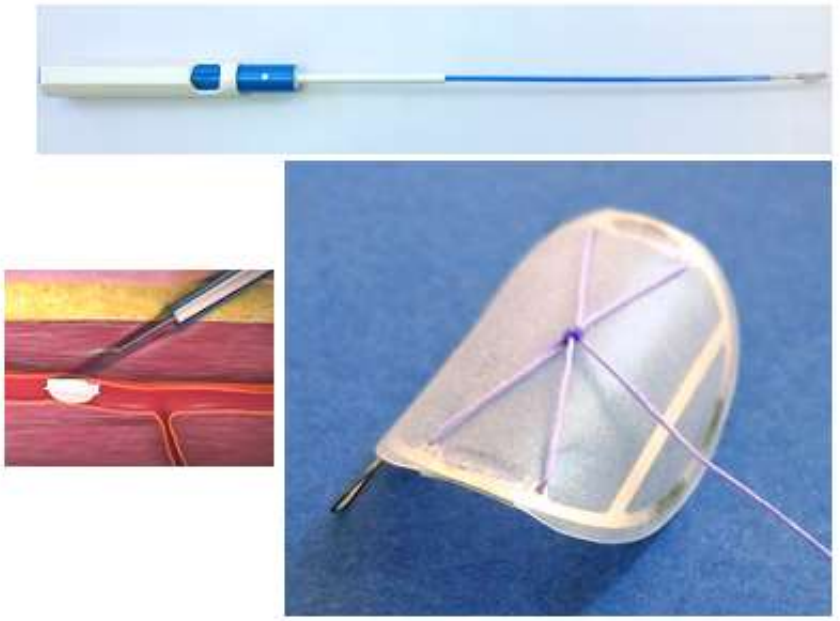


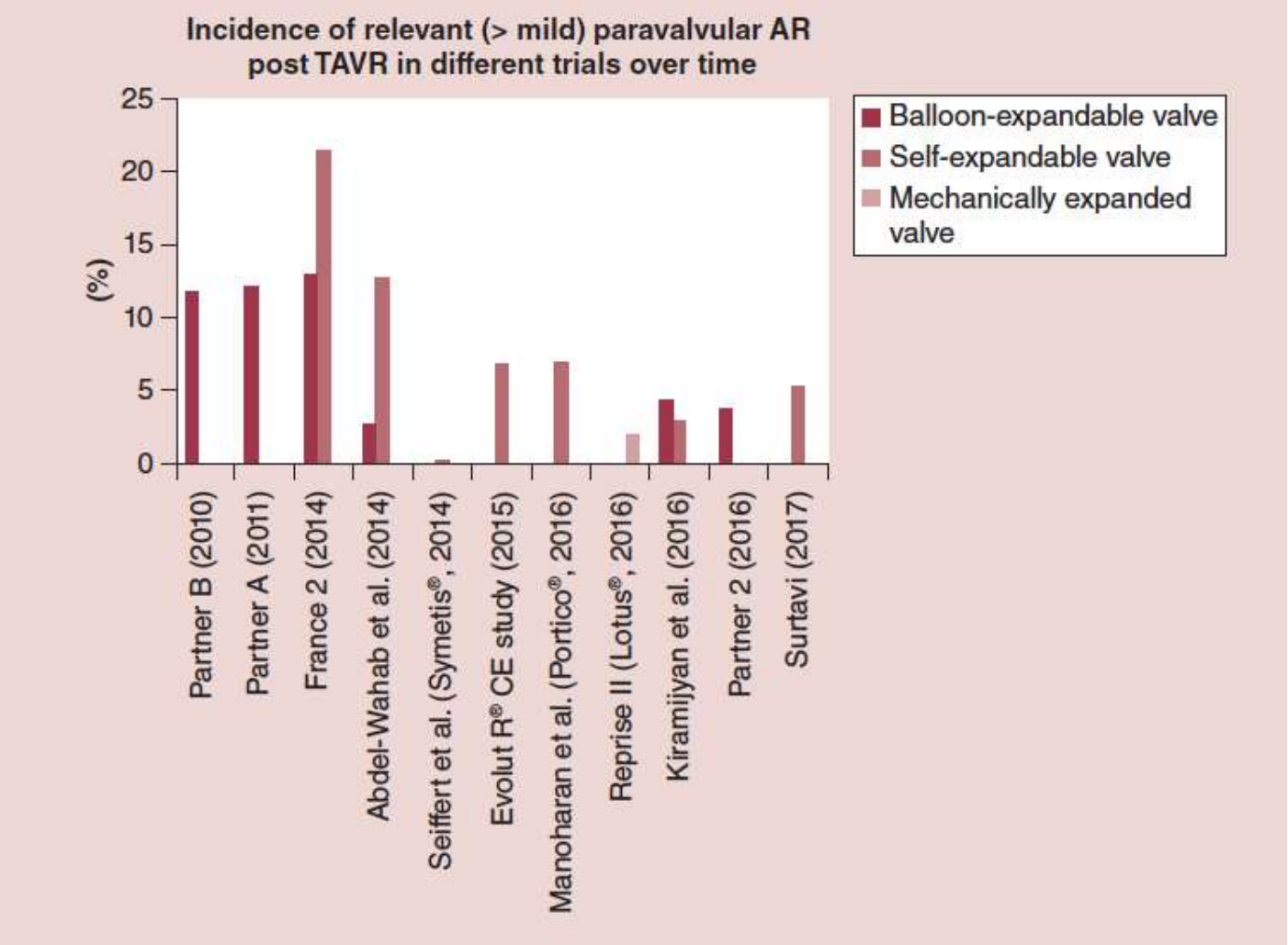
InClosure VCD

PerQseal

Paravalvular Regurgitation

Periprocedural Complications

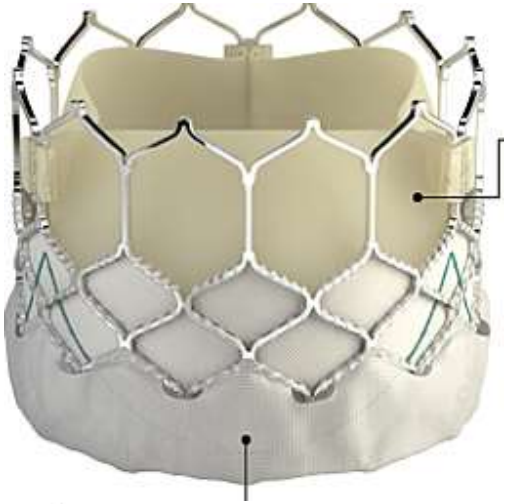
2a.Paravalvular AR-Incidence

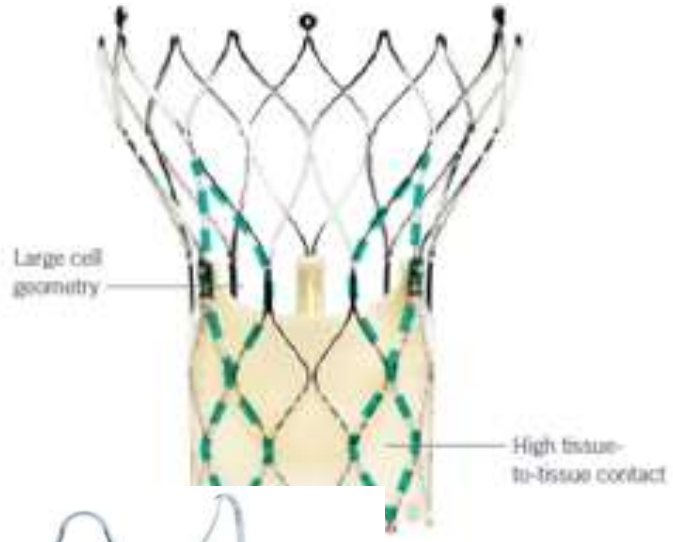


Schmidt-Salzmann et al, Future Caridiol, 2017

Periprocedural Complications

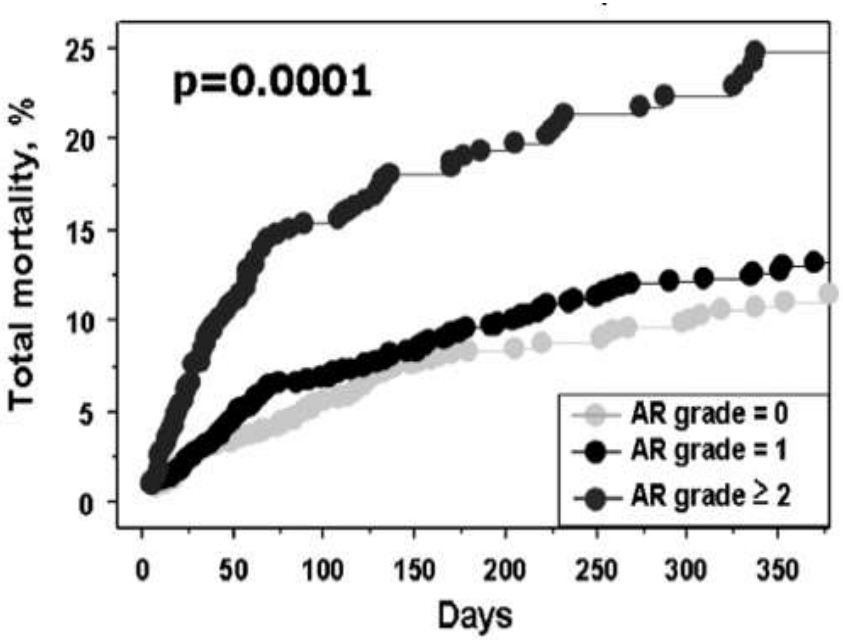
3b.PVR-Design Evolution

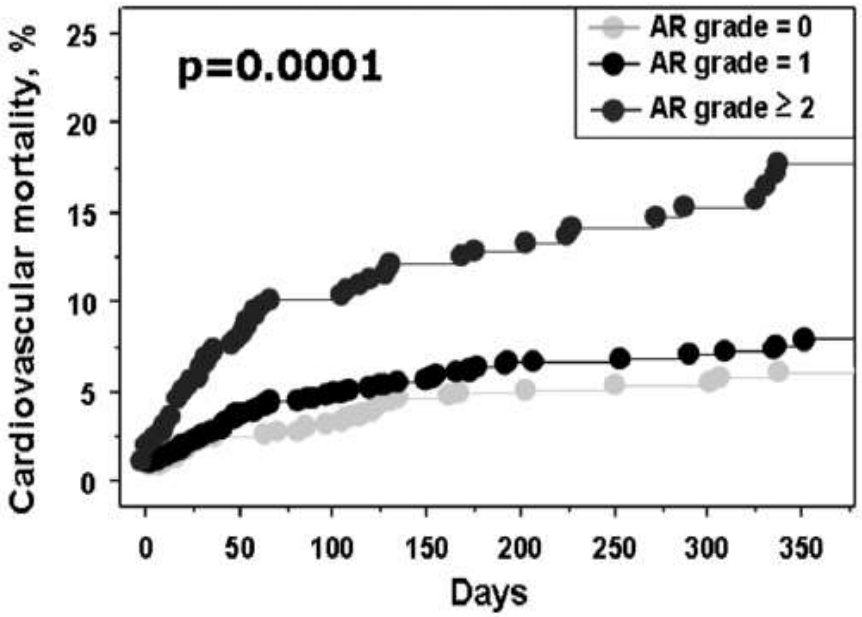




Periprocedural Complications

3c.PVR-Mortality

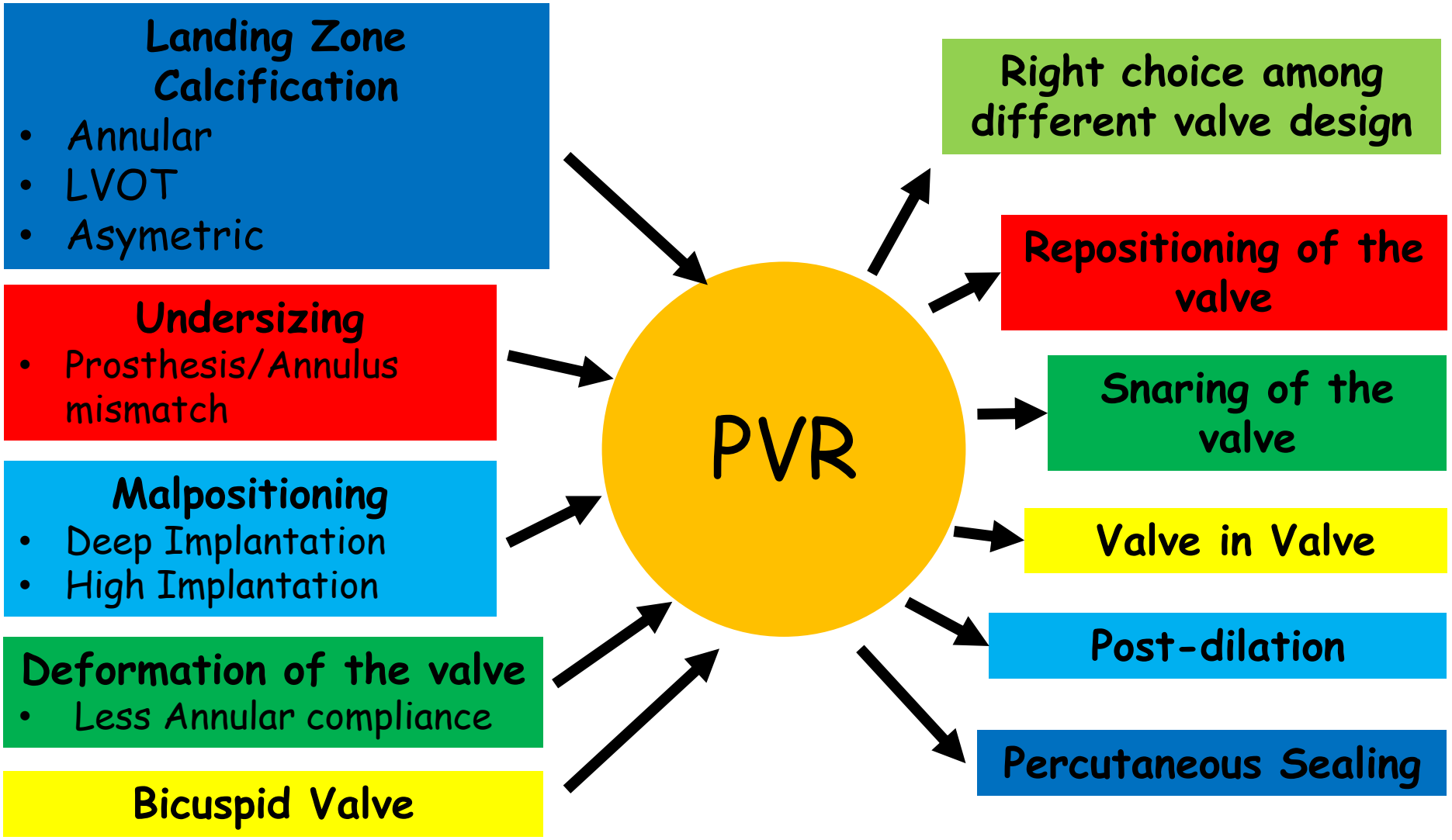




Van Belle et al, Circulation, 2014

Periprocedural Complications

3d. PVR-Risk Factors and Management



Conduction Disturbances

Periprocedural Complications

3a.High Degree AV Block-Incidence

- The most common TAVR complication (13%)

5-7% for SAPIEN/SAPIEN XT

25-28% for CoreValve

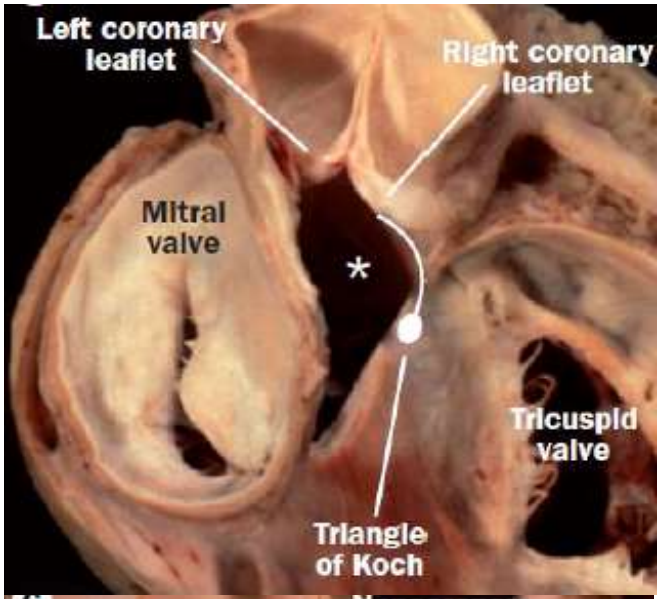
- 2nd generation Devices have little influence

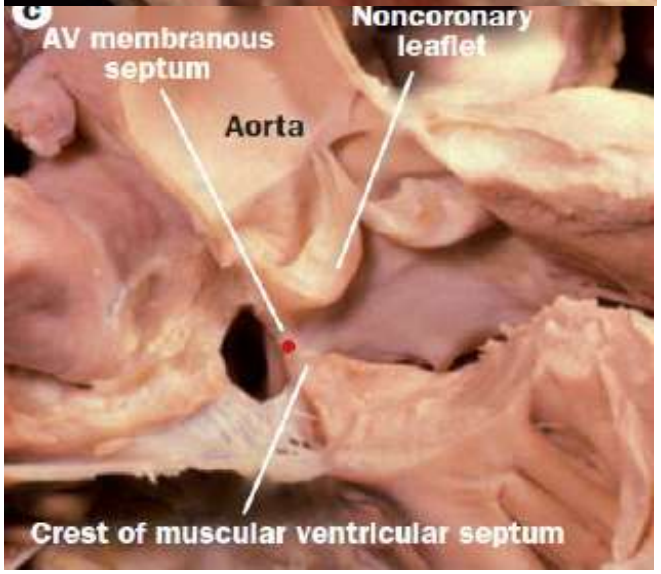
on the occurrence of conduction disturbances

11-14% for S3 (<10% in high implantation)

29% with the Lotus valve system

12% with the Portico Valve





Periprocedural Complications

3b.HAVB-Main Predictors

Variable	Multivariable Odds Ratio*
Baseline right bundle-branch block	2.8–46.7
Implantation of a Medtronic CoreValve (vs Edwards SAPIEN/ SAPIEN XT valves)	2.6–25.7
Depth of implantation	1.1–1.5/1 mm
Oversizing/stretching of the aortic annulus/ left ventricular outflow tract	1.02–1.5/1%
First-degree atrioventricular block	4.0–11.4

Auffret et al, Circulation, 2017

Periprocedural Complications

3c.HAVB-Timing and Evolution

- 85-90% of TAVR-induced HAVB occur within 7 days postoperatively, with the majority of these events recorded within 24 hours

Nazif et al, JACC Cardiovasc Interv, 2014

- Patients with no 1st-degree AVB and no LBBB after TAVI are of exceedingly low risk of very late conduction disturbances.

Toggweiler et al, JACC Cardiovasc Interv, 2016

- HAVB may resolve in up to 48% of cases in the first 7 days after TAVR

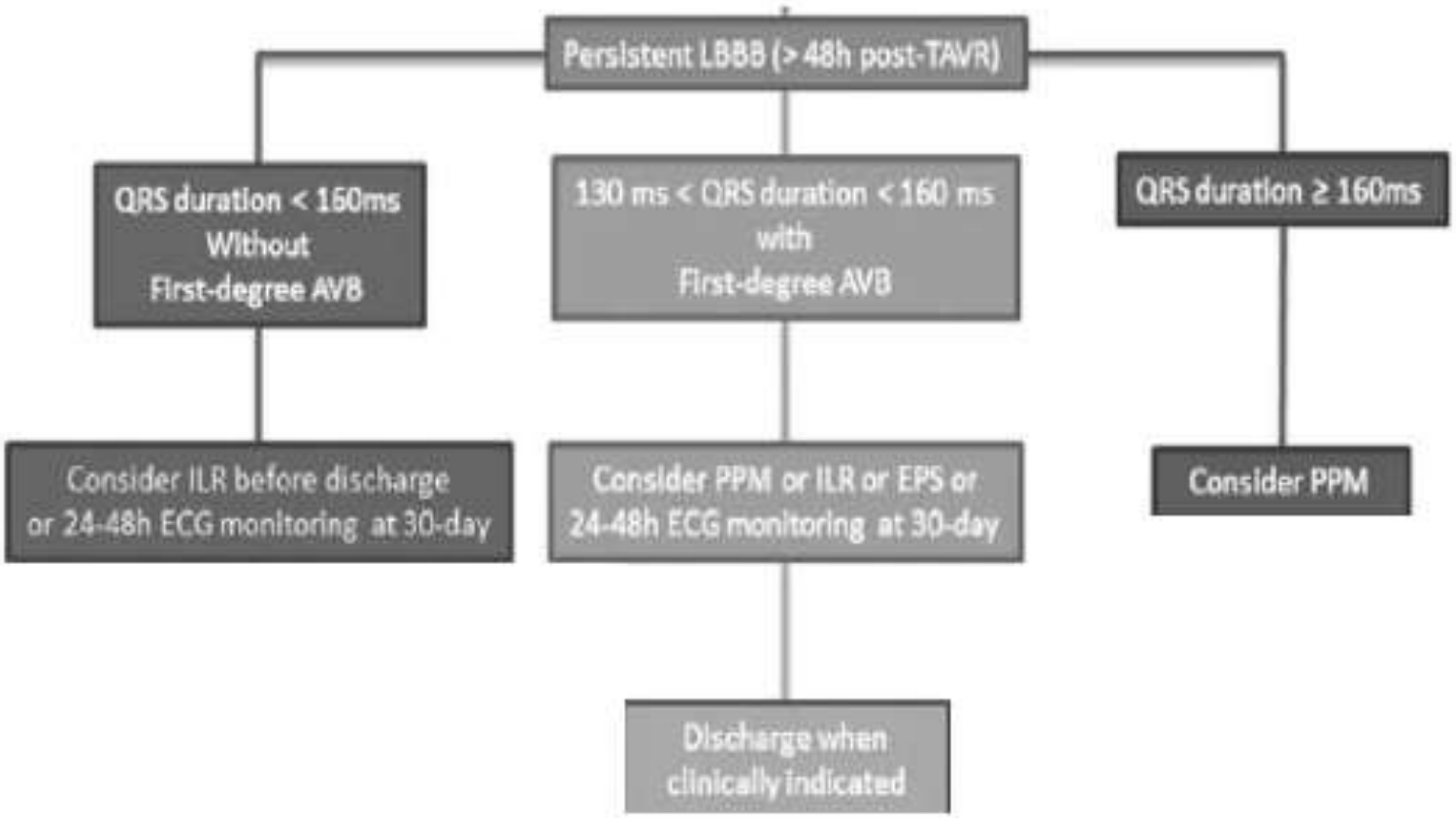
Kagase et al, Unpublished data, 2016

- New-onset LBBB is associated with a higher 30-day risk of PPM

Lopez-Aguiela et al, Am J Cardiol, 2016

Periprocedural Complications

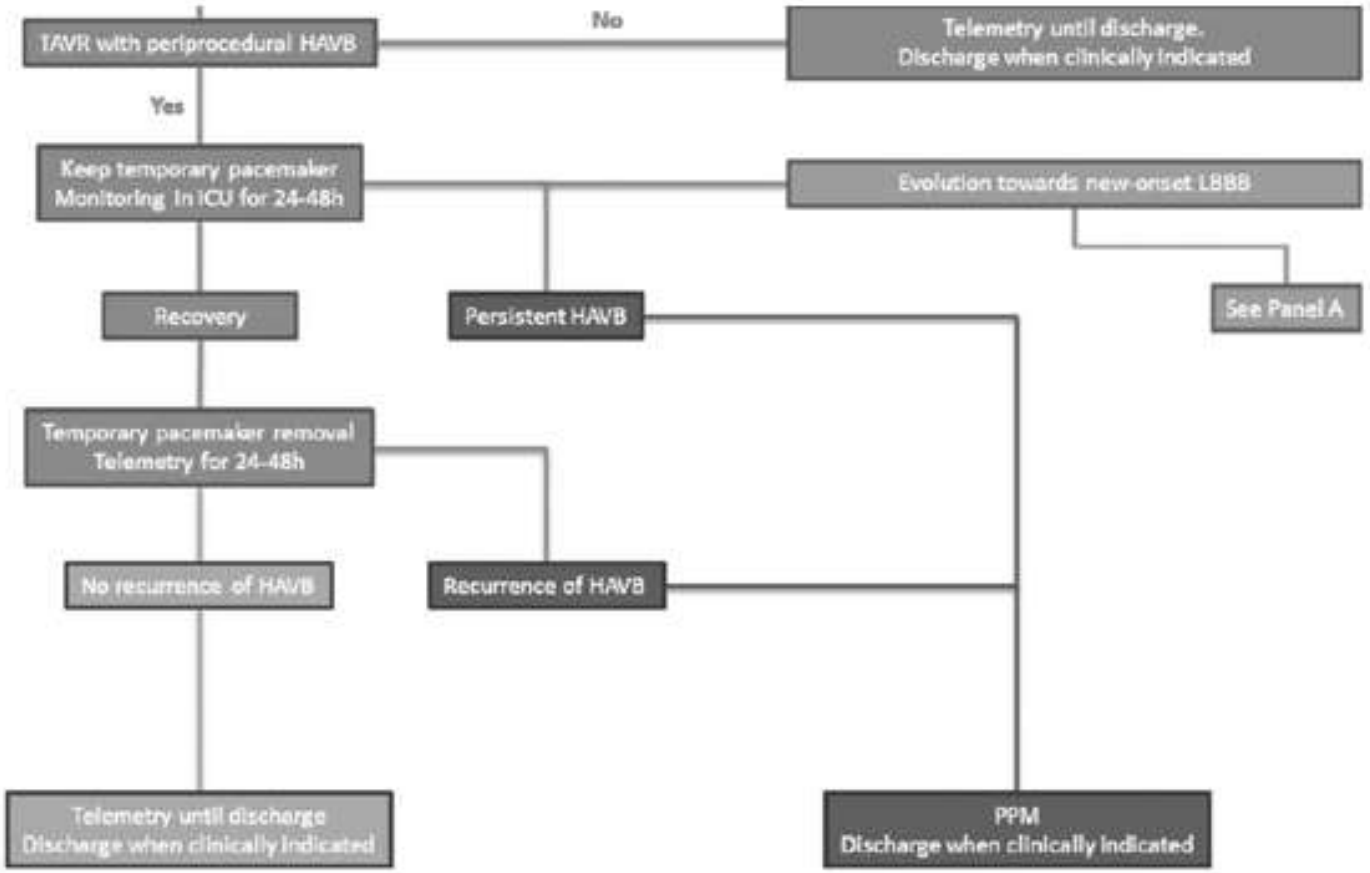
3c.LBBB Management



Auffret et al, Circulation, 2017

Periprocedural Complications

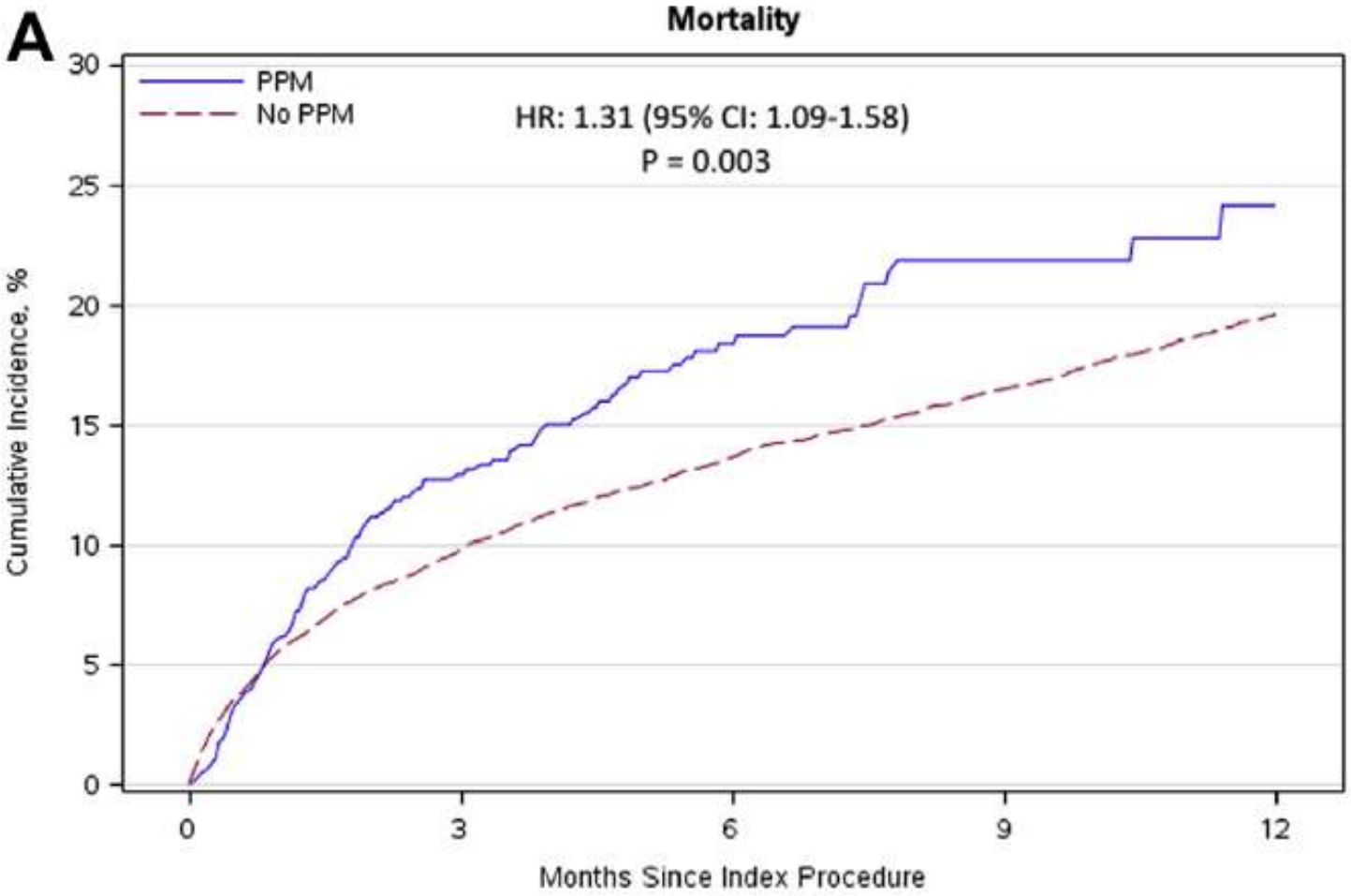
3d.HAVB Management



Auffret et al, Circulation, 2017

Periprocedural Complications

3e.PPM and Mortality

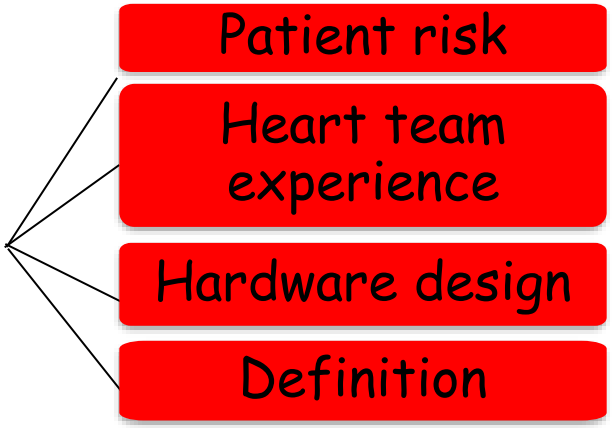


Fadahunsi et al, JACC Cardiovasc Interv, 2016

Stroke

Periprocedural Complications
4a. Stroke-Incidence

- Incidence of stroke: <5%
- Impressive improvement comparing to older studies (5-10%)

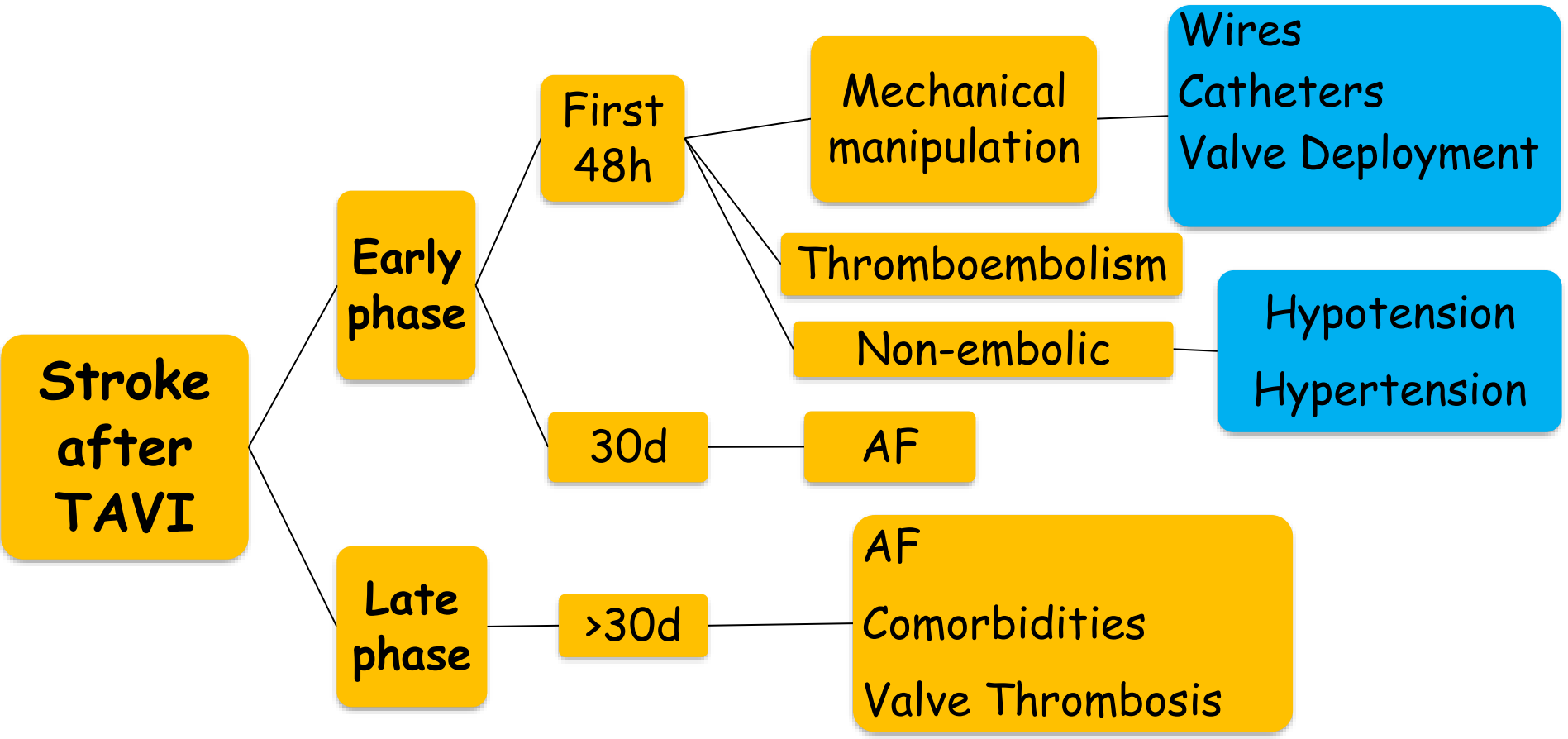


- Stroke-related 30-day mortality rate: x3,5

Prakash A et al, j Cardiothoracic and Vasc Anesth, 2017

Periprocedural Complications

4b. Stroke-Timing and Etiology



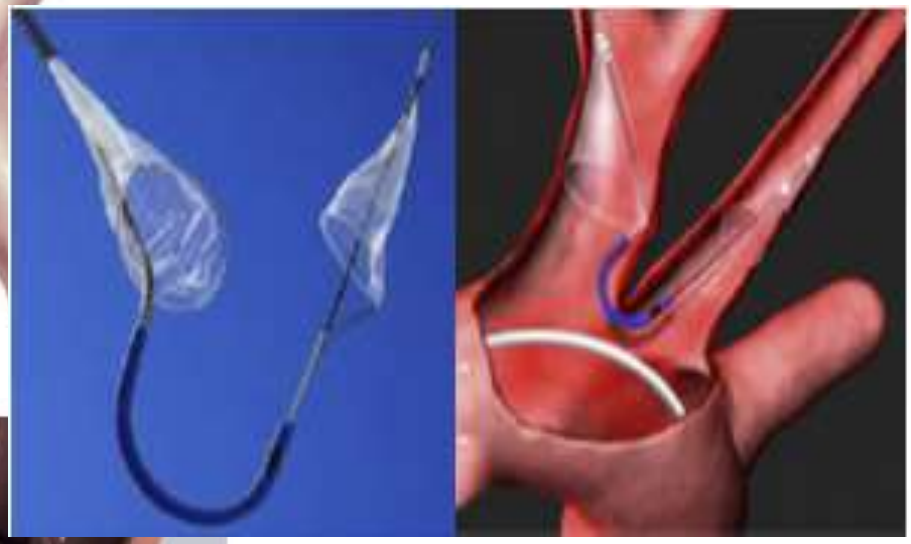
Prakash A et al, j Cardiothoracic and Vasc Anesth, 2017

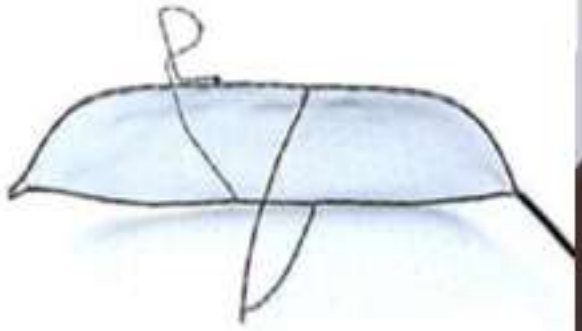
Periprocedural Complications
4c. Stroke-Prevention

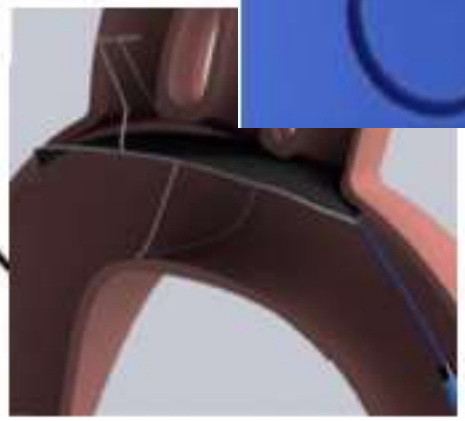
- Perioperative Anticoagulation
  - Unfractionated Heparin (ACT>300)
  - Bivalirudin (?)
- Embolic Protection Devices
  - Embrella
  - Sentinel
  - TriGuard
- Postoperative Pharmacology
  - Dual Antiplatelet Therapy
  - Peros Anticoagulation (?)

Periprocedural Complications

4d. Stroke-Embolic Protection Devices

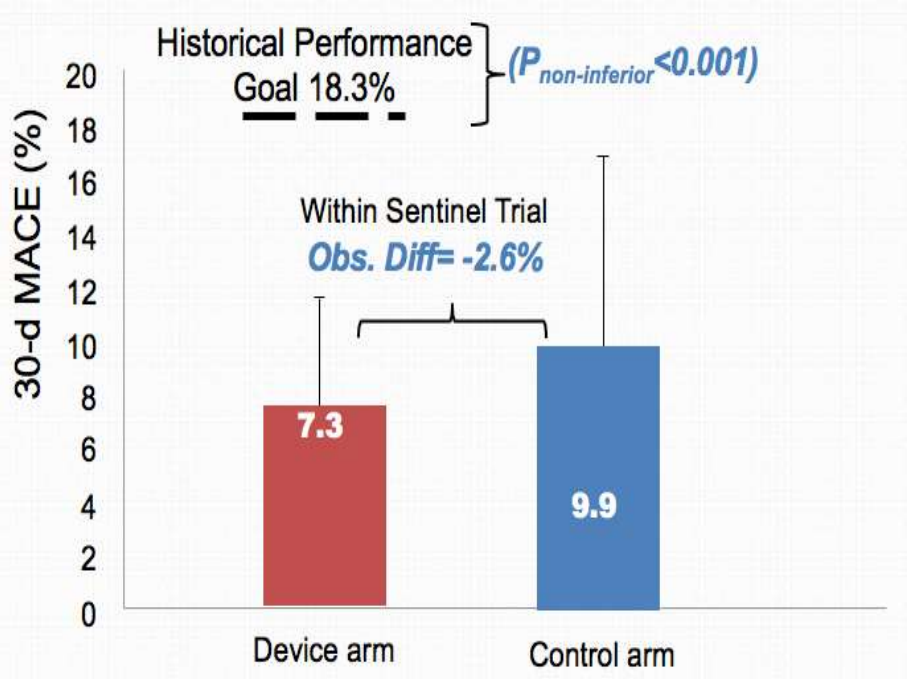


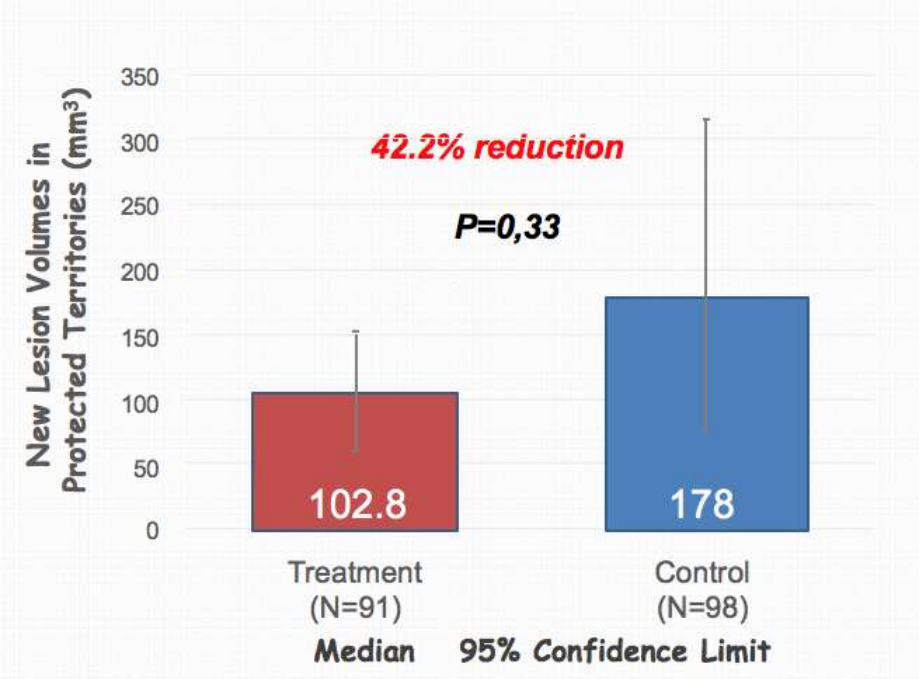




Periprocedural Complications

4e. Stroke-Embolic Protection Devices





- No significant difference in adverse cardiac and cerebrovascular events at 30days
- No significant reduction in new cerebral lesion volume, although the trend was favorable
- No difference in clinical stroke rate at 30days

Kapadia SR et al, JACC, 2017

Acute Kidney Injury

Periprocedural Complications

5a.AKI-Incidence and Definition

- Incidence of AKI: 4.0-57% (3-10% after VARC II)

Stage 1
Increase in serum creatinine to 150–199% (1.5–1.99 x increase compared with baseline) OR increase of >0.3 mg/dl (>26.4 mmol/l) OR
Urine output <0.5 ml/kg/h for >6 but <12 h
Stage 2
Increase in serum creatinine to 200–299% (2.0–2.99 × increase compared with baseline) OR
Urine output <0.5 ml/kg/h for >12 but <24 h
Stage 3†
Increase in serum creatinine to >300% (>3 × increase compared with baseline) OR serum creatinine of >4.0 mg/dl (>354 mmol/l) with an acute increase of at least 0.5 mg/dl (44 mmol/l) OR
Urine output <0.3 ml/kg/h for >24 h OR
Anuria for > 12 h

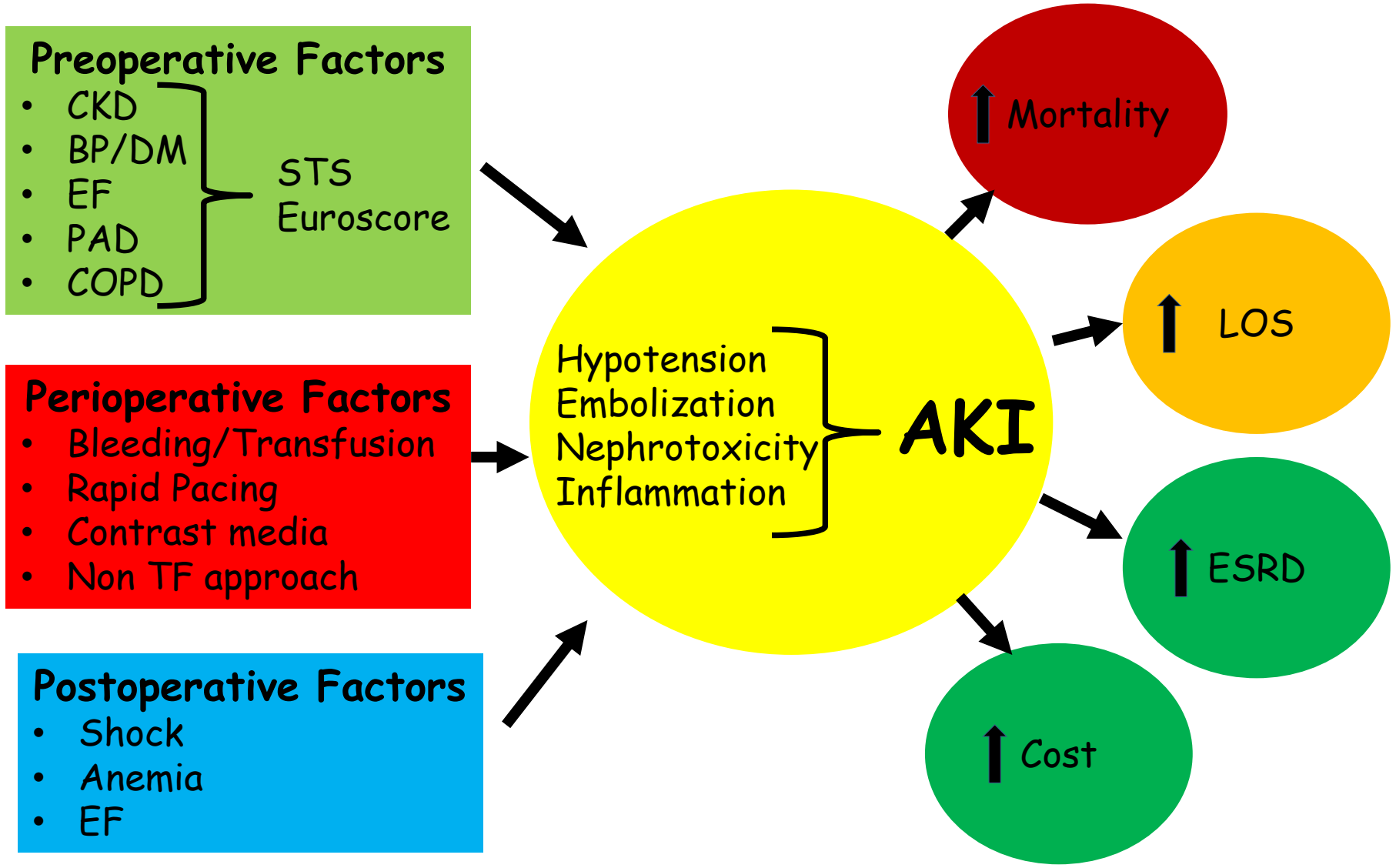
- AKI-related 30-day mortality rate: x2

  AKI-related 1-year mortality rate: x1.4

Liao et al, Eurointervention, 2017

Periprocedural Complications

5b.AKI-Risk Factors/Pathogenesis

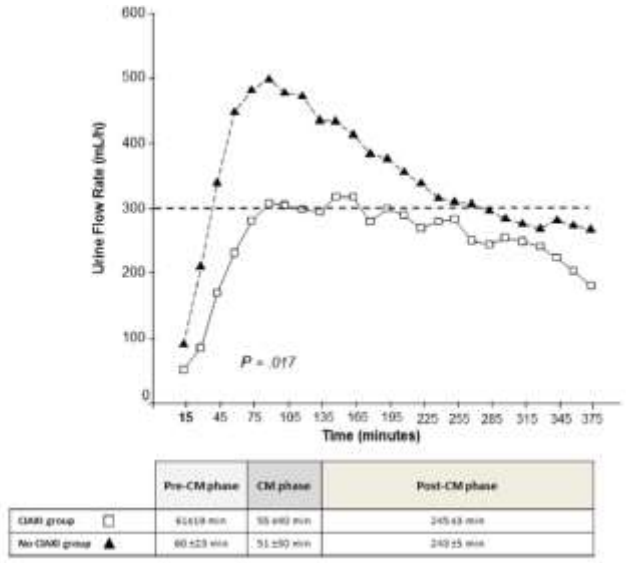


Ram et al, Clinical Cardiology, 2017

Periprocedural Complications

5c.AKI-Prevention

- Discontinuation of Nephrotoxic agents (Metformin, NSID…)
- Optimization of pre-TAVI volume status
  - RenalGuard system



Briguori et al, Am. Heart J, 2016

- No benefit of IV sodium bicarbonate or oral acetylcysteine over placebo for the prevention of contrast-associated acute kidney injury

Weisboard et al, NEJM, 2017

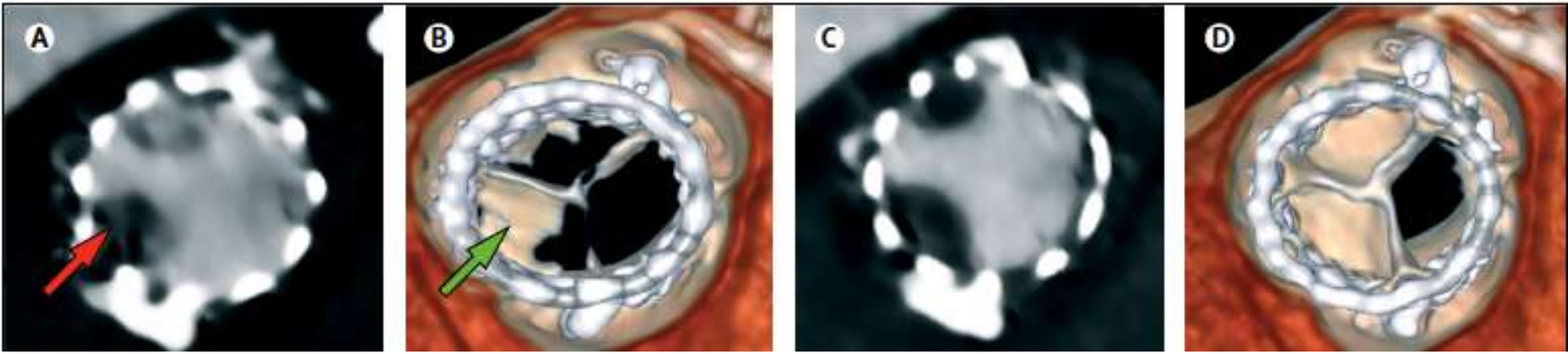
Subclinical Leaflet Thrombosis

Long-Term Complications

6a. Subclinical Leaflet Thrombosis

- Incidence: 15% for TAVI

  4% for SAVR

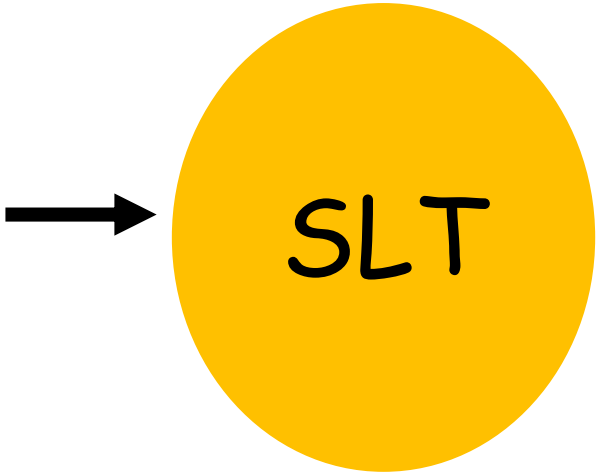


Chakravarty et al, Lancet,2017

Long-Term Complications

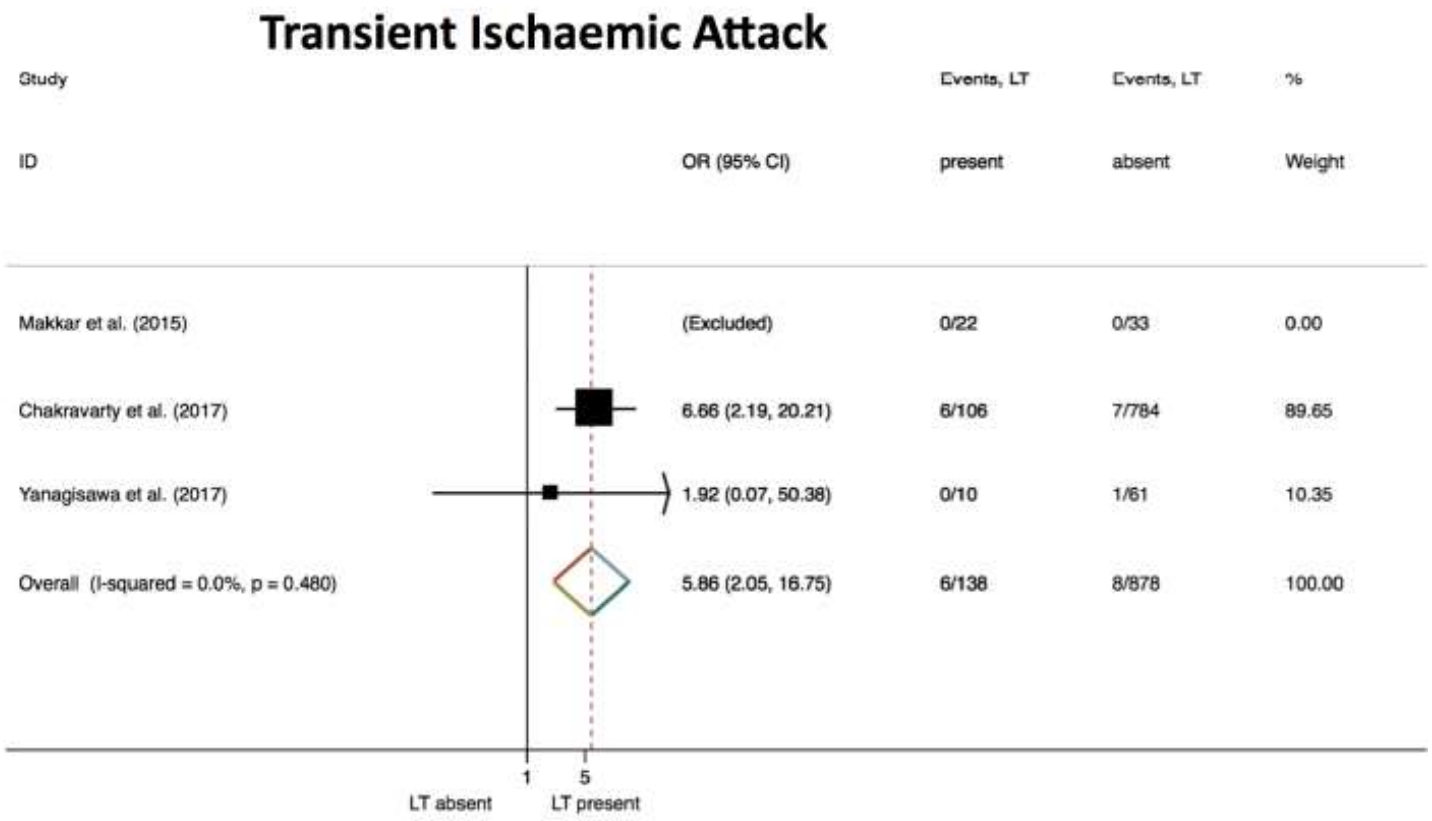
6b. SLT-Etiology

- Leaflet trauma during crimping
- Metallic THV frame
- Incomplete THV expansion
- Incomplete THV apposition
- Balloon expansion of the valve
- Large valves
- Valve in-valve
- Low EF



Long-Term Complications

6c. SLT-Cerebrovascular Events



Rashid et al, Eurointervention,2018

Long-Term Complications

6d. SLT-Prevention and Management

	AHA/ACC guidelines	ESC/EACTS guidelines	ACC expert consensus
Early after TAVI	Aspirin 75–100 mg/day+clopidogrel 75 mg/day for 6 months (IIb)	Low-dose aspirin+thienopyridine	Aspirin 75–100 mg/day+clopidogrel 75 mg/day for 3–6 months
	VKA to achieve an INR of 2.5 for at least 3 months in patients at low risk of bleeding (IIb) (newly added from 2017)	For patients with AF, VKA+aspirin or thienopyridine (it should be weighed against increased risk of bleeding)	Consider VKA (INR 2.0–2.5) if at risk of AF or VTE for 3 months
Late after TAVI	Lifelong aspirin 75–100 mg/day (IIb)	Aspirin or thienopyridine alone	Lifelong aspirin 75–100 mg/day

Nakatani et al, Heart,2017

Take home messages

- Complications of TAVI are divided in Periprocedural and Long-term complications
- Most common periprocedural complications are access site bleeding, PVR, HAVB and distal organ injury.
- Evolution in valve design targets in reducing complication rate.
- New generation valve systems managed to significantly reduce access site bleeding and PVR
- Further evolution of existing technology and the emerge of newer devices will improve clinical outcome in the near future


Thank you for your attention