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Taiwan Society of Cardiovascular Interventions



TAVR with Severe CAD Which First? How?

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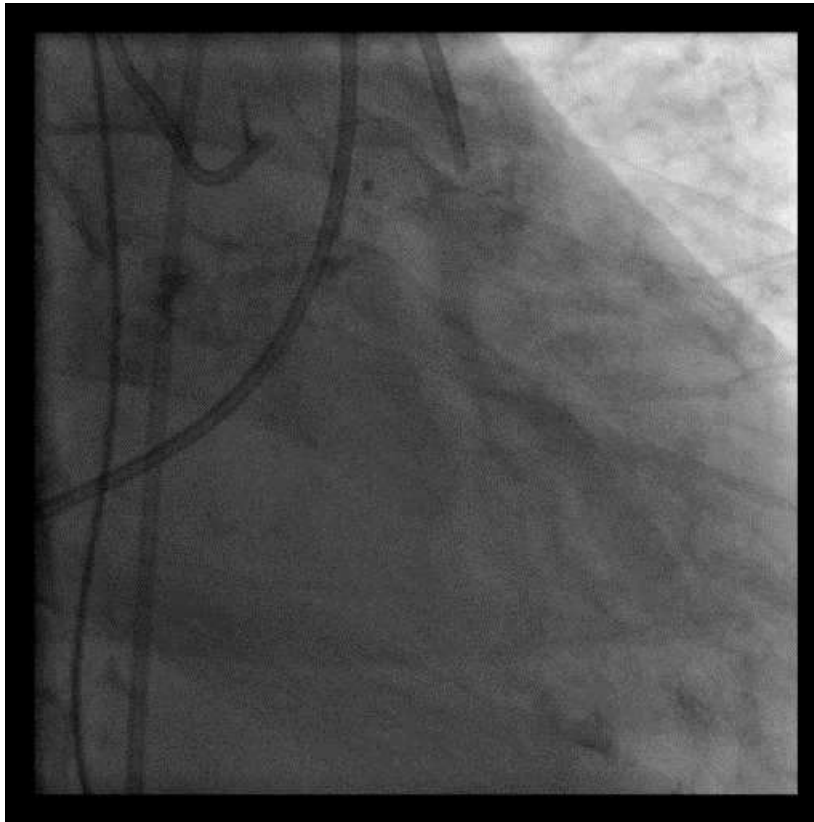
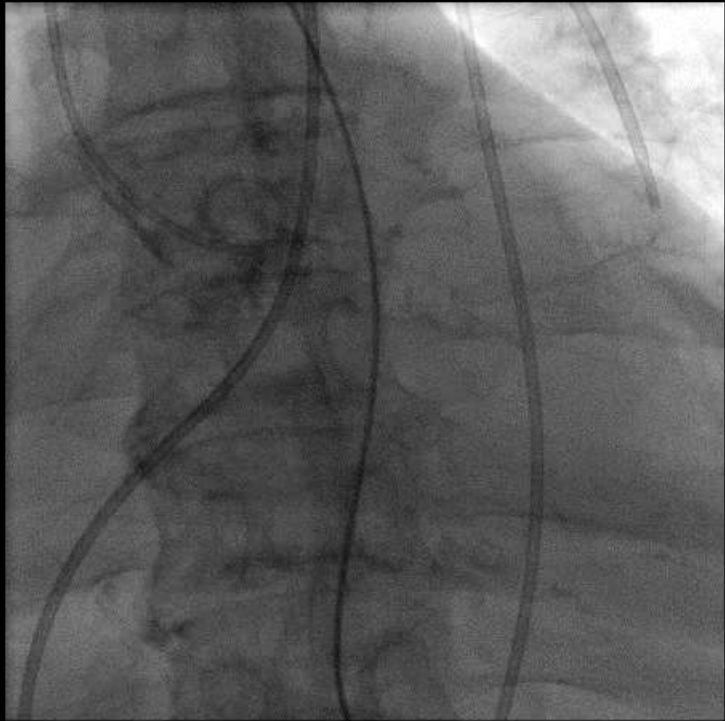
CHANG GUNG MEMORIAL HOSPITAL, TAIPEI, TAIWAN

Disclosure

- I have **NO** financial disclosure or conflicts of interest with the presented material in this presentation

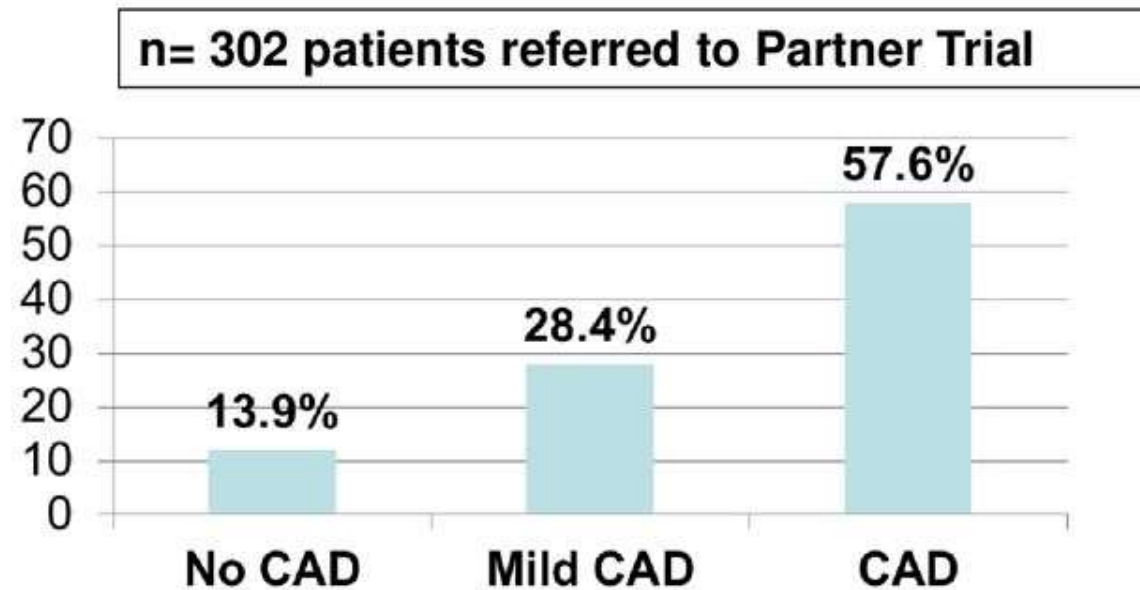
Case

- 81 Y/O male, 159cm, 55.3 kg, Hypertension, Severe AS



CAD in Patients with Severe AS.

WHC: Ben-Dor et al. Circulation 2010;122:S37-42



Patients with CAD had:

- higher STS and Euro scores,
- more females,
- more PVD,
- lower EF (all significant).

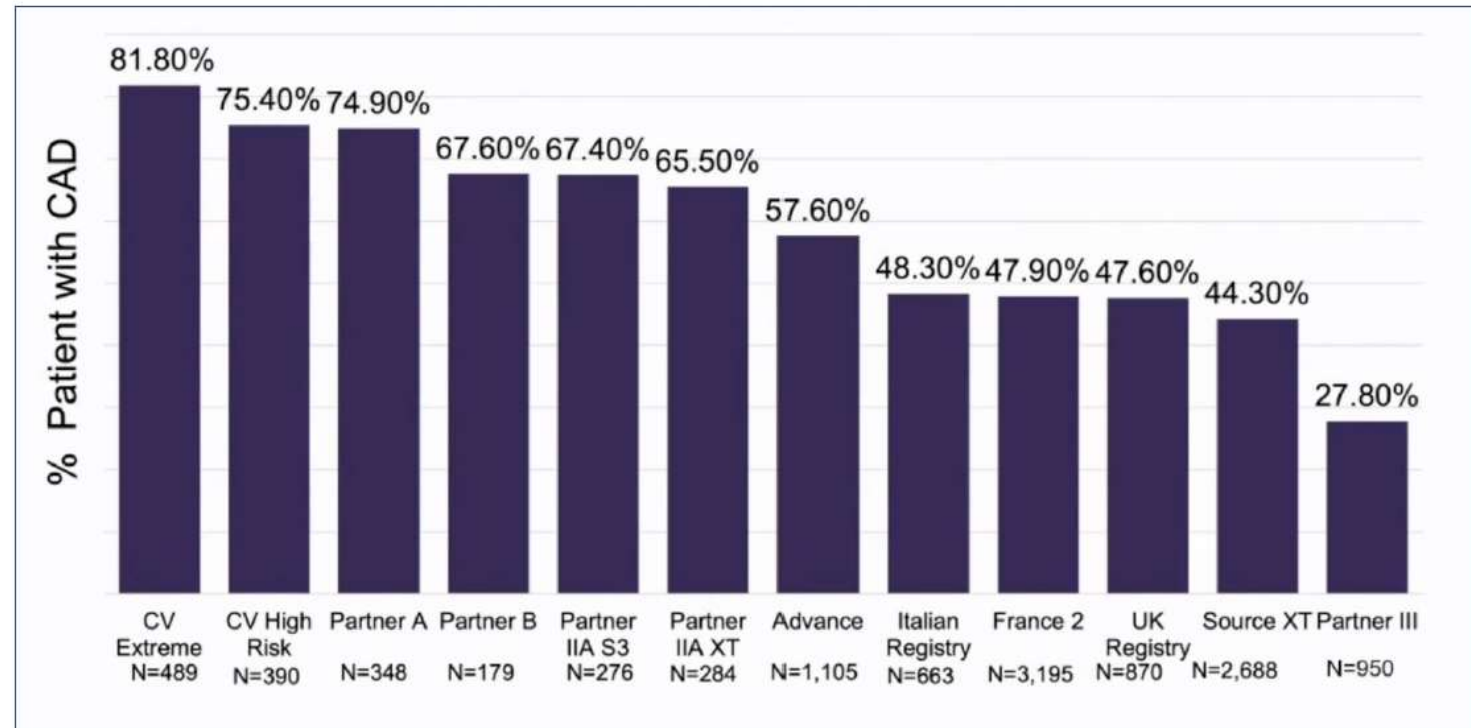
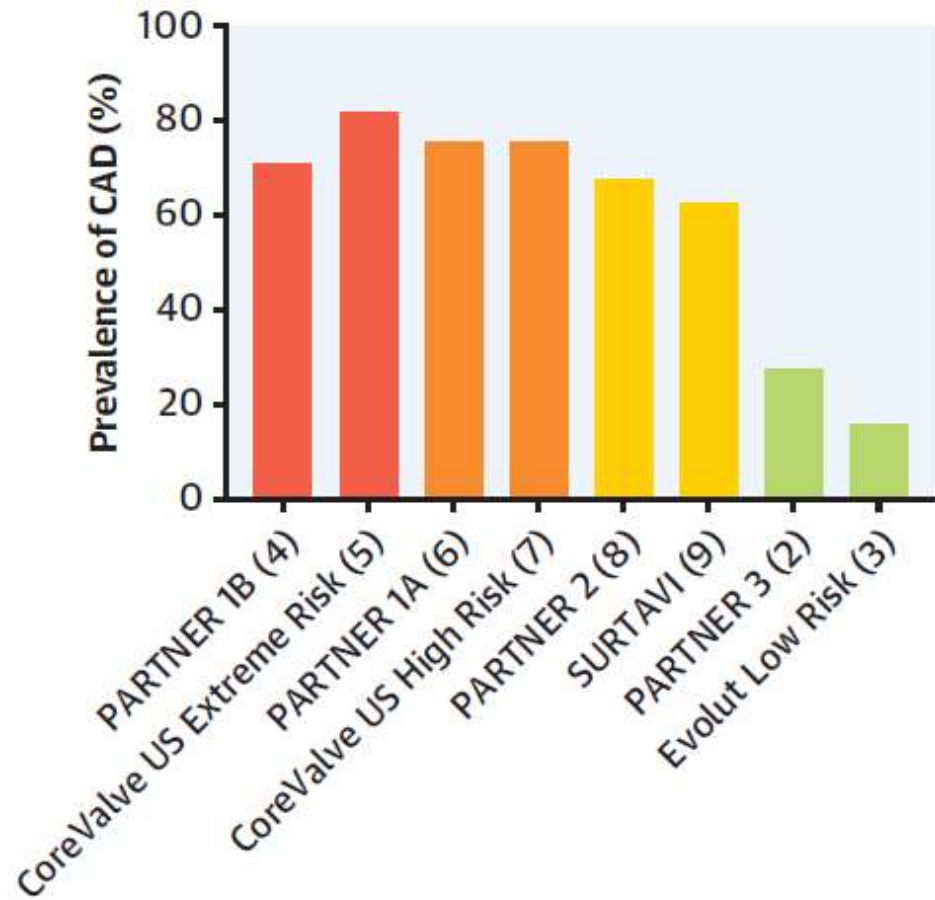
What is CAD prevalence in AS ?

CAD prevalence in severe AS

- The prevalence of CAD in the population undergoing transcatheter aortic valve implantation (TAVI) is higher than that in those undergoing surgical aortic valve replacement, and depending on the definition, the presence of significant CAD ranges from **50% to 75%**

Study	Design; Country; Y	No. of Participants; PCI+TAVI; TAVI Alone	Participant Inclusion Criteria and CAD Significance Definition
Masson et al 2010 ⁸	Retrospective cohort study; Canada; 2005–2007	104; 15; 89	Patients for TAVI with $\geq 50\%$ diameter stenosis in at least 1 coronary artery and DMUS score
Conradi et al 2011 ²³	Retrospective cohort study; Germany; 2008–2010	28; 28; 0	Patients for TAVI who underwent PCI
Gaußer et al 2011 ¹¹	Retrospective cohort study; France; 2006–2009	83; 11; 72	Patients for TAVI with $>70\%$ epicardial coronary artery stenosis or $\geq 50\%$ stenosis of left main
Nowakowski et al 2011 ²²	Cohort study; Australia; Unclear	70; 15; 55	Patients for TAVI with no information for determination of CAD significance
Wenaweser et al 2011 ¹⁰	Retrospective cohort study; Switzerland; 2007–2010	256; 59; 197	TAVI patient with $>50\%$ diameter stenosis in at least 1 coronary artery
Abdel-Wahab et al 2012 ¹²	Retrospective cohort study; Germany; 2007–2011	125; 55; 70	TAVI patients with $\geq 50\%$ stenosis on angiography or previous cardiac event
Bensaid et al 2012 ²⁴	Cohort study; France; Unclear	61; 23; 38	TAVI patients with $>70\%$ proximal vessel stenosis
Aktug et al 2013 ²⁵	Cohort study; Germany; 2008–2012	338; 66; 272	Patients for TAVI with CAD defined as clinically significant
Arnold et al 2013 ²⁶	Retrospective cohort study; Germany; Unclear	300; 73; 227	Patients for TAVI with CAD defined as clinically significant
Codner et al 2013 ²⁷	Retrospective cohort study; Israel; 2008–2012	153; 36; 117	Patients for TAVI with CAD defined as clinically significant
Czerwinska-Jelonkiewicz et al 2013 ³⁰	Retrospective cohort study; Poland; 2009–2011	83; 18; 65	Not reported
Gasparetto et al 2013 ²⁸	Retrospective cohort study; Italy; Unclear	152; 39; 113	Patients for TAVI with $\geq 50\%$ diameter stenosis of at least 1 epicardial coronary artery
Van Mieghem et al 2013 ²⁹	Retrospective cohort study; Netherlands; 2005–2012	138; 39; 99	Patients for TAVI with $>50\%$ diameter stenosis in any coronary artery
Abramowitz et al 2014 ³¹	Retrospective cohort study; Israel; 2009–2012	144; 61; 83	TAVI patients with $>70\%$ stenosis in major epicardial coronary artery
Griese et al 2014 ³³	Retrospective cohort study; Germany; 2009–2012	411; 65; 346	TAVI patients with CAD significance defined as per the institution's current local practice
Tatar et al 2014 ³²	Retrospective cohort study; France; 2008–2013	141; 38; 103	Patients for TAVI but no information of determination of CAD significance
Khawaja et al 2015 ³⁷	Retrospective cohort study; United Kingdom; 2008–2012	93; 25; 68	Patients for TAVI with epicardial coronary artery stenosis $\geq 70\%$ or left main stem stenosis of $\geq 50\%$
Mancio et al 2015 ³⁴	Retrospective cohort study; Portugal; 2007–2012	46; 13; 33	Patients for TAVI with $\geq 50\%$ stenosis in coronary artery
Penkalla et al 2015 ³⁵	Retrospective cohort study; Germany; 2008–2013	308; 76; 232	$>50\%$ stenosis in left main or $>90\%$ stenosis in LAD, LCx, and RCA
van Rosendaal et al 2015 ³⁶	Retrospective cohort study; Netherlands; Unclear	96; 96; 0	TAVI patients with $\geq 70\%$ stenosis of a coronary artery of ≥ 1.5 mm
Snow et al 2015 ³⁸	Retrospective cohort study; United Kingdom; 2007–2011	1339; 172; 1167	TAVI patients with $>50\%$ stenosis main, LAD, LCx, and RCA
Chakravarty et al 2016 ³⁹	Retrospective cohort and matched study; International; 2007–2014	256 (cohort); 128; 128	Patients with left main PCI from a TAVI-left main registry and matched controls
Singh et al 2016 ⁴⁰	Retrospective cohort study with propensity matching; United States of America; 2011–2013	2349; 588; 1761	TAVI patients with CAD according to ICD-9 coding
Paradis et al 2017 ⁴¹	Retrospective cohort study; North America; 2007–2012	377; 54; 323	Patients for TAVI with CAD defined as significant if $>50\%$ of vessel diameter

CAD prevalence in severe AS

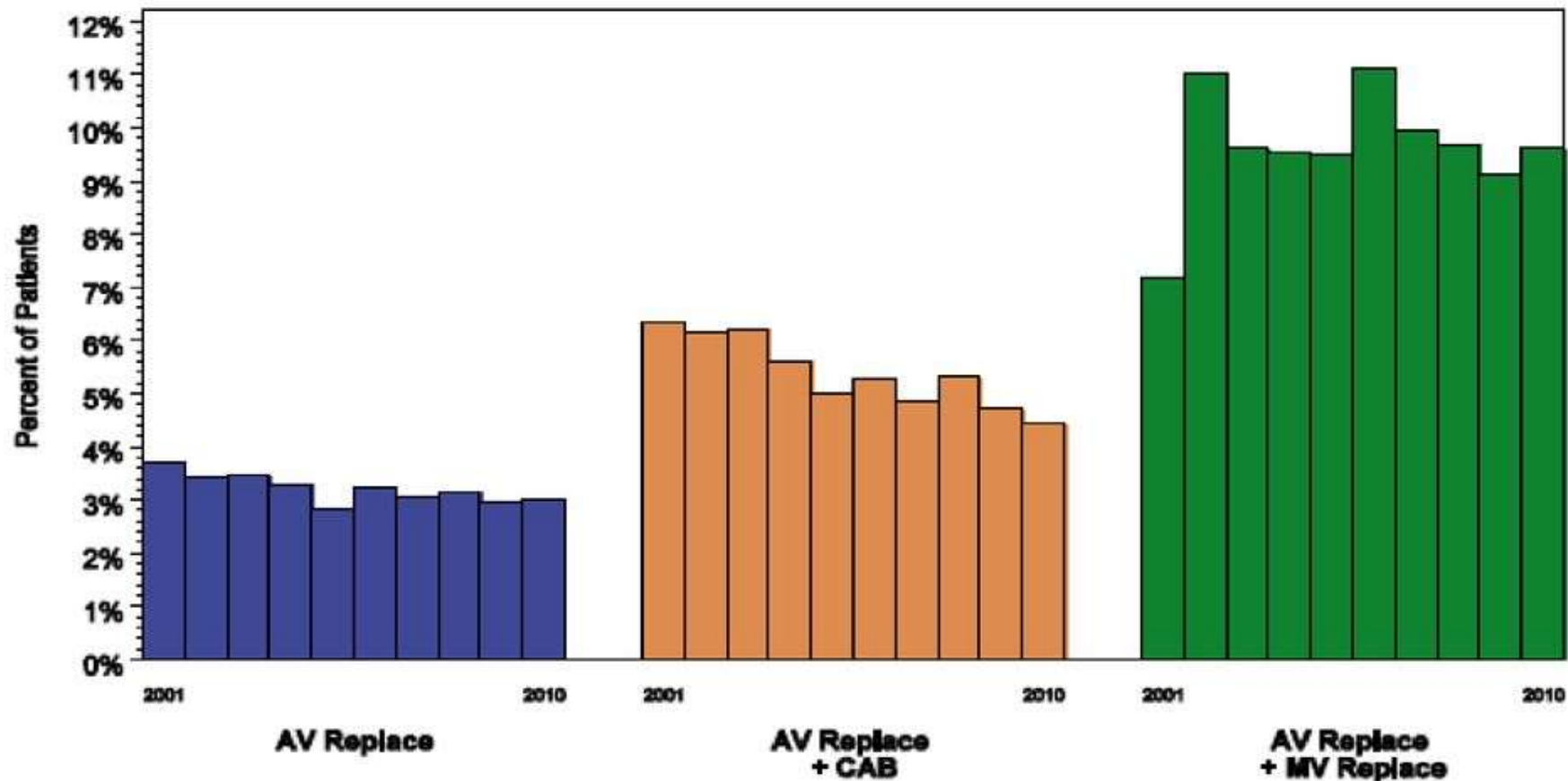


Mortality for AVR.

STS Executive Summary 2010

www.sts.org

Unadjusted Aortic Valve Operative Mortality Yearly over last 10 years



<10% of patients had STS >10

Treatment of Severe AS + CAD

- SAVR + CABG
- PCI + SAVR
- PCI + TAVR
 - PCI before TAVR
 - PCI during TAVR
 - PCI after TAVR
- Age is important
- TAVI center for PCI

What should we do with severe CAD in TAVR patients ?

- **Do nothing, proceed with TAVR**
- **Revascularize a few weeks before TAVR**
- **Revascularize during or after TAVR**

Transcatheter Aortic Valve Implantation With or Without Percutaneous Coronary Artery Revascularization Strategy: A Systematic Review and Meta-Analysis

Rafail A. Kotronias, MBChB, MSc; Chun Shing Kwok, MBBS, MSc; Sudhakar George, MBChB; Davide Capodanno, MD, PhD; Peter F. Ludman, MD, FRCP, FESC; Jonathan N. Townend, MD, FRCP; Sagar N. Doshi, MBChB, MD, FRCP; Saib S. Khogali, MBChB, MD, FRCP; Philippe Généreux, MD; Howard C. Herrmann, MD, FACC, MSCAI; Mamas A. Mamas, BMBCh, DPhil; Rodrigo Bagur, MD, PhD, FAHA

Background—Recent recommendations suggest that in patients with severe aortic stenosis undergoing transcatheter aortic valve implantation and coexistent significant coronary artery disease, the latter should be treated before the index procedure; however, the

evidence
outcomes
implantation

- No clinical advantage of patients outcomes
- Increased risk of major vascular complication and 30-day mortality

Methods
transcatheter
the intervention
were compared
higher rates
30-day mortality
0.42%
coronary artery

Conclusions
advantage

vascular complications and 30-day mortality. In the absence of definitive evidence, careful evaluation of patients on an individual basis is of paramount importance to identify patients who might benefit from elective revascularization. (*J Am Heart Assoc.* 2017;6:e005960. DOI: 10.1161/JAHA.117.005960.)

Current Guideline recommendation

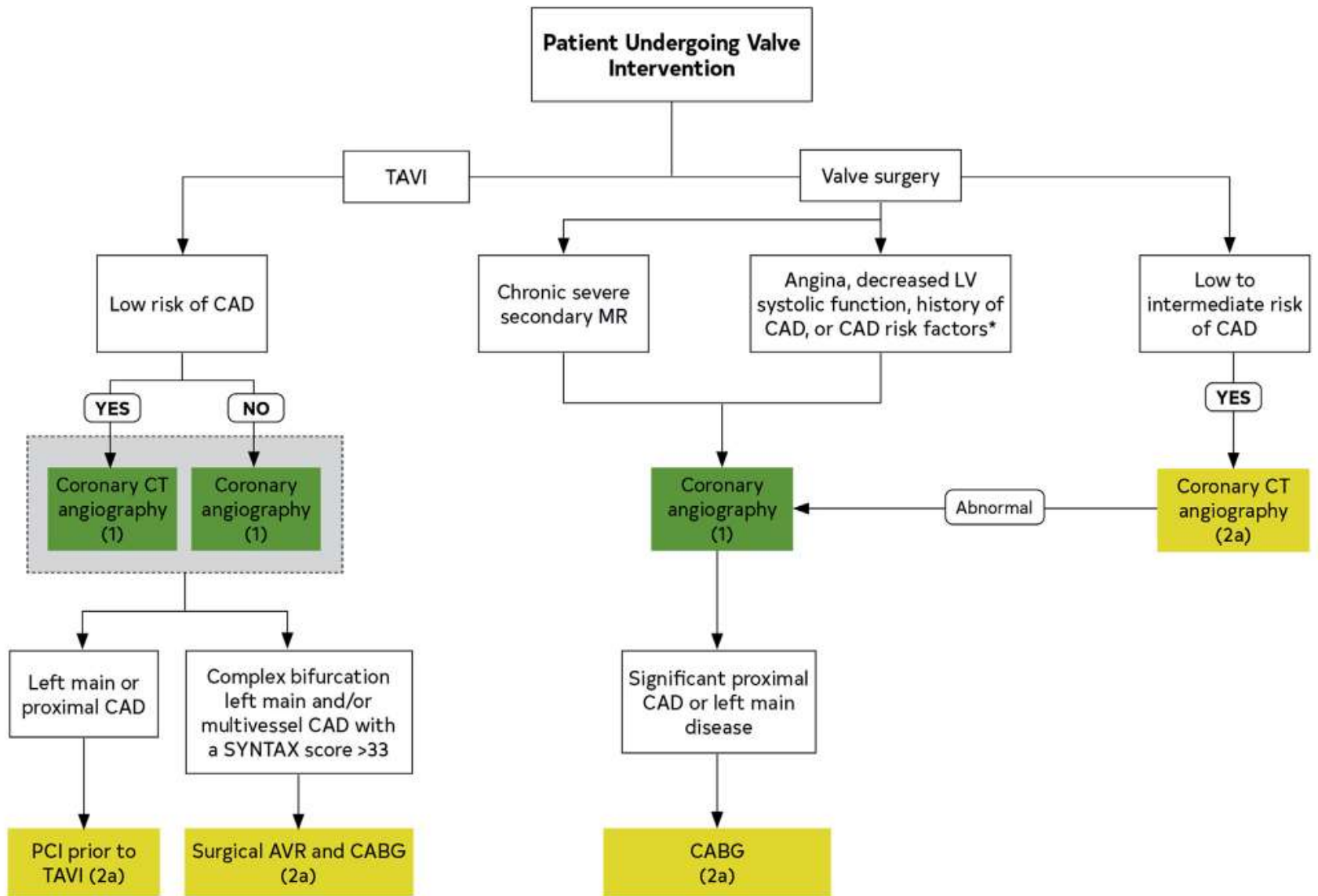
2020 ACC/AHA guideline

Recommendations for Management of CAD in Patients Undergoing TAVI

Referenced studies that support the recommendations are summarized in [Online Data Supplement 45](#).

COR	LOE	RECOMMENDATIONS
1	C-EO	1. In patients undergoing TAVI, 1) contrast-enhanced coronary CT angiography (in patients with a low pretest probability for CAD) or 2) an invasive coronary angiogram is recommended to assess coronary anatomy and guide revascularization.
2a	C-LD	2. In patients undergoing TAVI with significant left main or proximal CAD with or without angina, revascularization by PCI before TAVI is reasonable (1,2).
2a	C-LD	3. In patients with significant AS and significant CAD (luminal reduction >70% diameter, fractional flow reserve <0.8, instantaneous wave-free ratio <0.89) consisting of complex bifurcation left main and/or multivessel CAD with a SYNTAX (Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery) score >33, SAVR and CABG are reasonable and preferred over TAVI and PCI (3,4).

FIGURE 19 Management of CAD in patients undergoing valve interventions



Recommendations for management of CAD in patients with VHD (1)

Recommendations	Class	Level
<i>Diagnosis of CAD</i>		
Coronary angiography is recommended before valve surgery in patients with severe VHD and any of the following: <ul style="list-style-type: none"> • History of cardiovascular disease. • Suspected myocardial ischaemia. • LV systolic dysfunction. • In men >40 years of age and postmenopausal women. • One or more cardiovascular risk factors. 	I	C
Coronary angiography is recommended in the evaluation of severe SMR.	I	C
Coronary CT angiography should be considered as an alternative to coronary angiography before valve surgery in patients with severe VHD and low probability of CAD.	IIa	C

Recommendations for management of CAD in patients with VHD (2)

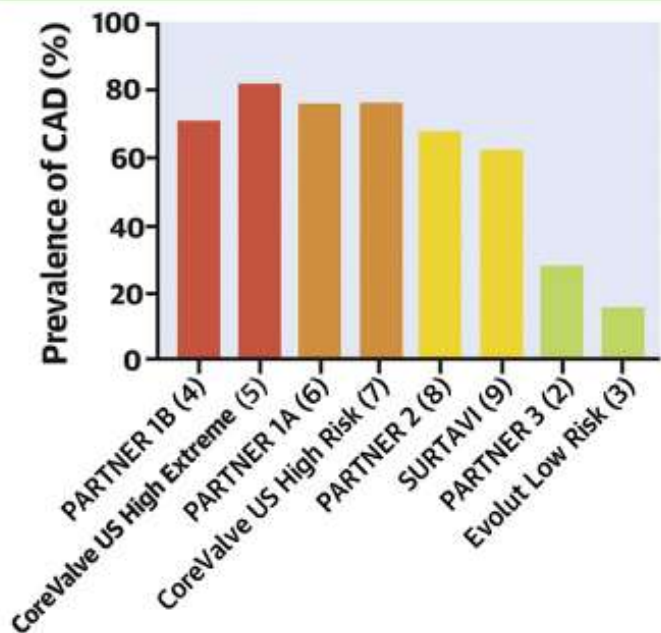
Recommendations	Class	Level
<i>Indications for myocardial revascularization</i>		
CABG is recommended in patients with a primary indication for aortic/mitral/tricuspid valve surgery and coronary artery diameter stenosis $\geq 70\%$. ^{*,**}	I	C
CABG should be considered in patients with a primary indication for aortic/mitral/tricuspid valve surgery and coronary artery diameter stenosis $\geq 50\text{--}70\%$.	IIa	C

* Stenosis $\geq 50\%$ can be considered for left main stenosis.

** FFR ≤ 0.8 is a useful cut-off indicating the need for an intervention in patients with mitral or tricuspid diseases, but has not been validated in patients with aortic stenosis.

CAD Management Before TAVR

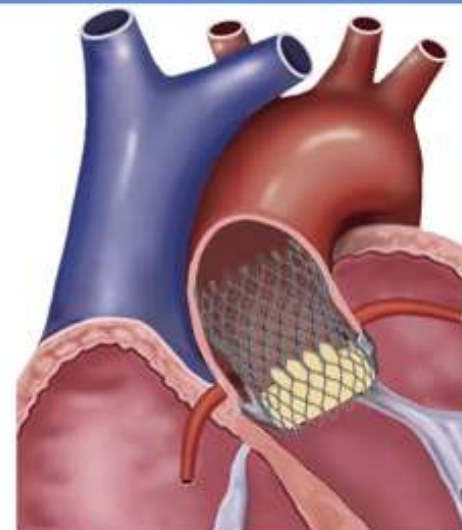
Prevalence of CAD in TAVR Recipients According to Surgical Risk



Future Perspectives

- CTA: Reasonable alternative to coronary angiography for the evaluation of CAD pre-TAVR
- FFR/iFR: Feasible and safe, promising preliminary results

CAD Management After TAVR



Coronary Access After TAVR

- No expected difficulties (in most cases) for coronary access (particularly valves with shorter stent frame/sealing skirt, larger stent cell size)
- Potential increased difficulties for coronary access (particularly RCA) in some cases (taller stent frame/sealing skirt, small sinus of Valsalva, low coronary height)

Poor Outcomes Associated With ACS Post-TAVR

PCI before TAVR ?

REVASC-TAVI

The multicenter REVASC-TAVI registry

Patients undergoing TAVI with significant, stable CAD at baseline (n=2402)

No follow-up data available (n=231)

No data about the completeness of myocardial revascularization (n=146)

Patients with available data about baseline CAD and PCI performed (n=2025)

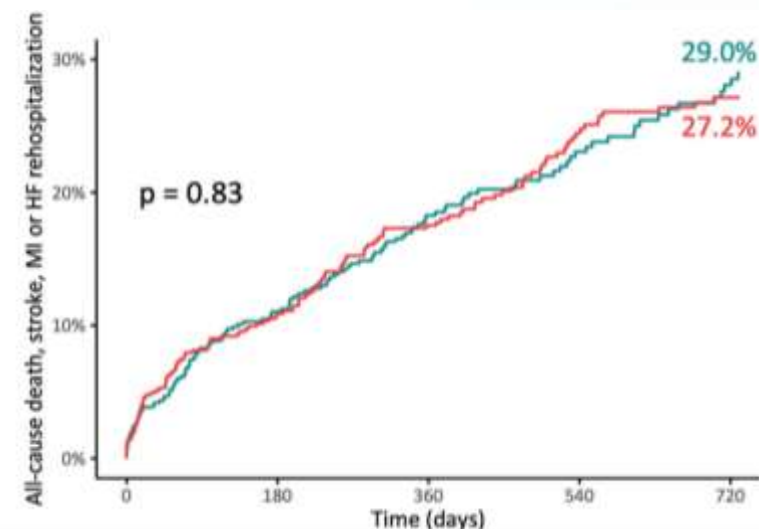
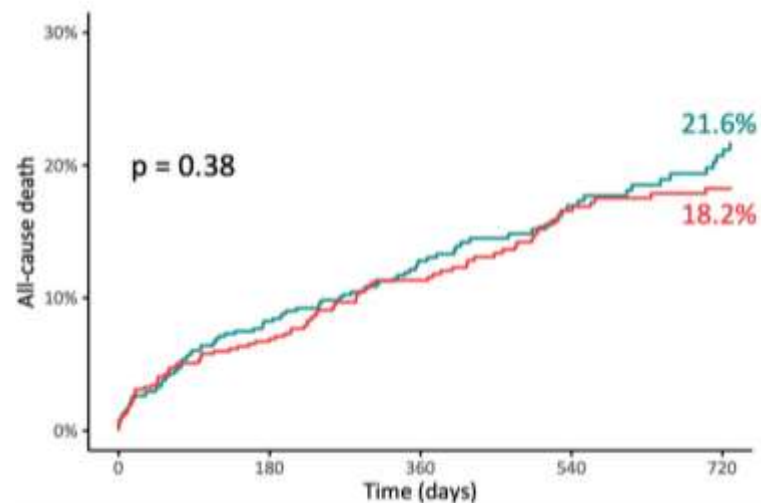


Complete revascularization
(n=1310)



Incomplete revascularization
(n=715)

*657 pairs of patients compared
through 1:1 PS matching*

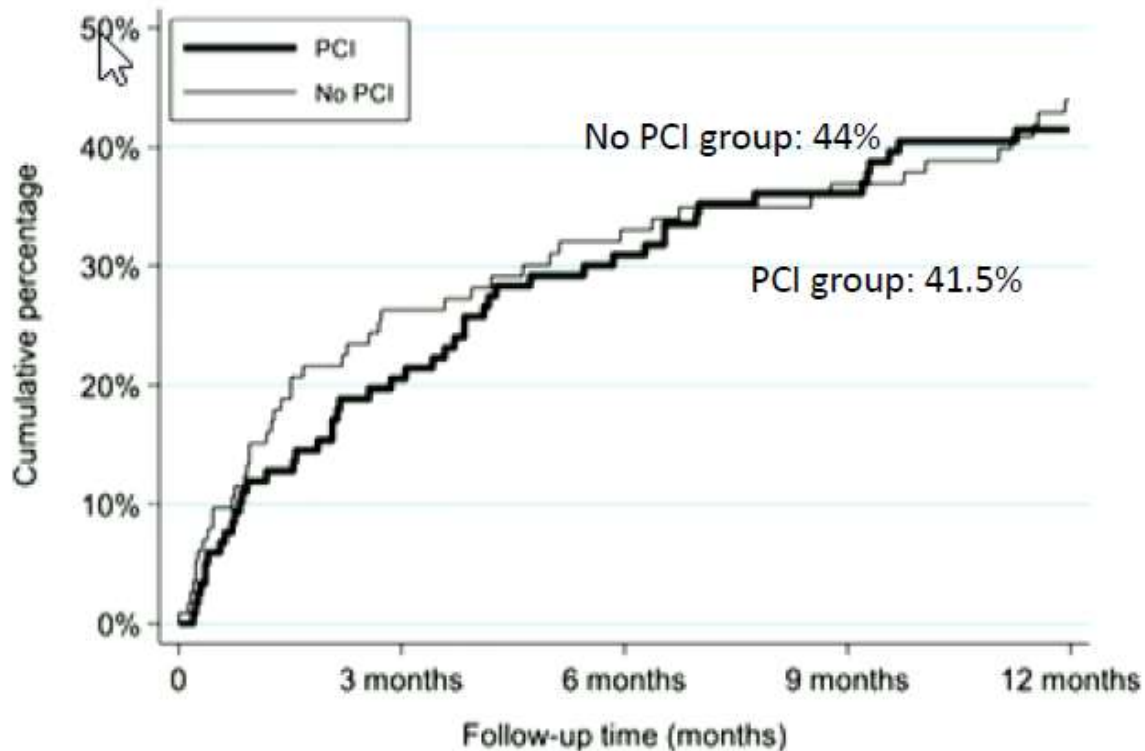


ACTIVATION:

PCI versus no PCI in patients with AS & CAD undergoing TAVI

Primary Endpoint:
Comparable rates of death & cardiac rehospitalization at 1 year

Limitation:
RCT prematurely stopped due to slow recruitment



	0	3 months	6 months	9 months	12 months
PCI	119	92	80	73	56
No PCI	116	78	69	65	50

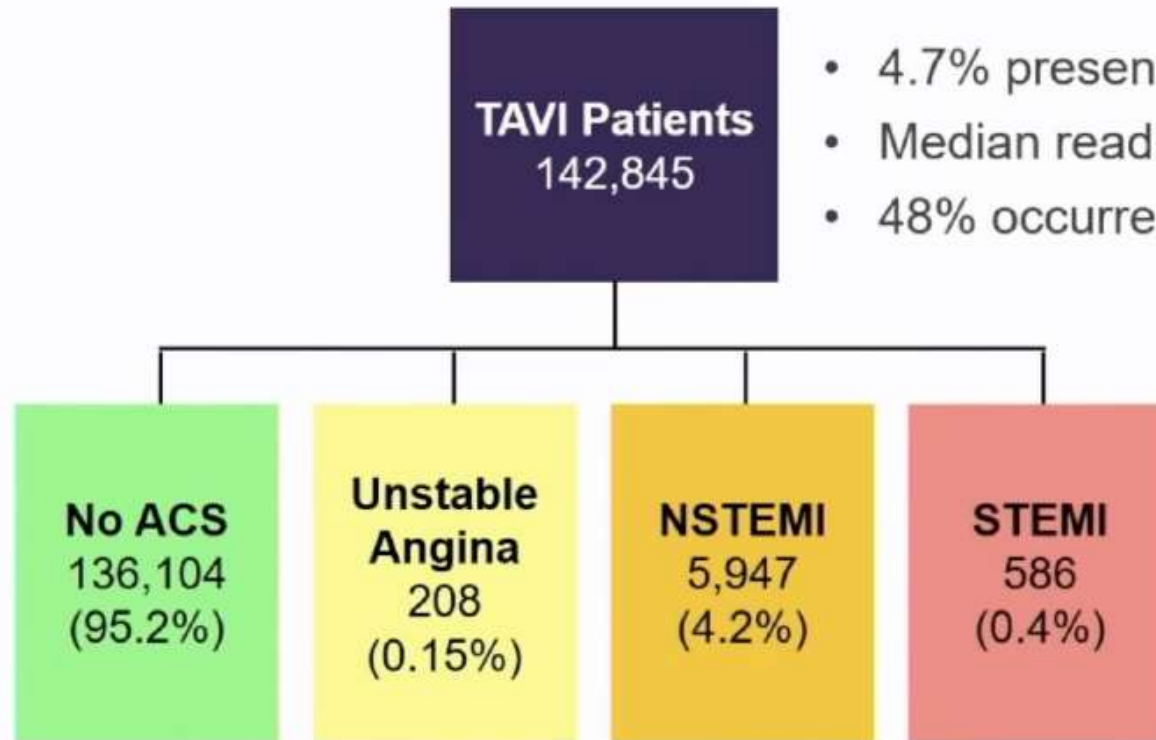
	PCI	No PCI	Total
N of patients	119	116	235
Age (years)	83.6±5.0	84.3±5.0	83.9±5.0
Males (%)	58	65	61
STS-PROM	6.7±6.0	6.8±6.0	6.8±7.7
Number of vessels treated			
1	85 (71.4%)		
2	29 (24.4)		
≥3	3 (2.5%)		

Higher bleeding in PCI vs no PCI group
(44.5% vs 28.4%, p=0.02)

CT-CA (NCT03291925)	Randomized open-label trial (pilot study)	Patients with symptomatic severe AS eligible for TAVR	200	Selective invasive angiography based on CT/coronary CTA imaging vs. systematic invasive angiography	Number of patients enrolled in the study of all those that are eligible
FORTUNA (NCT03665389)	Prospective open-label registry (exploratory)	Patients with moderate stenotic lesions (30%–<70%) or severe stenotic lesions on CTA who are candidates for PCI following TAVR	25	Measurement of iFR before TAVR, FFRct before TAVR and FFR + iFR after TAVR	FFRct before TAVR
TCW (NCT03424941)	Randomized open-label noninferiority trial	Patients age ≥ 70 yrs with severe AS feasible for treatment by both TF or TSc approach TAVR as well as conventional SAVR, and ≥ 2 de novo coronary lesions $\geq 50\%$ diameter stenosis on main artery or side branch > 2 mm or single LAD lesion > 20 mm length or involving a bifurcation, feasible for treatment with CABG as well as PCI	328	FFR-guided PCI and TAVR vs. CABG and SAVR	Composite of all-cause mortality, myocardial infarction, disabling stroke, unscheduled clinically-driven target vessel revascularization, valve reintervention, and life threatening or disabling bleeding at 1 yr
FAITAVI (NCT03360591)	Randomized open-label trial	Patients with severe AS with the indication of TAVR and at least one coronary stenosis $> 50\%$ at angiography	320	Physiologically-guided strategy (PCI of lesions with $FFR \leq 0.80$) vs. angiographically guided strategy (PCI of all lesions $> 50\%$ by visual estimation of major branches > 2.5 mm)	Composite of all-cause death, myocardial infarction, stroke, major bleeding and target vessel revascularization at 1 yr
ACTIVATION (ISRCTN75836930)	Randomized trial	Patients with symptomatic severe AS accepted for TAVR, and ≥ 1 proximal stenosis of $\geq 70\%$ in a major epicardial artery deemed suitable for PCI	310	Pre-TAVR PCI vs. no pre-TAVR PCI	Mortality and rehospitalization at 1 yr
NOTION-3 (NCT03058627)	Randomized open-label trial	Patients with severe aortic stenosis selected for TAVR and at least one coronary stenosis with $FFR \leq 0.80$ or diameter stenosis $> 90\%$ in a coronary artery ≥ 2.5 mm	452	TAVR only vs. TAVR + FFR-guided complete revascularization	All-cause mortality, myocardial infarction, or urgent revascularization at 1 yr

PCI after TAVR, what do we need ?

Presentation with ACS post TAVR (Medicare 2012-2017)

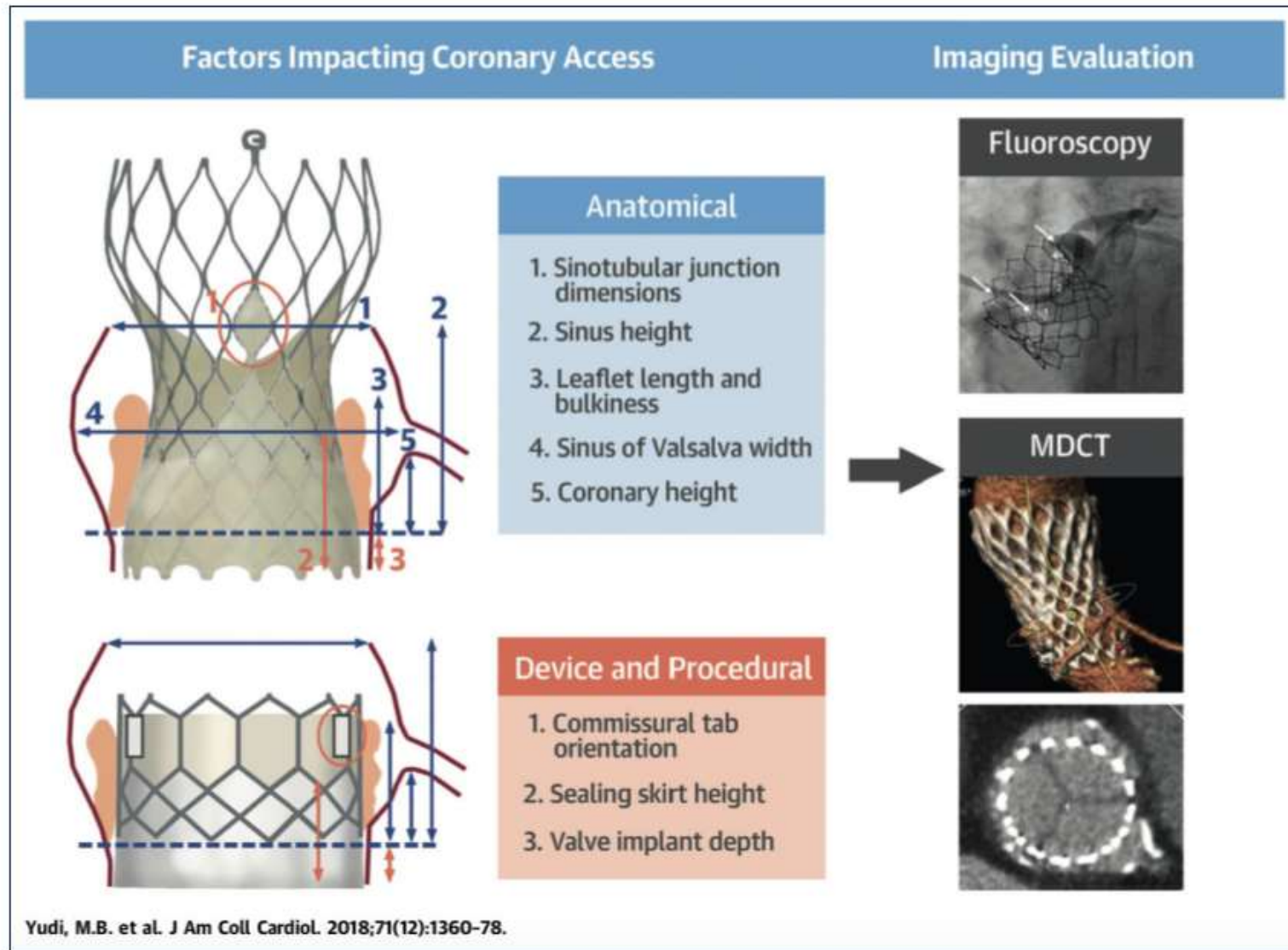


- 4.7% presented at least 1 episode of ACS
- Median readmission time of 297 days
- 48% occurred within 6 months

	Without ACS	With ACS
Mean Age	81.7 ± 8.1 Years	80.7 ± 8.8 Years
Prior CAD	79.8%	90.8%

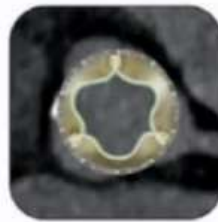
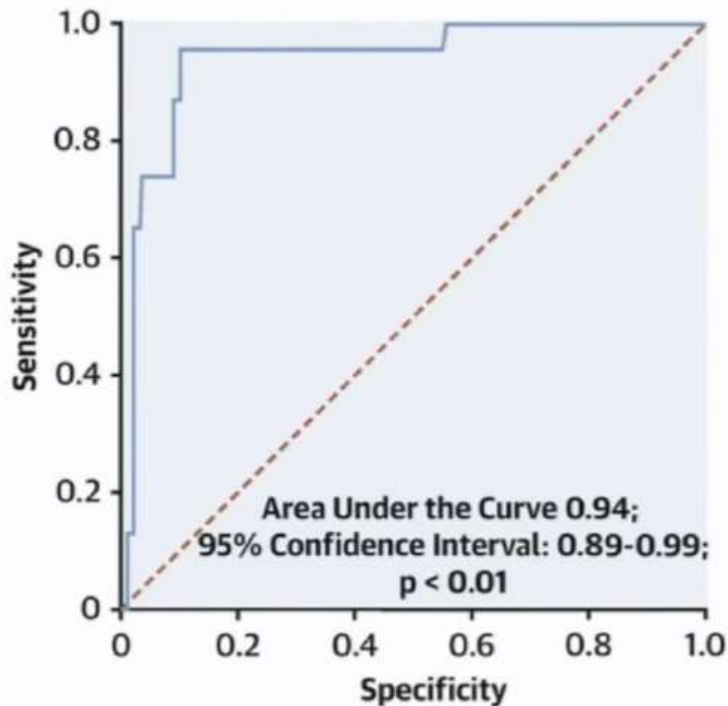
Mentias, et al., JACC Cardiovasc Interv. 2020;13:938-950.

Factors impacting coronary access post TAVI



Coronary access after TAVR

RE-ACCESS: Predictors of unsuccessful coronary access



**Transcatheter Aortic Valve/
Sinuses of Valsalva Relation**
Odds Ratio 1.1;
95% CI: 1.0-1.2; p < 0.01



Transcatheter Aortic Valve Implant Depth
Odds Ratio 1.7;
95% CI: 1.3-2.3; p < 0.01



Evolut Transcatheter Aortic Valve
Odds Ratio 29.6;
95% CI: 2.6-335.0; p < 0.01

Barbanti, M. et al. J Am Coll Cardiol Interv. 2020;13(21):2542-55.

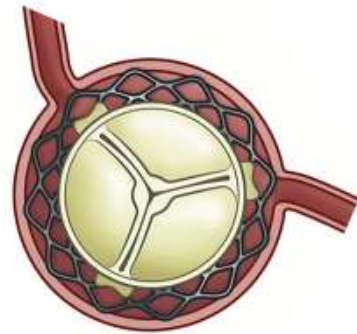
Commissure Alignment

TAVR – NEO-COMMISSURAL ALIGNMENT

A



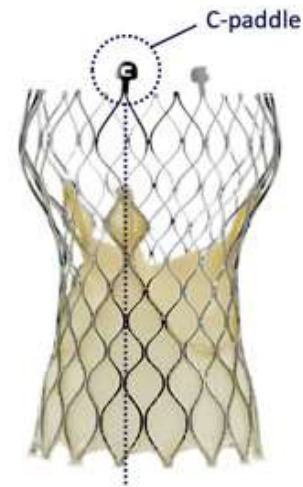
✓ Commissural alignment



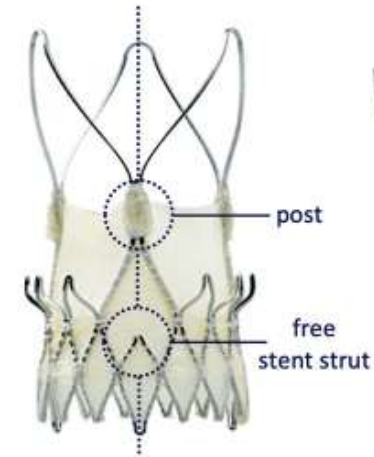
✗ Commissural misalignment (CMA)

THV MARKERS CORRESPONDING WITH THV COMMISSURE(S)

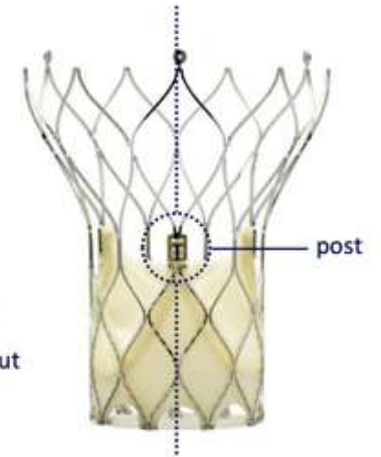
B



Evolut R/PRO™

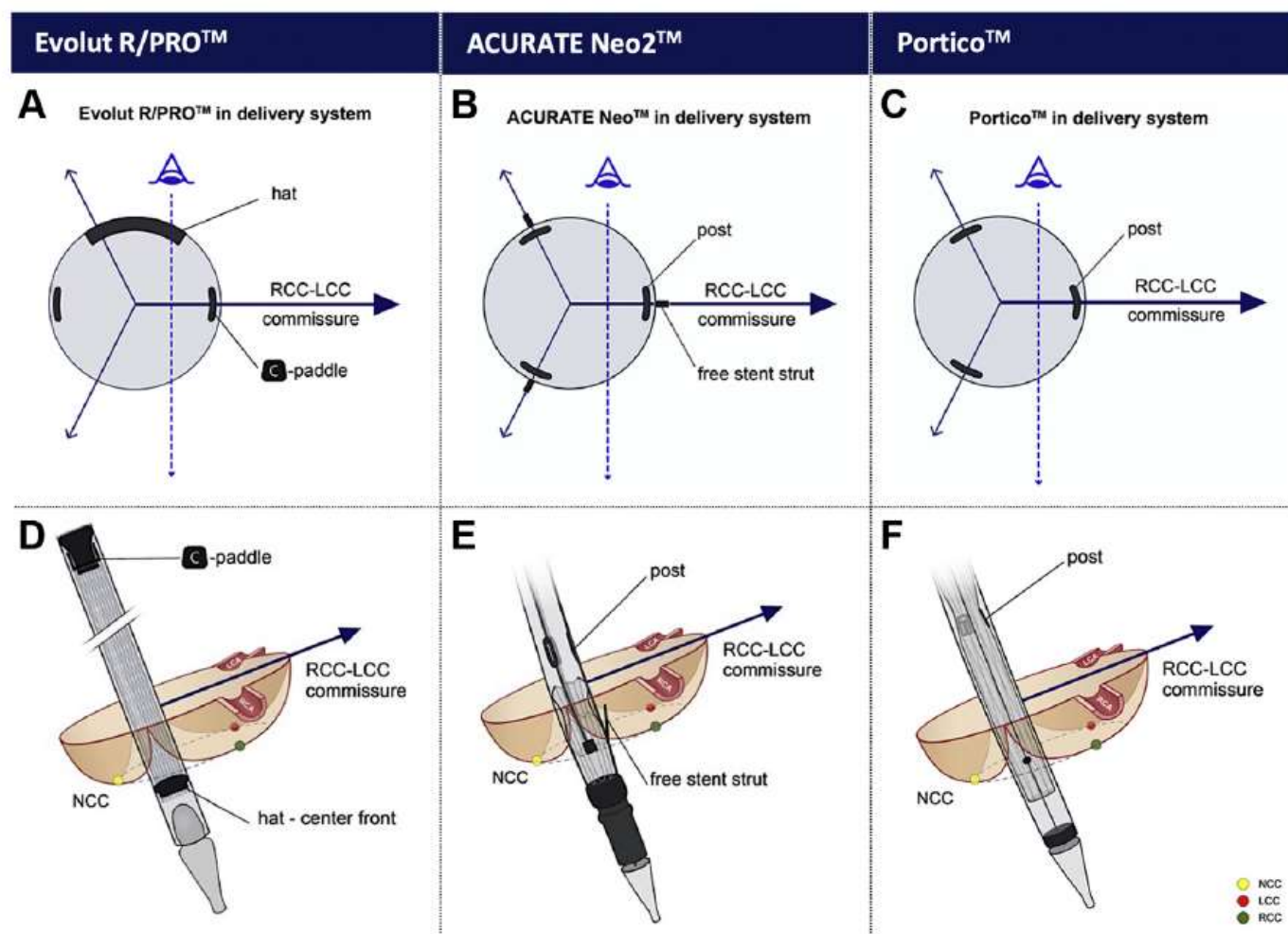
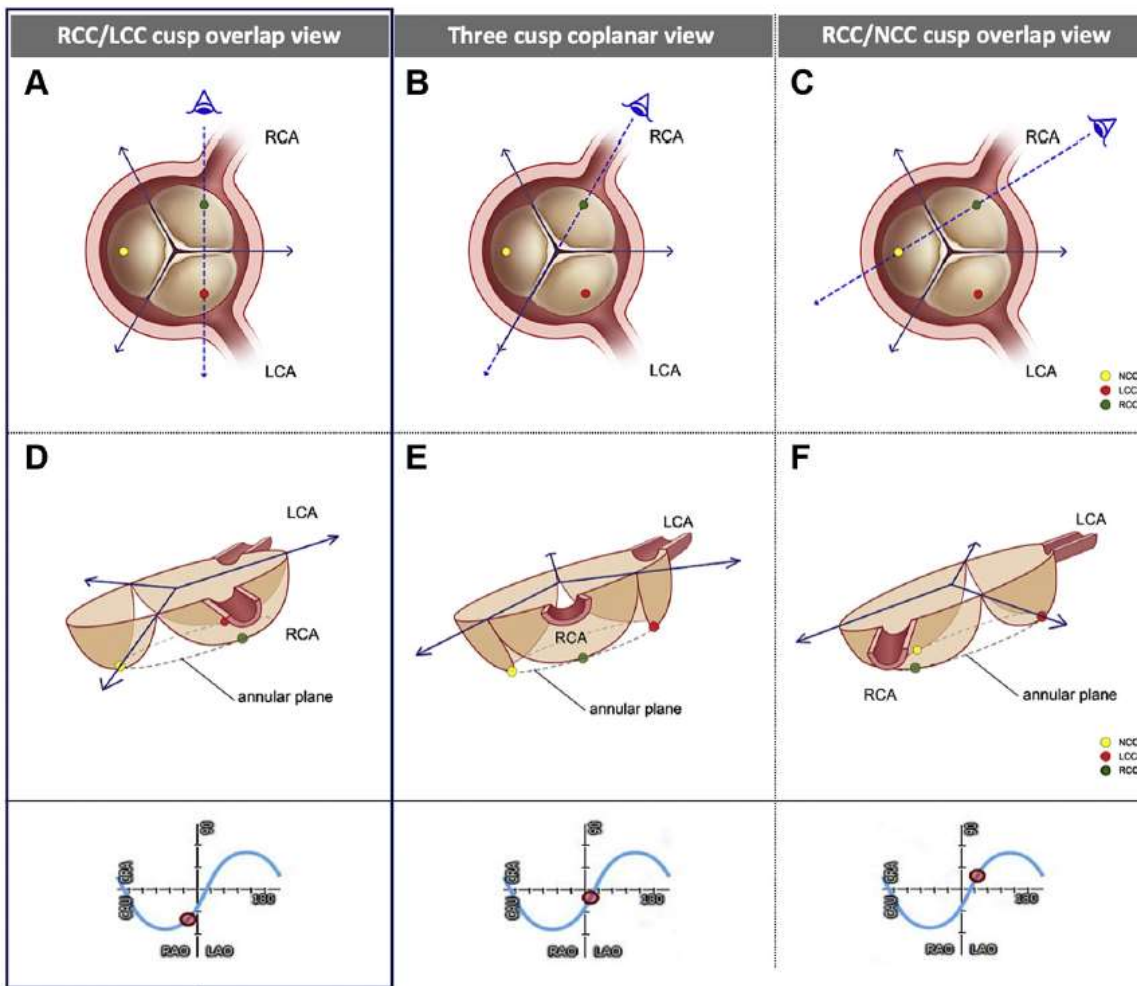


ACURATE neo2™

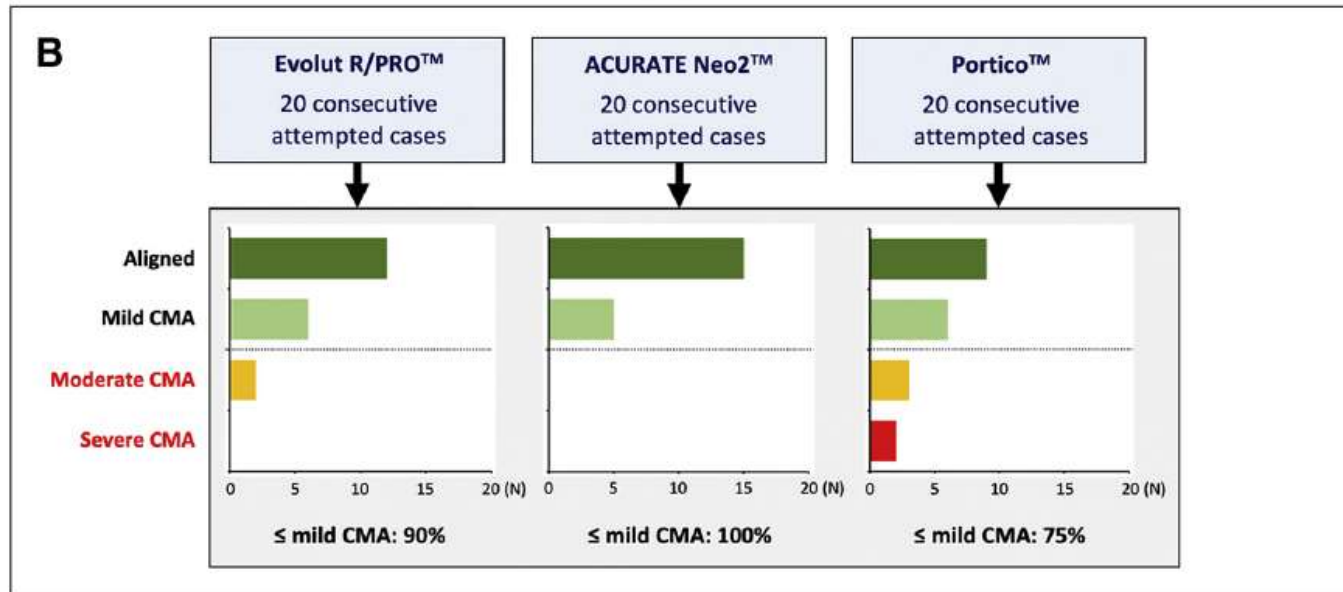
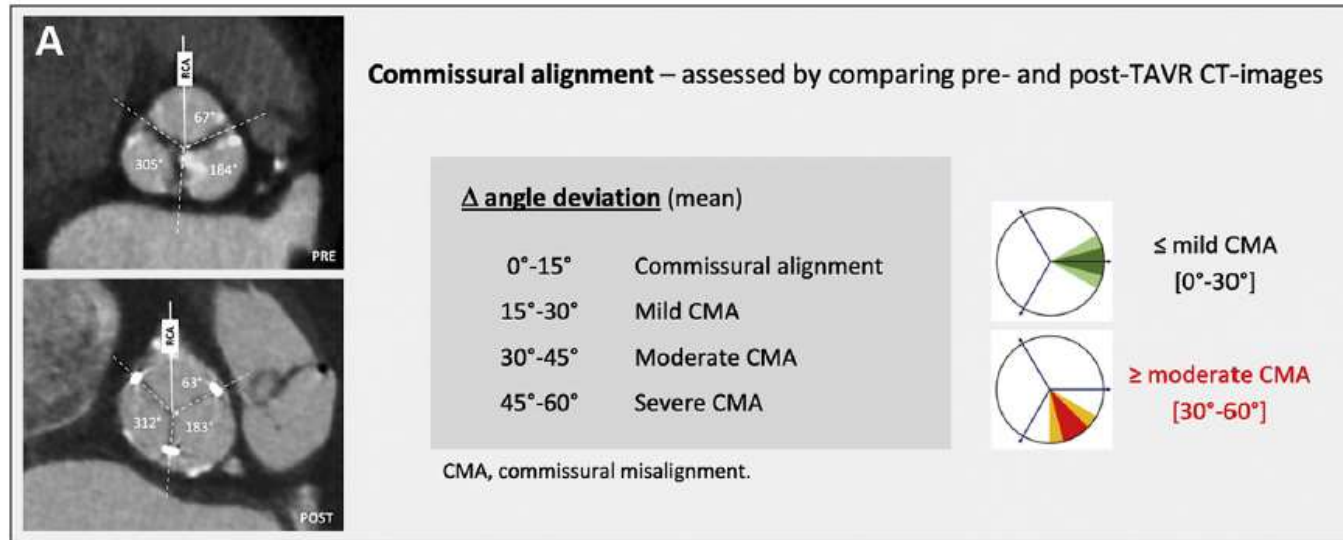


Portico™

Commissure Alignment



Commissure Alignment



Conclusion

- In patients with AS and CAD, the selection of the optimal treatment strategy is guided by the **severity** and **complexity** of CAD.
- Factors determining **timing of PCI** before/during or after TAVI include coronary accessibility, complexity of CAD.
- From current evidence, PCI before TAVR showed **no clinical benefit** and **increase vascular complications**.
- PCI after TAVR can be challenging, depending on coronary ostia height, sinus of Valsalva width, height/width of STJ, stent frame height, degree of oversizing and depth of THV implantation.
- **Neo-commissures alignment** with native commissures facilitates coronary access and reduces the risk of coronary obstruction with ViV implantation.