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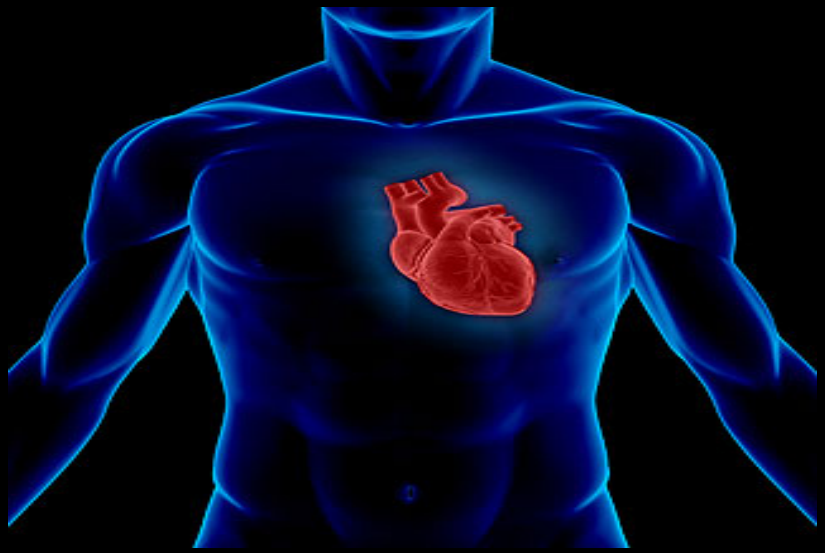
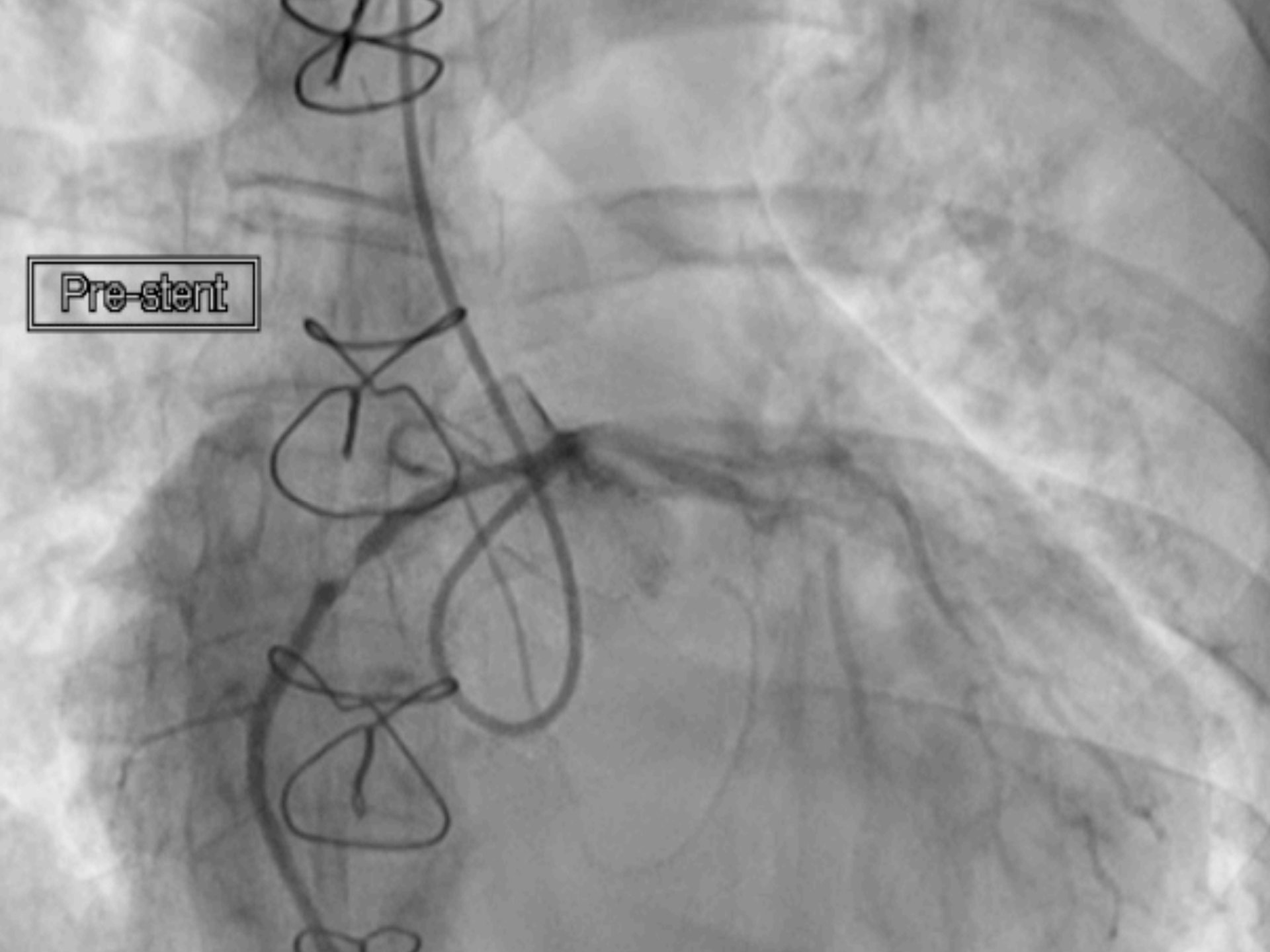
Interventional Procedures :- Updates and New Treatments



Dr James Roy
Physician & Interventional Cardiologist
MB,BCh,BAO(Hons),FRACP

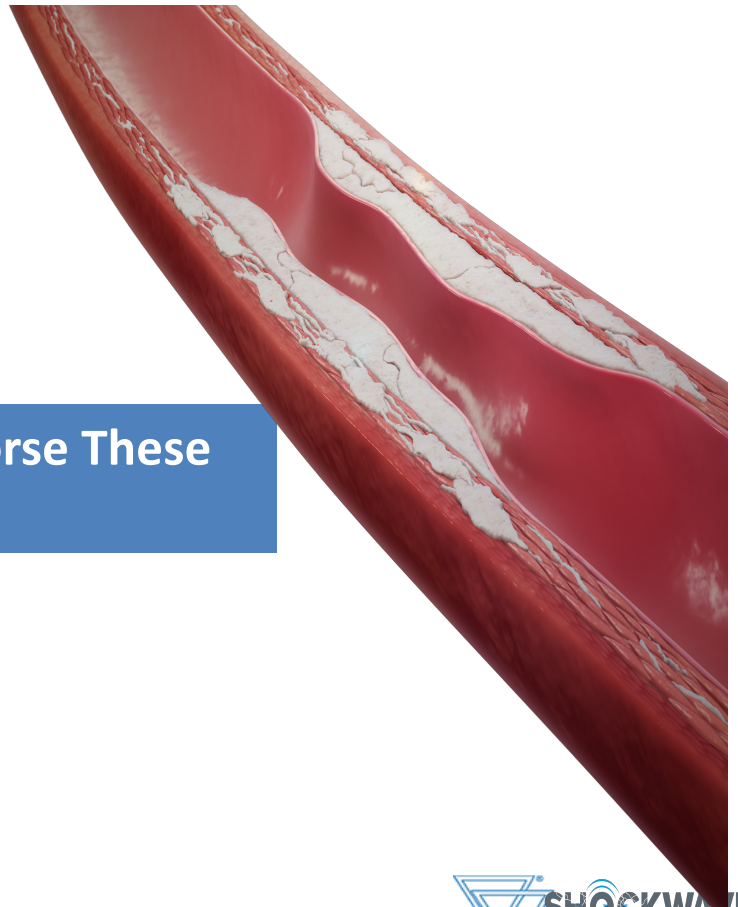

Pre-stent

The Problem With Calcium

Challenges Persist Peri- and Post-Procedure

- Impedes Stent Deliverability
- Inhibits Uniform Stent Expansion
- Worsens Long Term Outcomes

The More Severe The Calcium, The Worse These Challenges Will Be



Calcium Worsens Long-Term Outcomes

- Meta-analysis reviewed the impact of severely calcified* lesions on patient outcomes across 7 contemporary PCI studies – found that it was an independent predictor of worse outcomes
- Patients with **severe lesion calcification** with 3-year follow-up showed:
  - Lower rates of complete revascularization
  - **Increased mortality**

	With Severe CAC (N=1291)	Without Severe CAC (N = 5005)	P Value
Mortality	10.8%	4.4%	P <0.001
Combined Endpoint:			
MI & Death	22.9%	10.9%	P <0.001
MI, Death & Revascularization	31.8%	22.4%	P <0.001

**Severe Calcium: radiopacities noted without cardiac motion before contrast, generally compromising both sides of arterial lumen*

Bourantas, et al. Prognostic implications of coronary calcification in patients with obstructive coronary artery disease treated by percutaneous coronary intervention: a patient-level pooled analysis of 7 contemporary stent trials. BMJ 2014; 100: 1158-1164.

Shockwave Coronary IVL System Components

COMPACT & RECHARGABLE
Portable, IV-pole Mountable
Battery-Powered
No External Connections

SIMPLE & QUICK
Smart Magnetic Connection
Push-Button Activated

INTUITIVE & SAFE
RX System
Any .014" Guidewire
Standard PCI Technique
80 Lithotripsy Pulses

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 10, NO. 3, 2017

ISSN 1936-8798/$36.00
http://dx.doi.org/10.1016/j.jcin.2016.11.048

A Calcific, Undilatable Stenosis

Lithoplasty, a New Tool in the Box?

Kalpa De Silva, MBBS, PhD, James Roy, MD, Ian Webb, MA, PhD, Rafal Dworakowski, MD, PhD, Narbeh Melikian, BSc, MD, Jonathan Byrne, MBBS, PhD, Philip MacCarthy, BSc, MBBS, PhD, Jonathan Hill, MA

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Figure 1; Pre-PCI angiogram

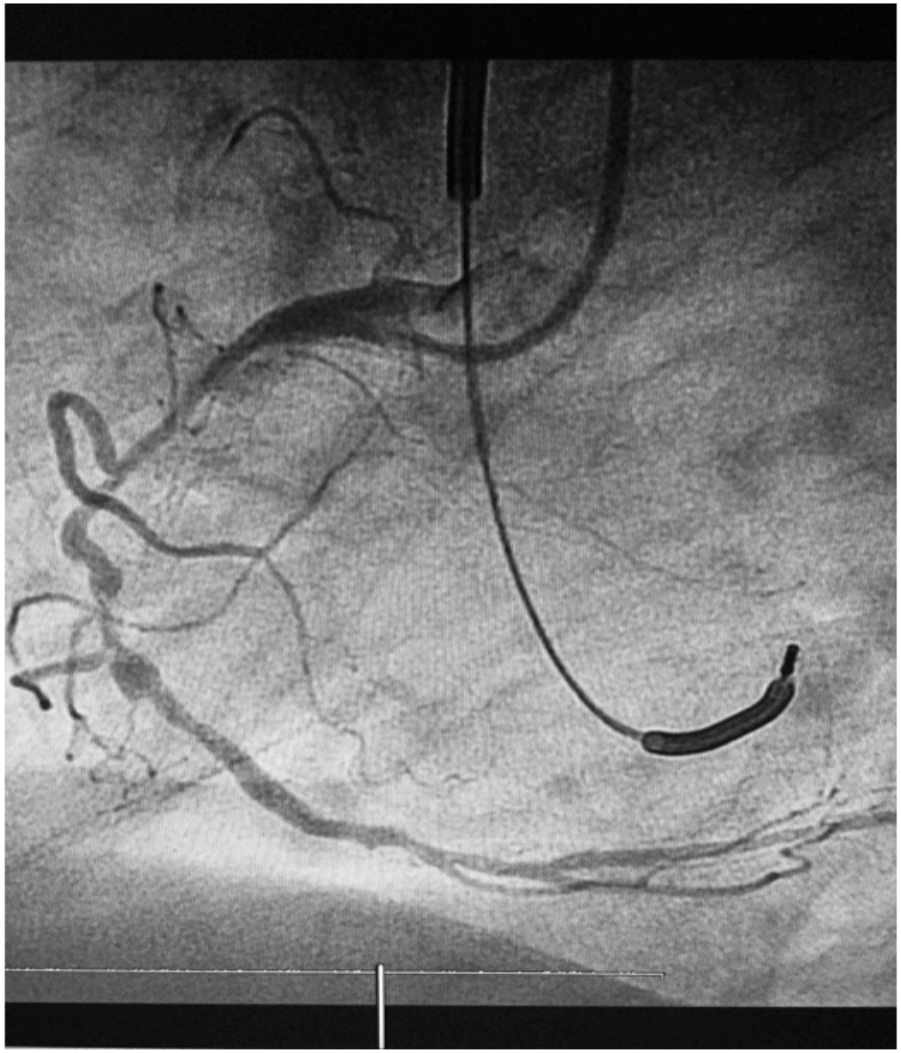

Figure 2; 'Dog-bone' appearance of non-compliant balloon

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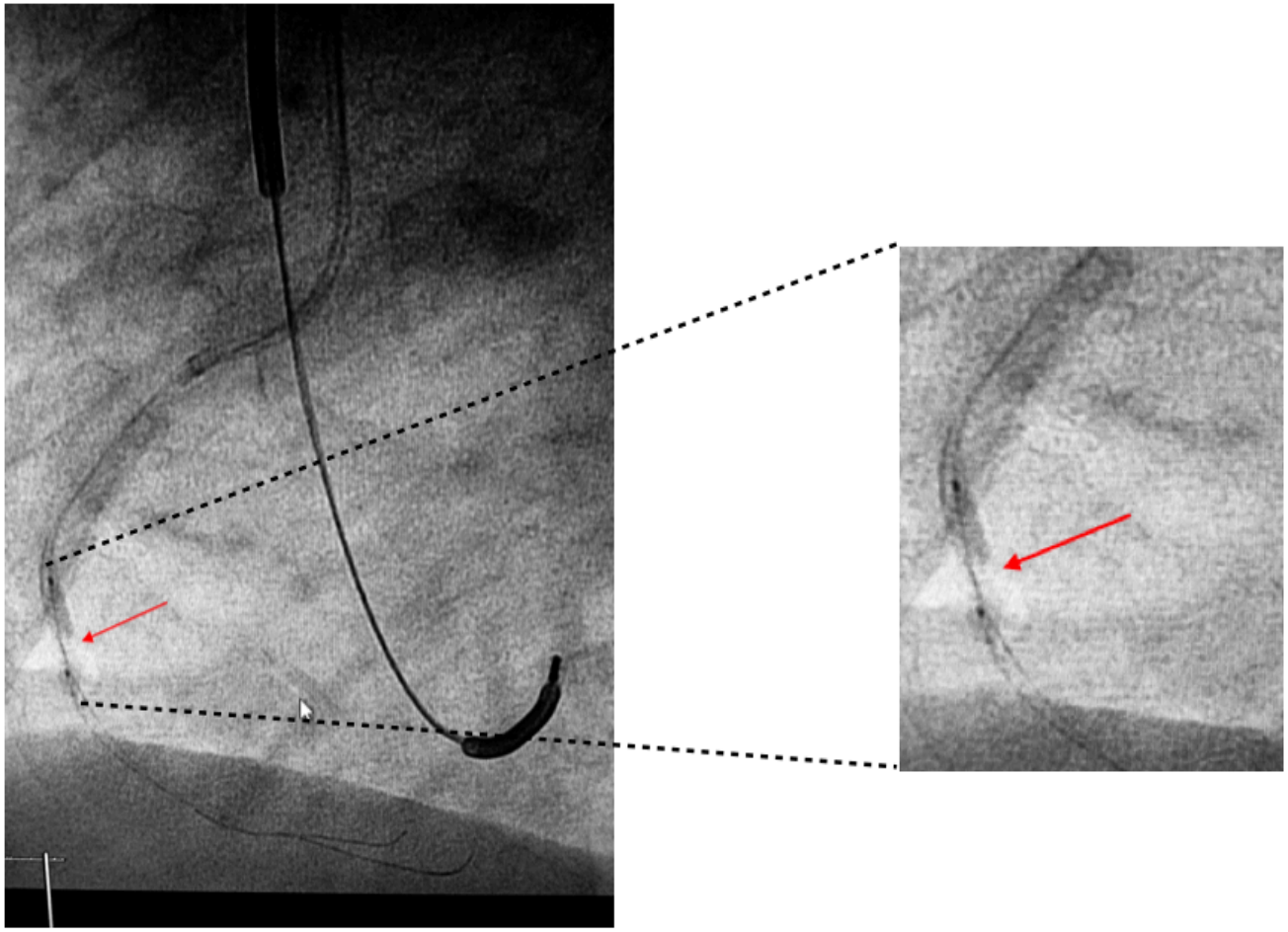
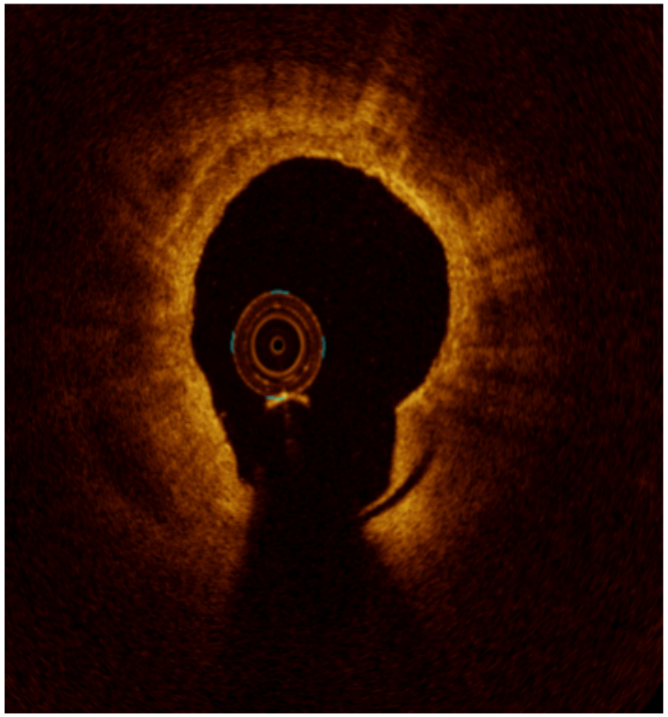


Figure 3: Pre- and post-PCI OCT showing calcification and post Lithoplasty Calcium 'fracturing' (white arrow)



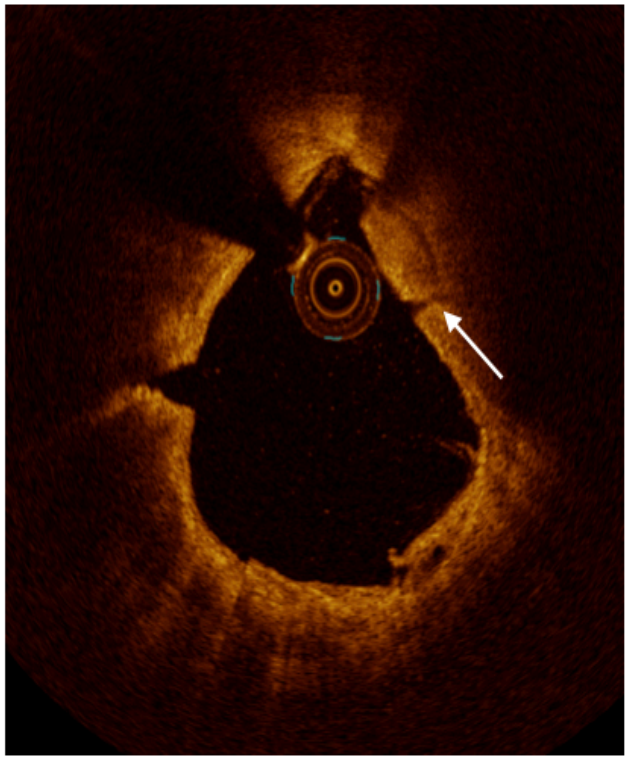


Figure 4 ; Co-registered OCT/angiogram view confirming result

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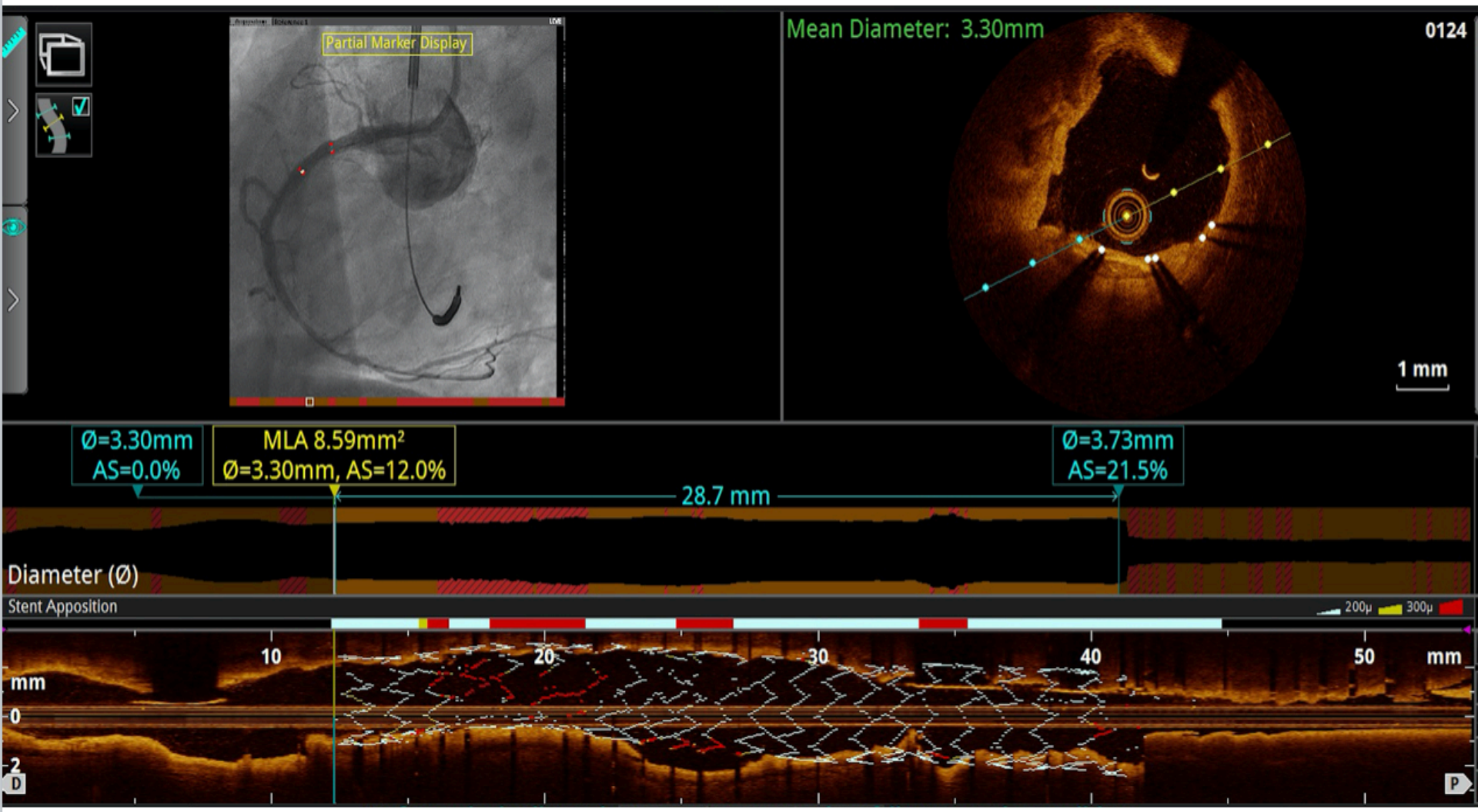

Figure 5: Post PCI angiographic result

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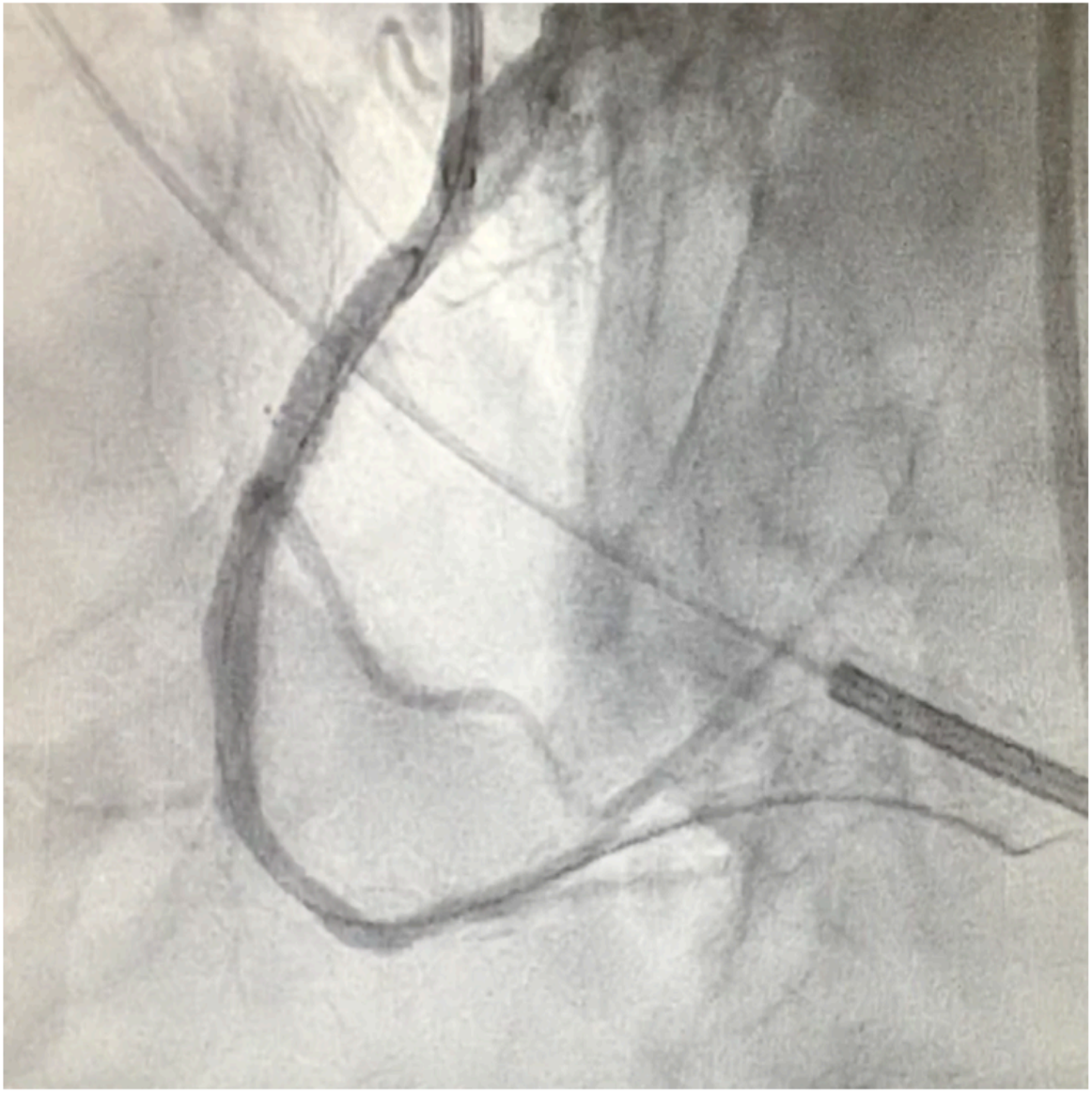


DISRUPT CAD I Results Published in *Circulation*

Low Complications and Strong Initial Performance & Safety

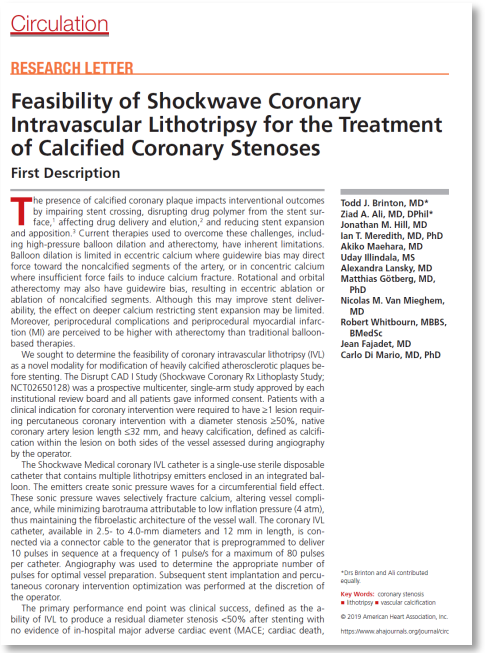
Complications	Procedural	Final
Type D Dissections	3.3%*	0%
Type E Dissections	0%	0%
Type F Dissections	0%	0%
Perforation	0%	0%
Abrupt Closure	0%	0%
Slow flow	0%	0%
No reflow	0%	0%

*2 grade D dissections post-IVL resolved at the final angiography and did not result in adverse events

Safety	Results	Events
30 day MACE‡ Cardiac death, MI or TVR	5%	Death N = 0 QWMI N = 0 *NQWMI N = 3 TVR N = 0
6 month MACE‡ Cardiac death, MI or TVR	8.5%	Death N = 2¥ QWMI N = 0 **NQWMI N = 3 TVR N = 0

¥ Adjudicated by CEC as 'not related to device'

Performance	Results
Clinical Success‡† Residual stenosis <50% post-PCI with no evidence of in-hospital MACE	95%
Device Success Successful device delivery and IVL treatment at target lesion	98.3%
Stent Delivery	100%



Circulation

RESEARCH LETTER

Feasibility of Shockwave Coronary Intravascular Lithotripsy for the Treatment of Calcified Coronary Stenoses

First Description

Todd J. Brinton, MD*; Ziad A. Ali, MD, DPhil*; Jonathan M. Hill, MD; Ian T. Meredith, MD, PhD; Akiko Maehara, MD; Uday Illindala, MS; Alexandra Lansky, MD; Matthias Götberg, MD, PhD; Nicolas M. Van Mieghem, MD; Robert Whitbourn, MBBS, BMedSc; Jean Fajadet, MD; Carlo Di Mario, MD, PhD

- †Core Lab adjudicated ‡CEC adjudicated **NQMI defined as 3x upper limit CK-MB Brinton et al. *Circulation.* 2019;139:834–836. DOI: 10.1161/CIRCULATIONAHA.118.036531

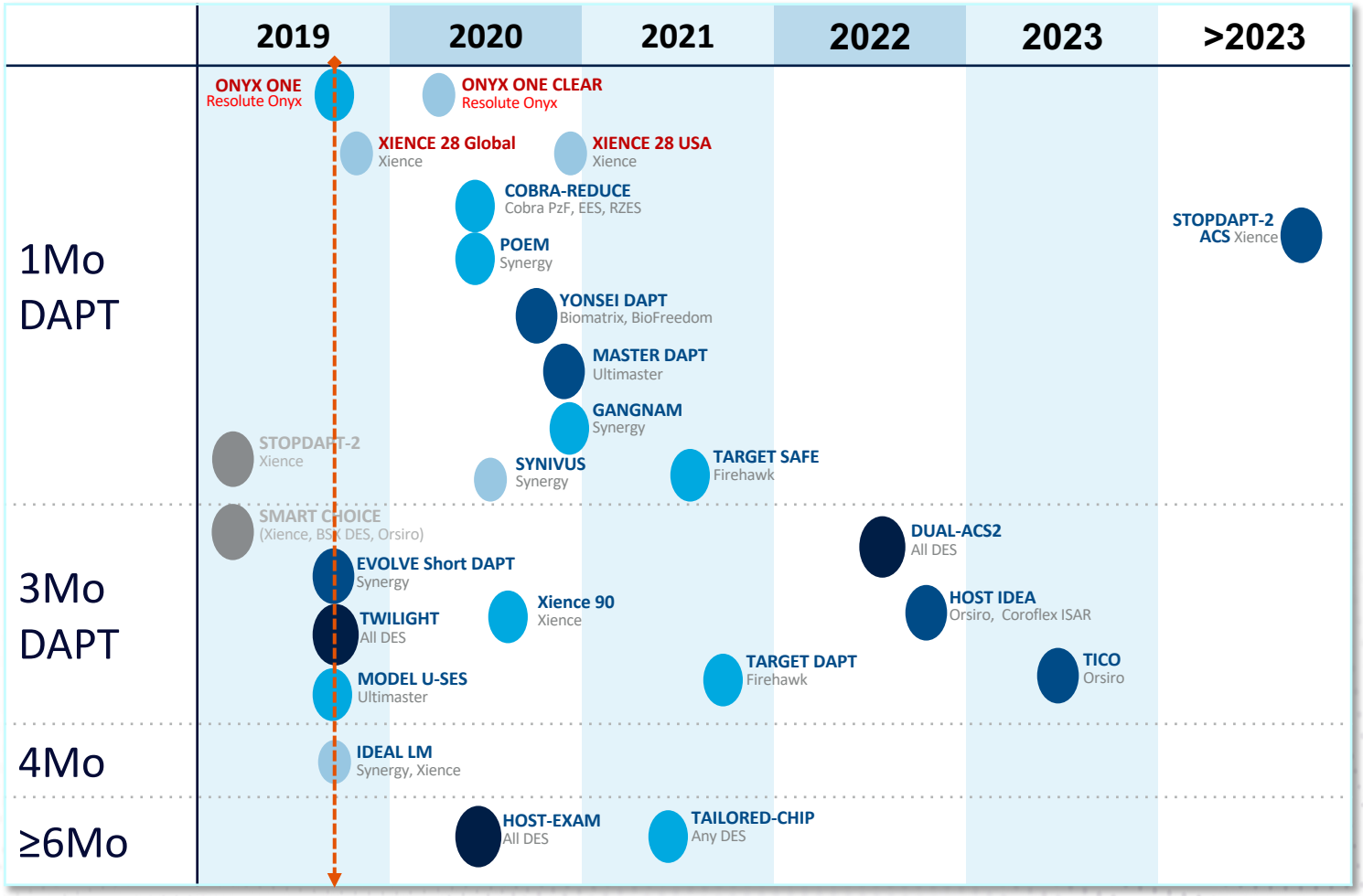
ANTIPLATELETS
What are the known knowns - PCI

•Aspirin plus a thienopyridine needed after stenting STAR, CREDO.

•Aspirin plus clopidogrel is superior to aspirin for ACS/STEMI: COMMIT, CLARITY

• Ticagrelor is superior to clopidogrel for ACS: PLATO

Short DAPT Trials



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Complex PCI with 1-month DAPT in High Bleeding Risk Patients: Analysis from the Onyx ONE Clear Study

David Kandzari, Ajay J. Kirtane, Roxana Mehran, Matthew J. Price, Daniel I. Simon, Azeem Latib, Elvin Kedhi, Alexandre Abizaid, Stephen Worthley, Azfar Zaman, Lilian Lee, Te-Hsin Lung, Stephan Windecker, and Gregg W. Stone

on behalf of the Onyx ONE Program Investigators

Onyx ONE Clear Study Design

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Prospective, Multicenter, Single-arm Study

High Bleeding Risk patients undergoing PCI (no lesion, vessel limitations)

Onyx ONE RCT
Resolute Onyx™ ZES arm, with 1 Month DAPT (N=1019)

+

Onyx ONE US & Japan
Single arm study of Resolute Onyx ZES with 1 Month DAPT (N=752)

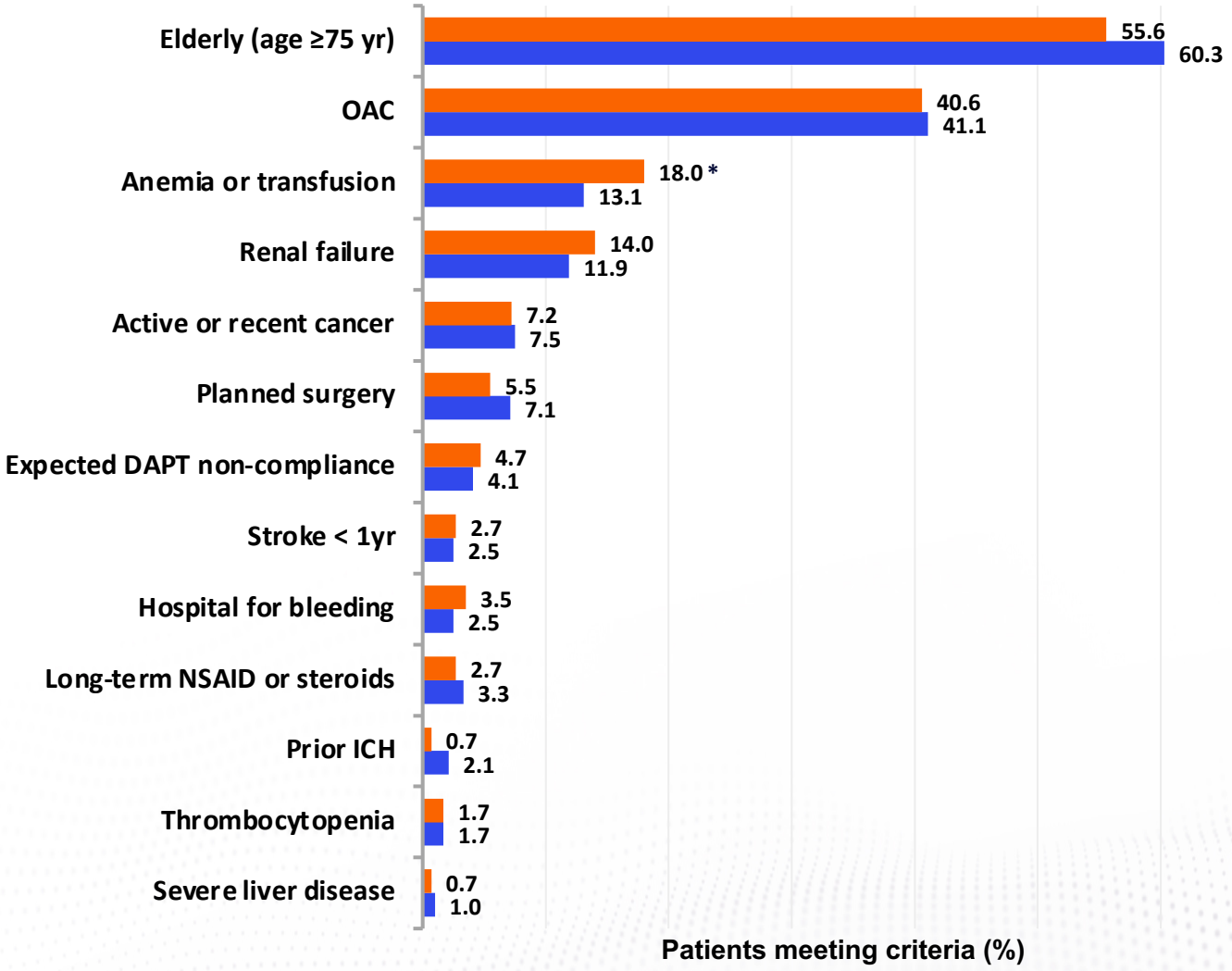
Primary endpoint: Cardiac death/MI assessed in "1-month clear"* patients from 1-12 Mo

Methods current analysis: Compared outcomes between patients with high vs low complexity using propensity score adjustment to adjust for baseline differences**

* "1-month clear" defined as patients who were adherent to DAPT within 1st month after PCI and free of events that would preclude 1-month DAPT cessation
** Propensity score adjustment performed for differences in baseline characteristics, based on sex, previous MI, previous CABG, hyperlipidemia, cardiac admissions ≤30 days, diabetes, LVEF≤35%, lesion length, baseline RVD, multivessel CAD, and worst CCS Angina Class as the confounding variables

NCT03647475

HBR Inclusion Criteria



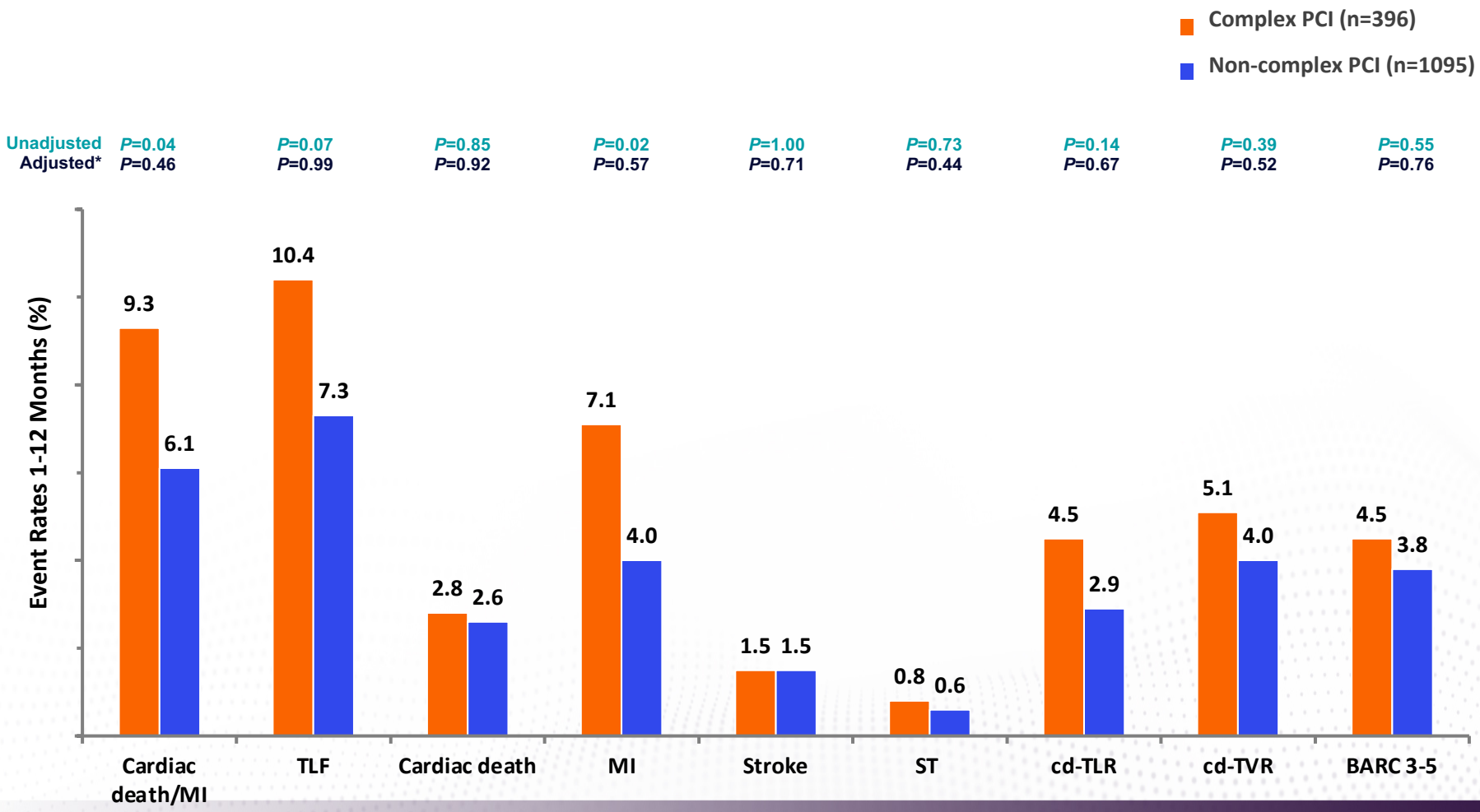
Mean **1.6** criteria / pt

Complex PCI (N=401)

Non-Complex PCI (N=1105)

* *P*-value < 0.05

Clinical Outcomes
Between 1 – 12 Months



*Propensity score adjusted *P*-values for differences in baseline characteristics, based on sex, previous MI, previous CABG, hyperlipidemia, cardiac admissions ≤30 days, diabetes, LVEF≤35%, lesion length, baseline RVD, multivessel CAD, and worst CCS Angina Class as the confounding variables

Complex PCI Definition

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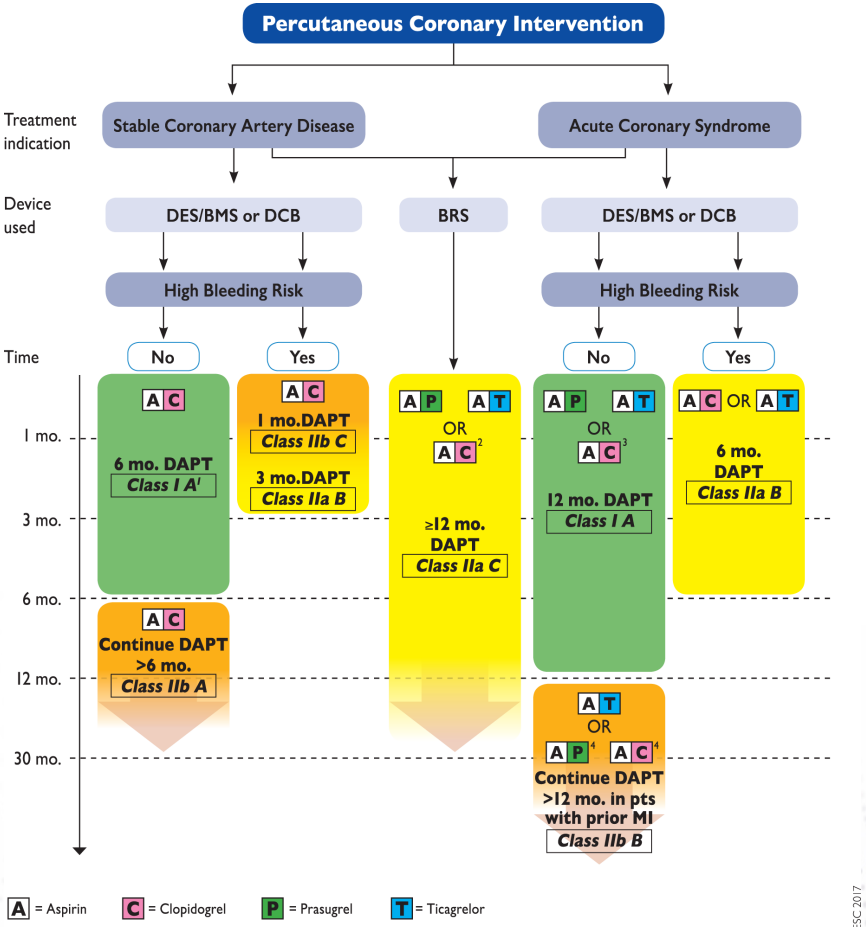
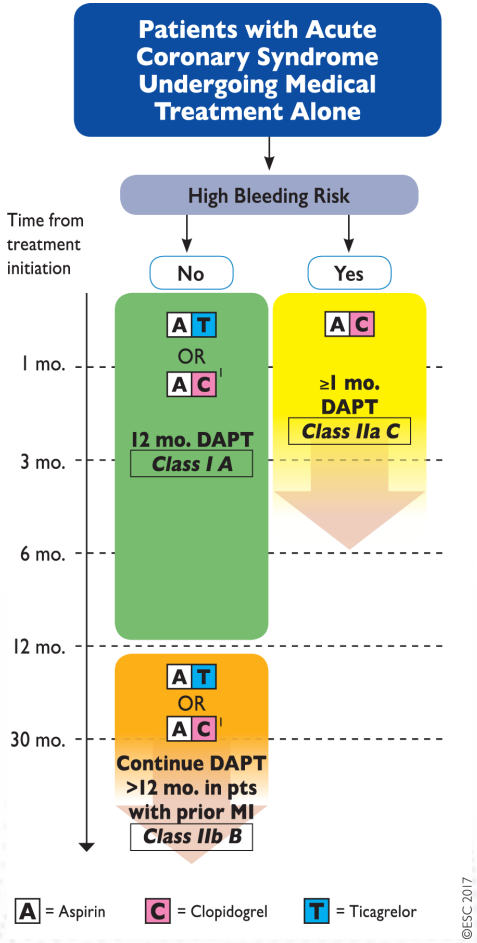
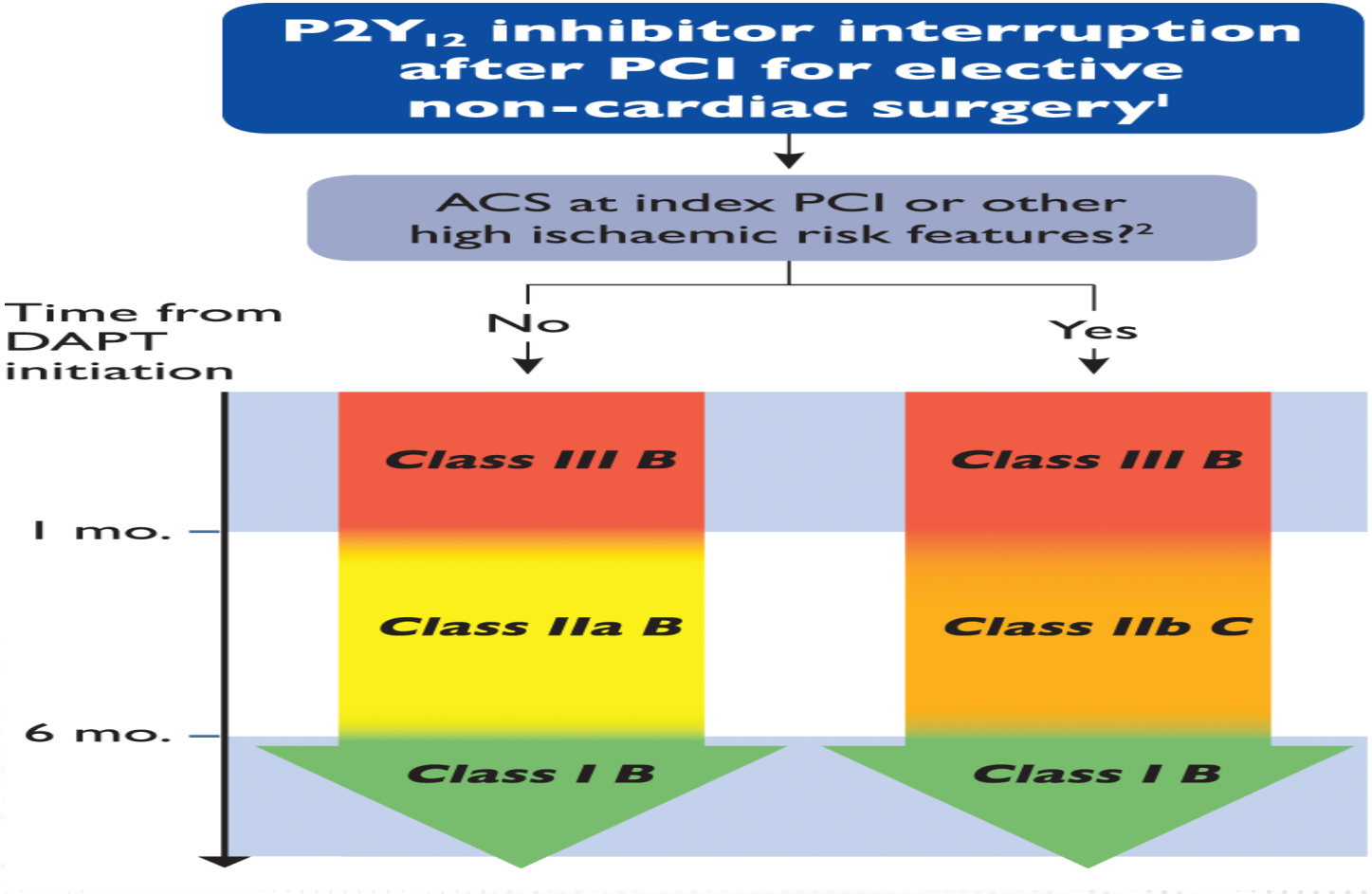
PCI with ≥1 of the following characteristics:

- 3 vessels treated
- ≥3 lesions treated
- Total stent length >60 mm
- Bifurcation with ≥2 stents implanted
- Use of any atherectomy device
- Left main
- Surgical bypass graft
- Chronic total occlusion

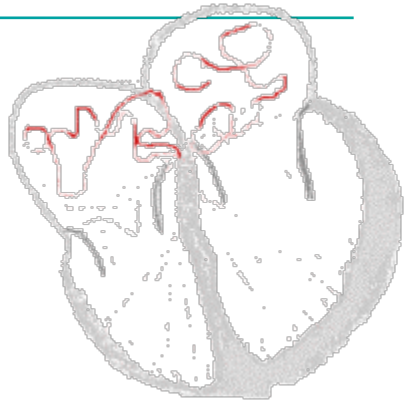
(TWILIGHT) Dangas G, et al. *J Am Coll Cardiol* 2020







The Optimal Management of Atrial Fibrillation and Coronary Disease Differ



Atrial Fibrillation (ACTIVE W)[1]: The combination of aspirin and clopidogrel is not as effective as *warfarin* in patients with AF[1]

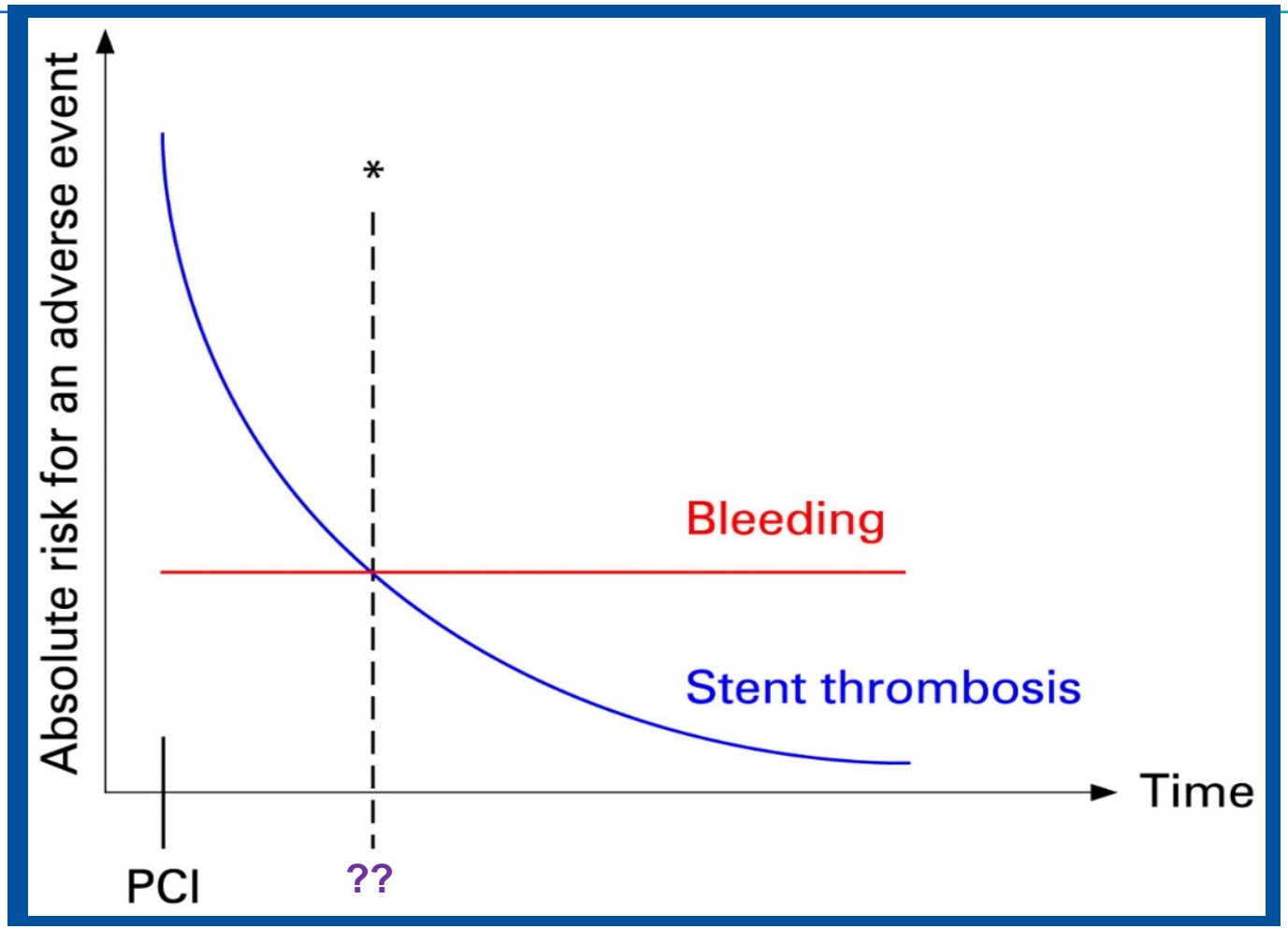
However

Stenting (STARS)[2]: The combination of *aspirin and a thienopyridine* is more effective than warfarin in patients with coronary stents [2]

1. Lancet 2006 Jun 10;367(9526):1903-12. 2. N Eng J Med 1998 Dec 3;339(23):1665-71.

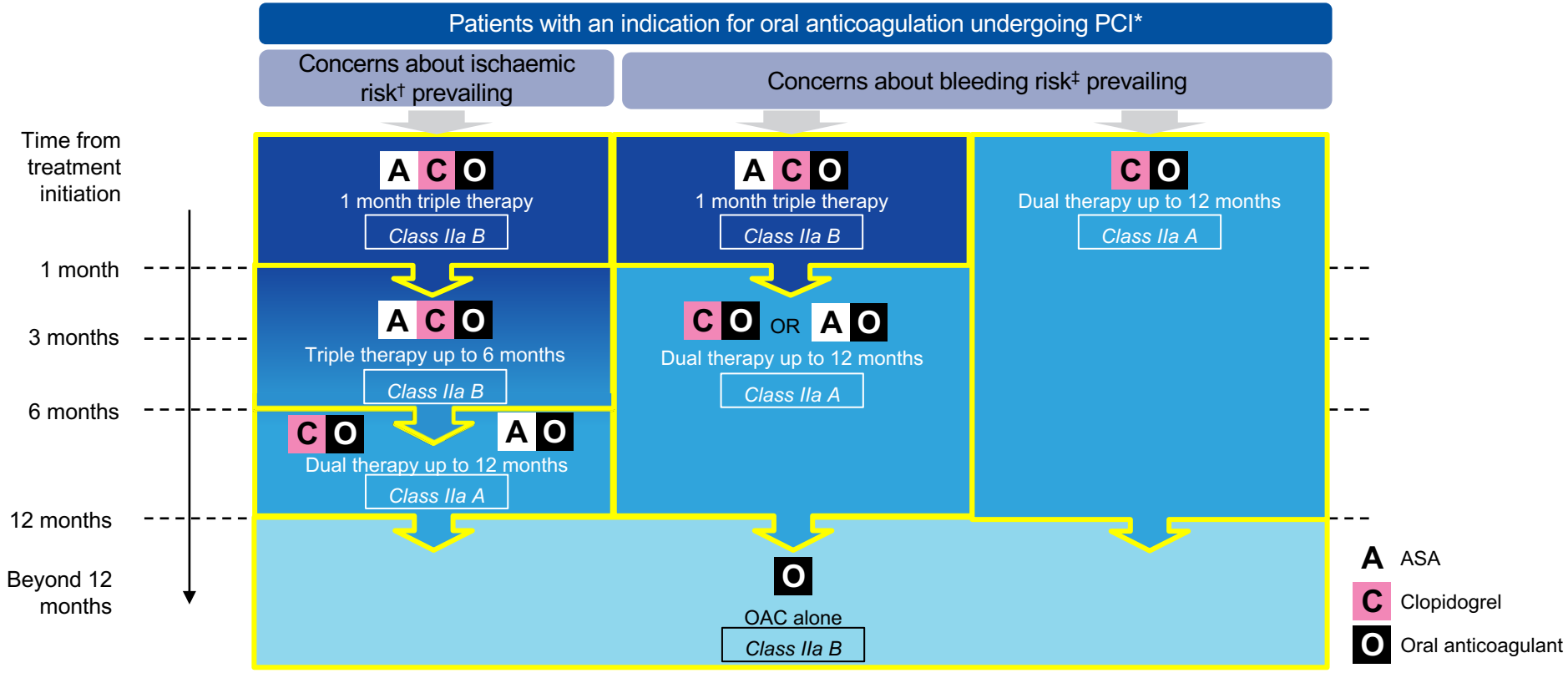
Bleeding Risk vs Stent Thrombosis Risk

Triple Therapy



Schomig A et al , Heart. 2009 Aug;95(15):1280-5

2017 ESC focused update on dual antiplatelet therapy in coronary artery disease

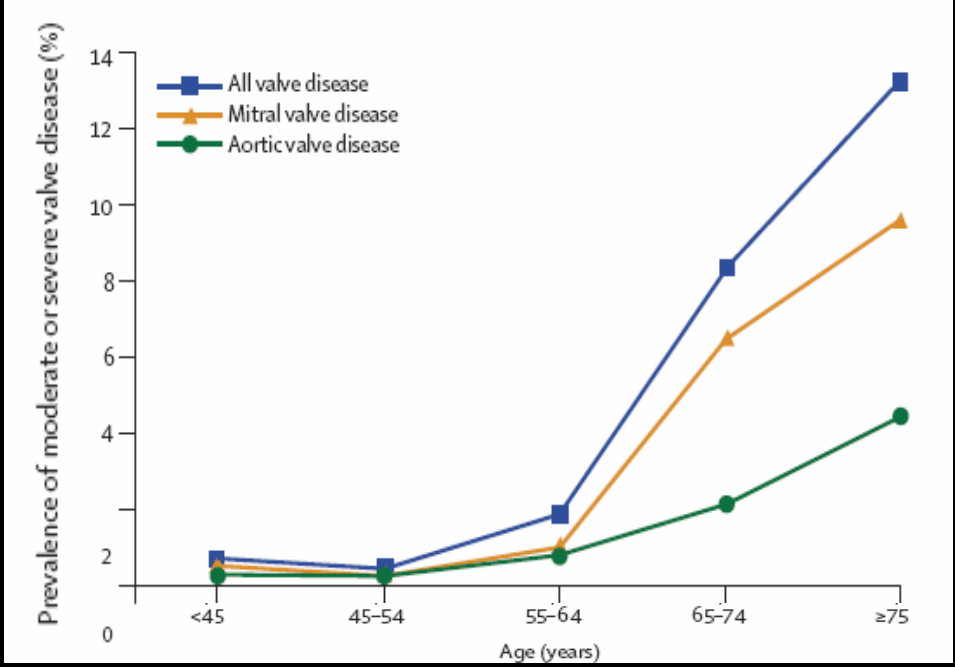


*Periprocedural administration of aspirin and clopidogrel during PCI is recommended irrespective of the treatment strategy; †High ischaemic risk is considered as an acute clinical presentation or anatomical/procedural features, which might increase the risk for myocardial infarction;
‡Bleeding risk can be estimated by HAS-BLED or ABC score.
PCI, percutaneous coronary intervention; ASA, aspirin; OAC, oral anticoagulant.

1. Adapted from Valgimigli M et al. Eur Heart J 2018

Aortic Stenosis – A Common Disease

Prevalence of Valve Disease by Age Group

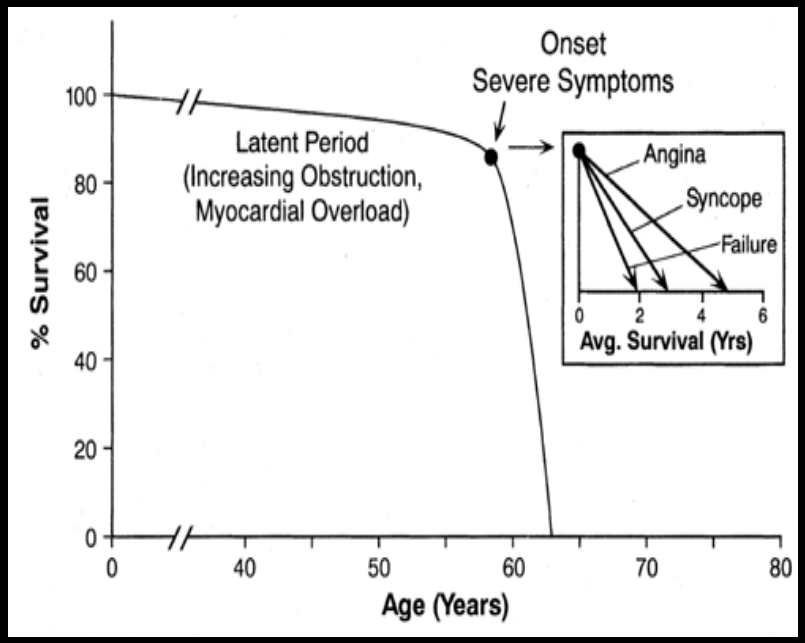


Nkomo et al. Burden of valvular heart diseaase: a population based study. Lancet 2006; 368: 1005-11.

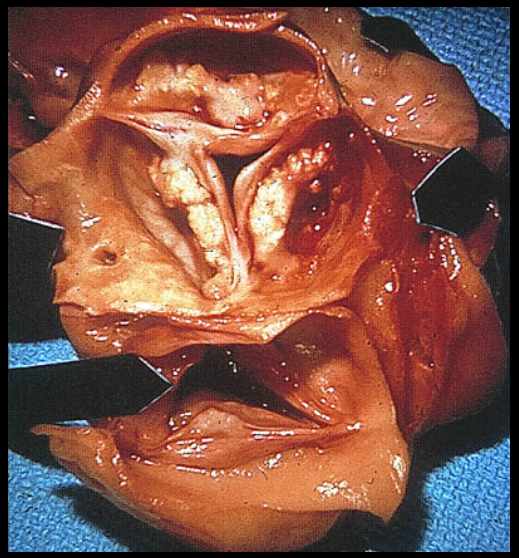
In adults ≥ 75 years of age, aortic stenosis is present in as many as 4.6% of population

Symptomatic Patients with Severe AS Require Urgent Attention

Valvular Aortic Stenosis in Adults



"Surgical intervention should be performed promptly once even… minor symptoms occur"[1]



[1]C.M. Otto. Valve Disease: Timing of Aortic Valve Surgery. *Heart* 2000.

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Transcatheter Aortic Valve Implantation (TAVI/TAVR) Now the standard of care for all aortic stenosis patients?

Mick Jagger underwent successful heart valve replacement surgery in New York after postponing The Rolling Stones' United States tour.

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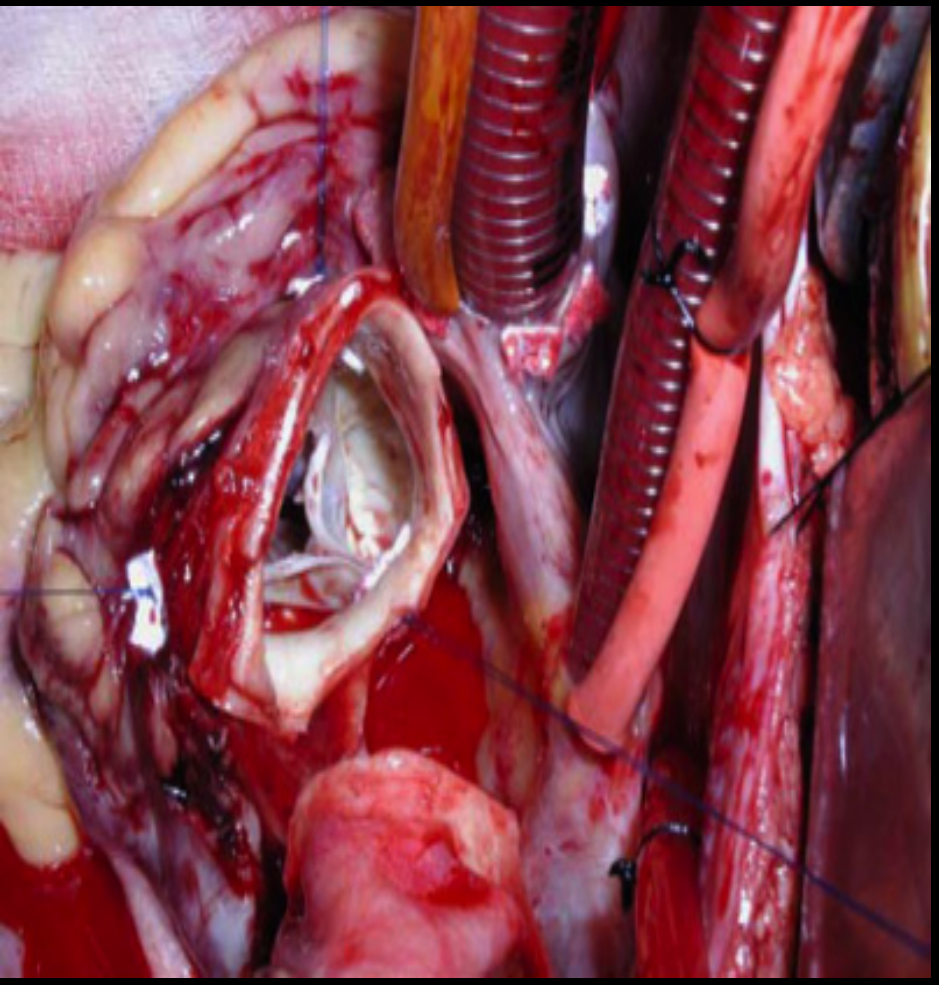
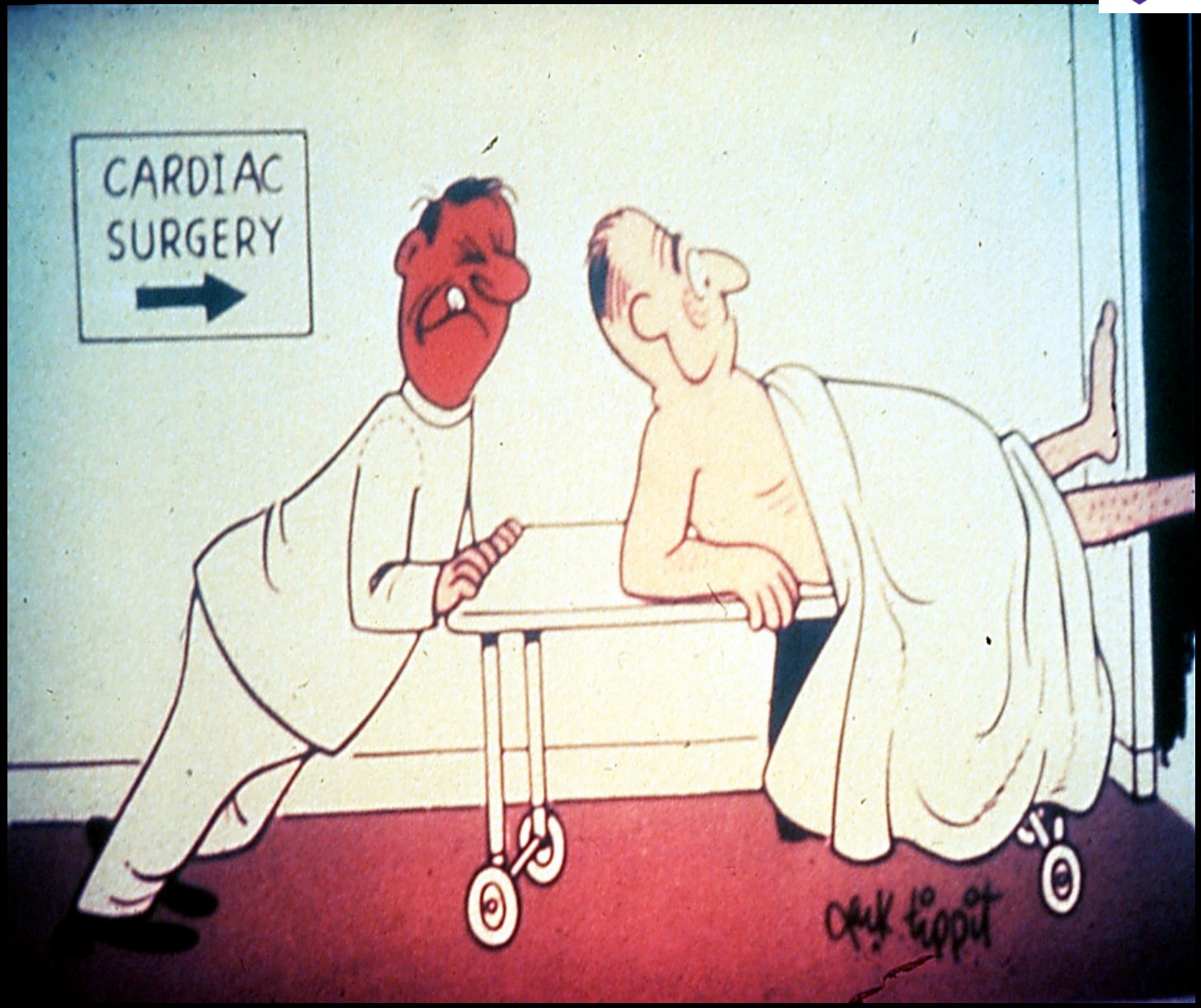
...it is maximally invasive surgery





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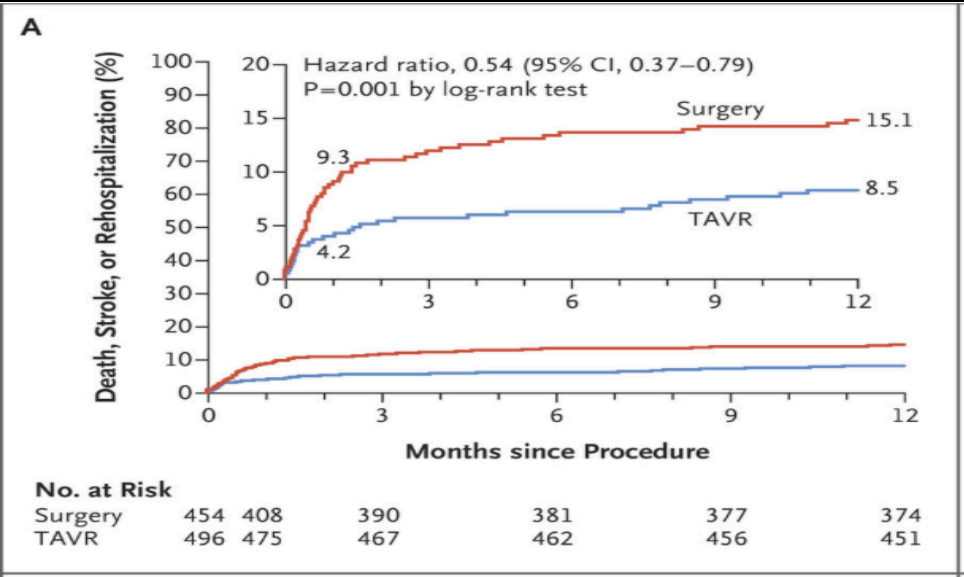
Low Surgical Risk TAVI Trials

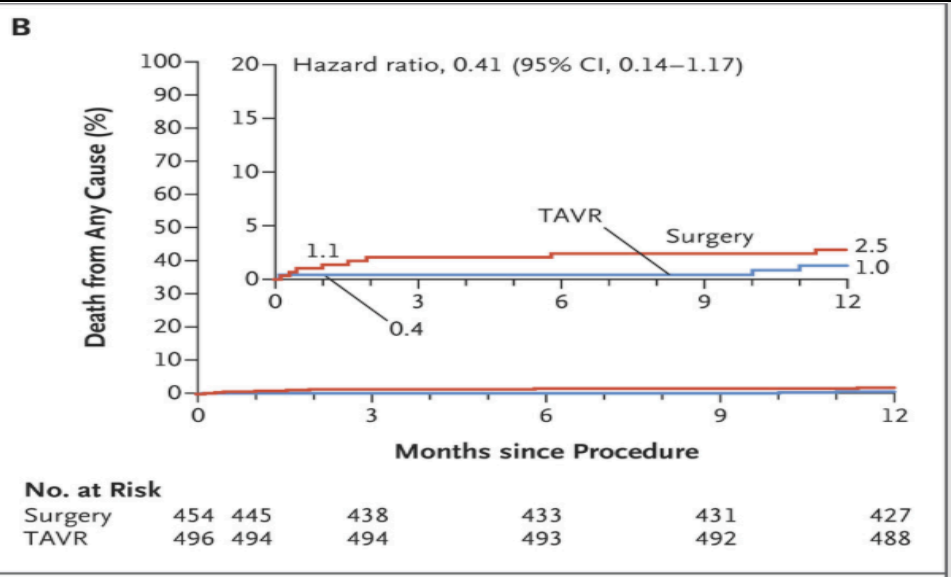
ORIGINAL ARTICLE

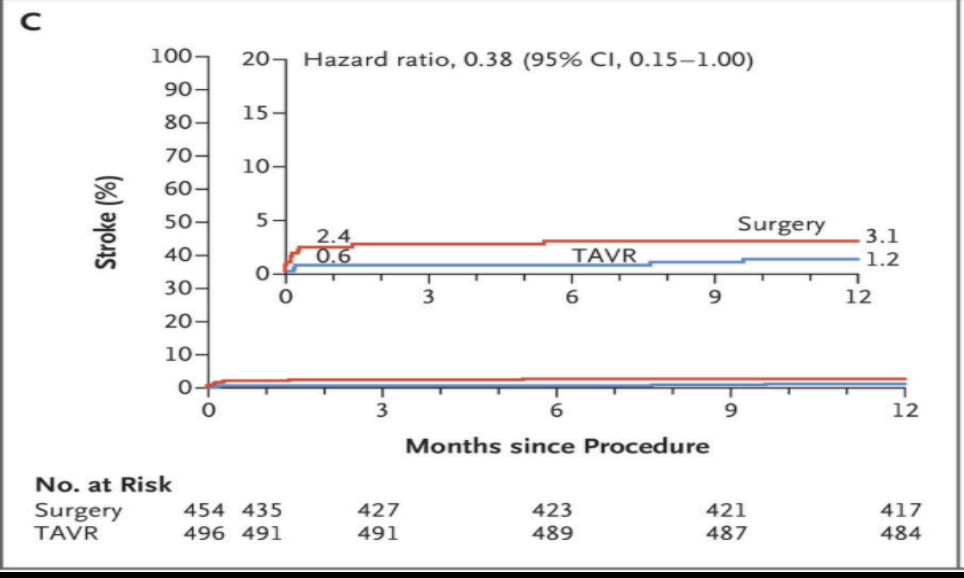
Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients

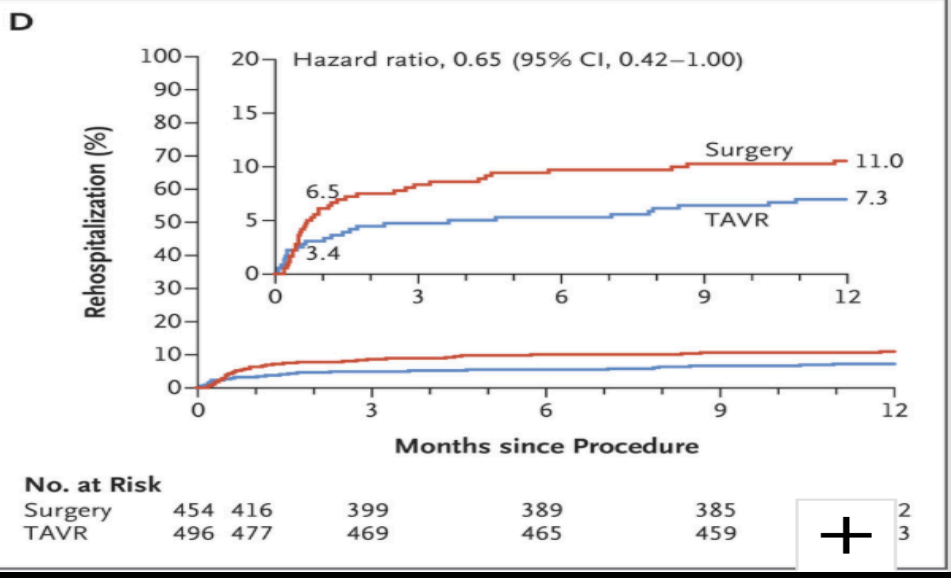
Michael J. Mack, M.D., Martin B. Leon, M.D., Vinod H. Thourani, M.D., Raj Makkar, M.D., Susheel K. Kodali, M.D., Mark Russo, M.D., Samir R. Kapadia, M.D., S. Chris Malaisrie, M.D., David J. Cohen, M.D., Philippe Pibarot, D.V.M., Ph.D., Jonathon Leipsic, M.D., Rebecca T. Hahn, M.D., et al., for the PARTNER 3 Investigators*

LOW RISK PARTNER 3 TRIAL

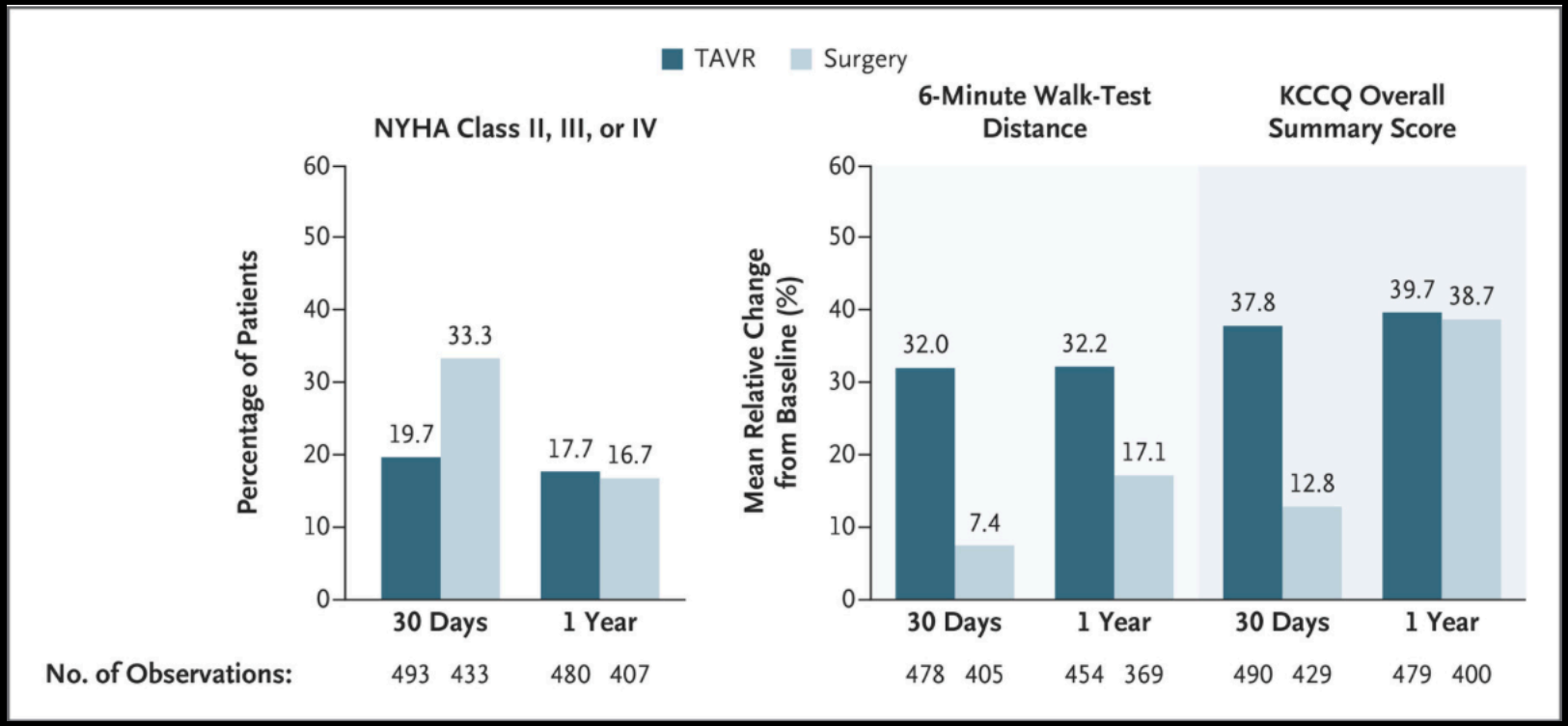








FUNCTIONAL STATUS & QUALITY OF LIFE AT 30DAYS & 1 YEAR



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Thank You
for your attention

2.5m