

Severe Calcified Coronary Lesions: *Predictors, Managing Strategy, and Outcomes*

Duk-Woo Park, MD, PhD

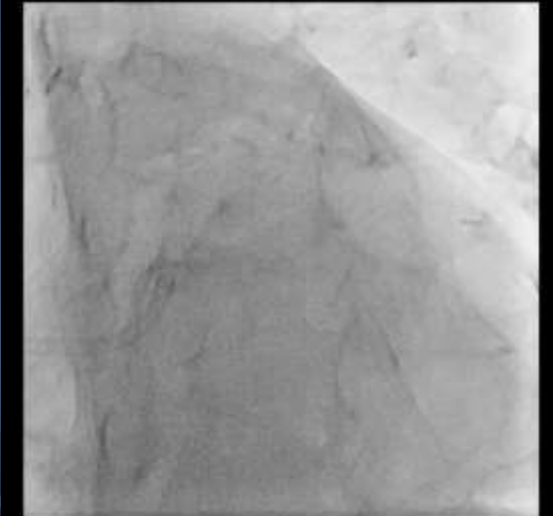
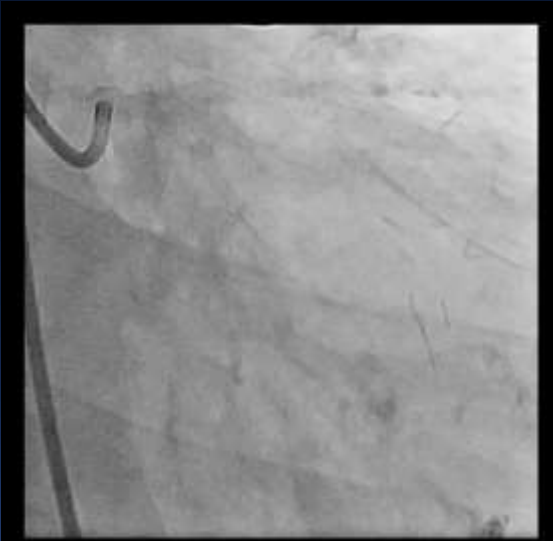
Professor of Medicine, University of Ulsan College of Medicine,
Heart Institute, Asan Medical Center, Seoul, Korea

Disclosure

- Institutional grant/research funding to CardioVascular Research Foundation (CVRF, Korea) and/or Asan Medical Center from Daiichi-Sankyo, Abbott, Boston Scientific, Medtronic, Edwards, Biosensor, ChongKunDang Pharm and Daewoong Pharm,

Severe Calcified Lesions: How Much Catastrophic?

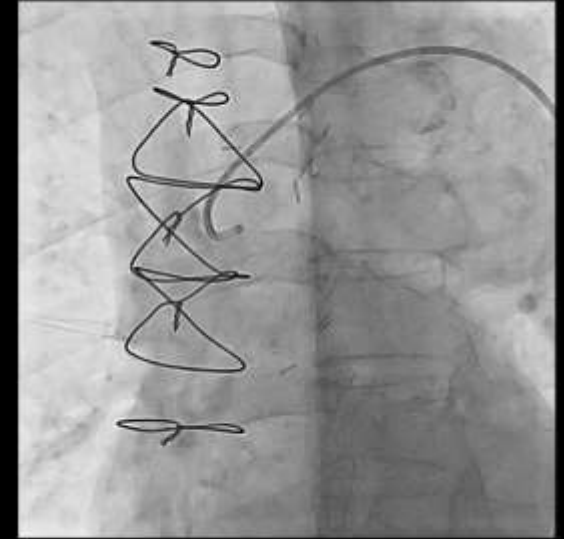
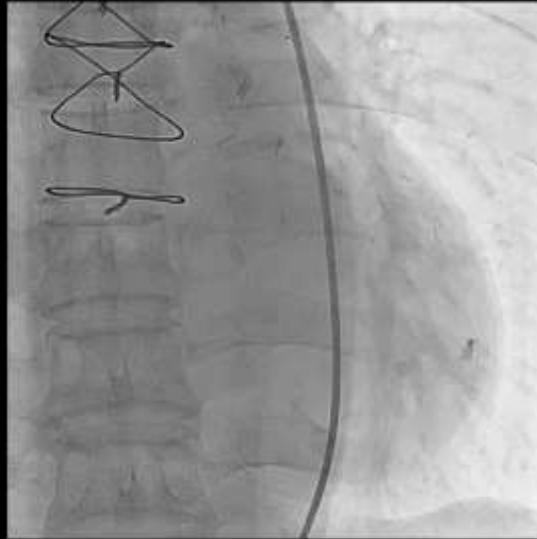
68 years, female with PMH of DM,
s/p CABG 2 month ago, recurrent chest pain



Failed CABG Grafts

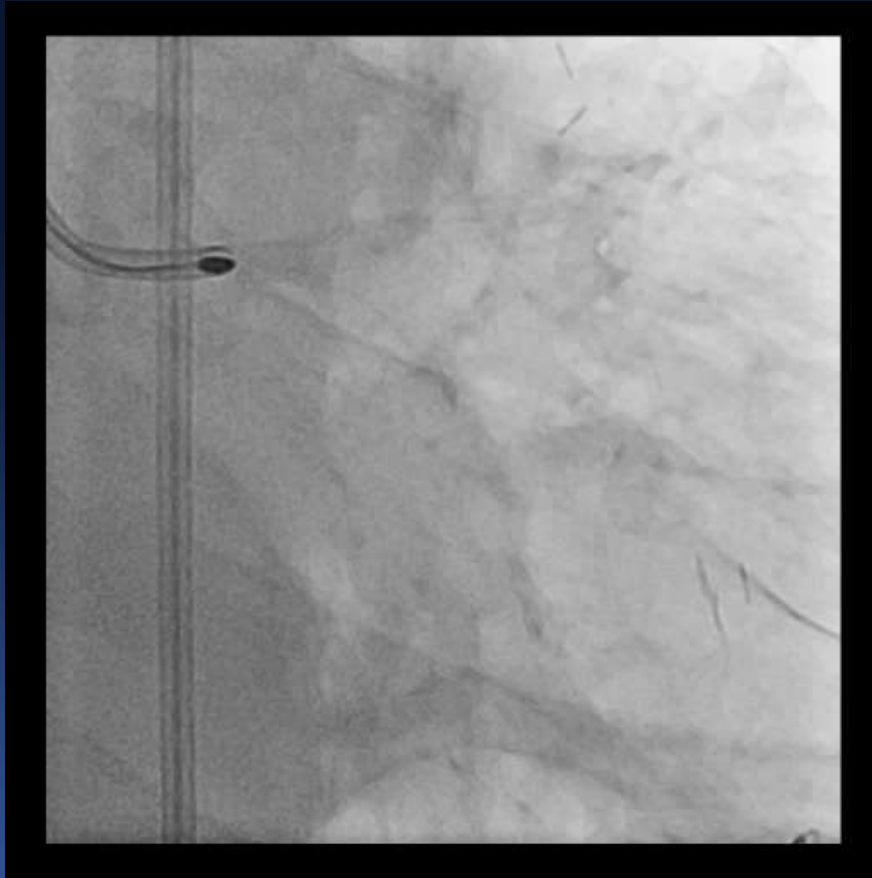


LIMA-LAD



SVG-OM

PCI

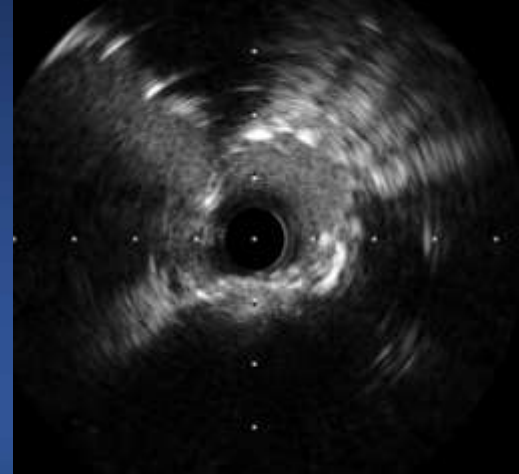
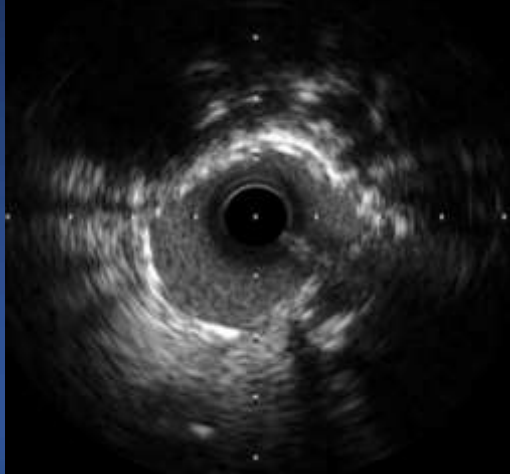
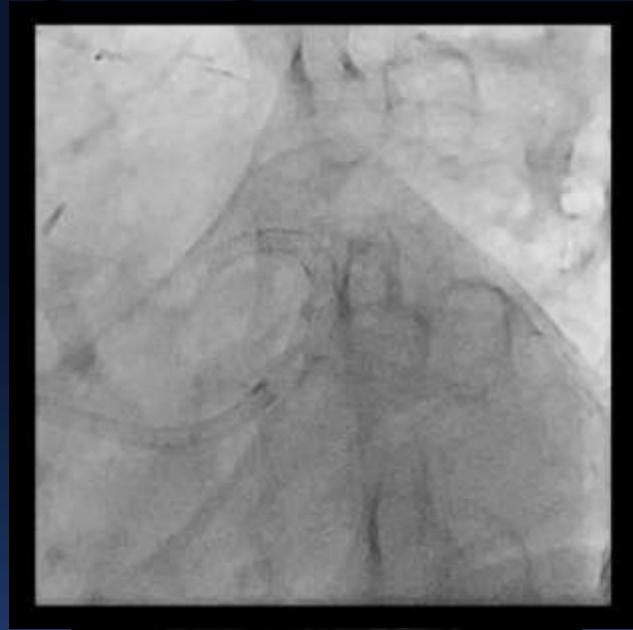
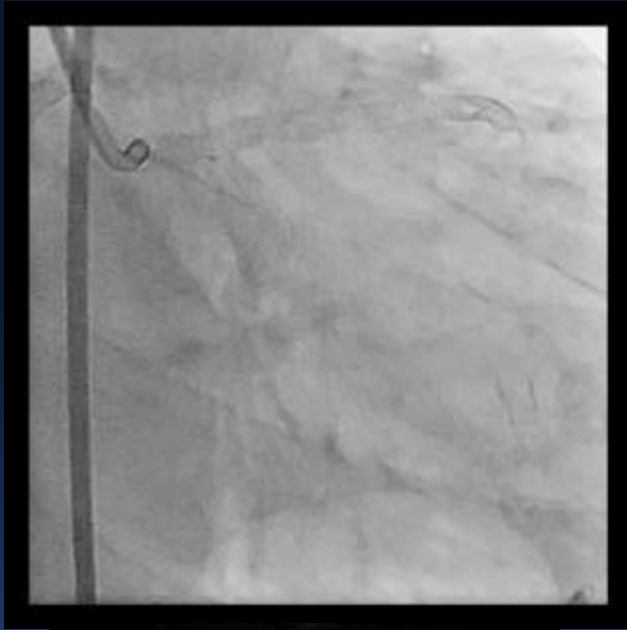


LCX Rotablator



Crush and
Kissing balloon

Post-PCI Angiogram



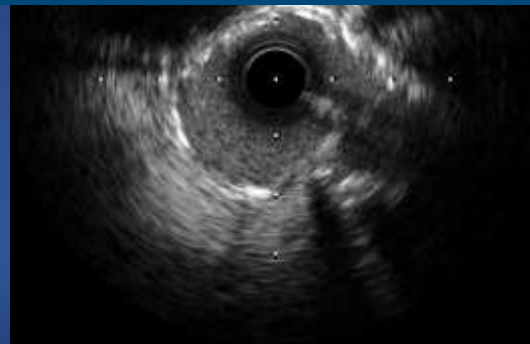
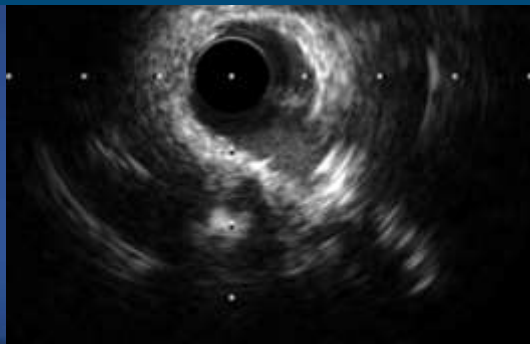
LAD OS MLA 7.0 mm²

LCX OS MLA 4.3 mm²

Final: “Stent Regret”



- NC balloons, Angiosculpt, Cutting ineffective because unable to impact lesion outside of stent
- Rotablation is an option in underexpanded stents but may be associated with burr entrapment and distal embolization

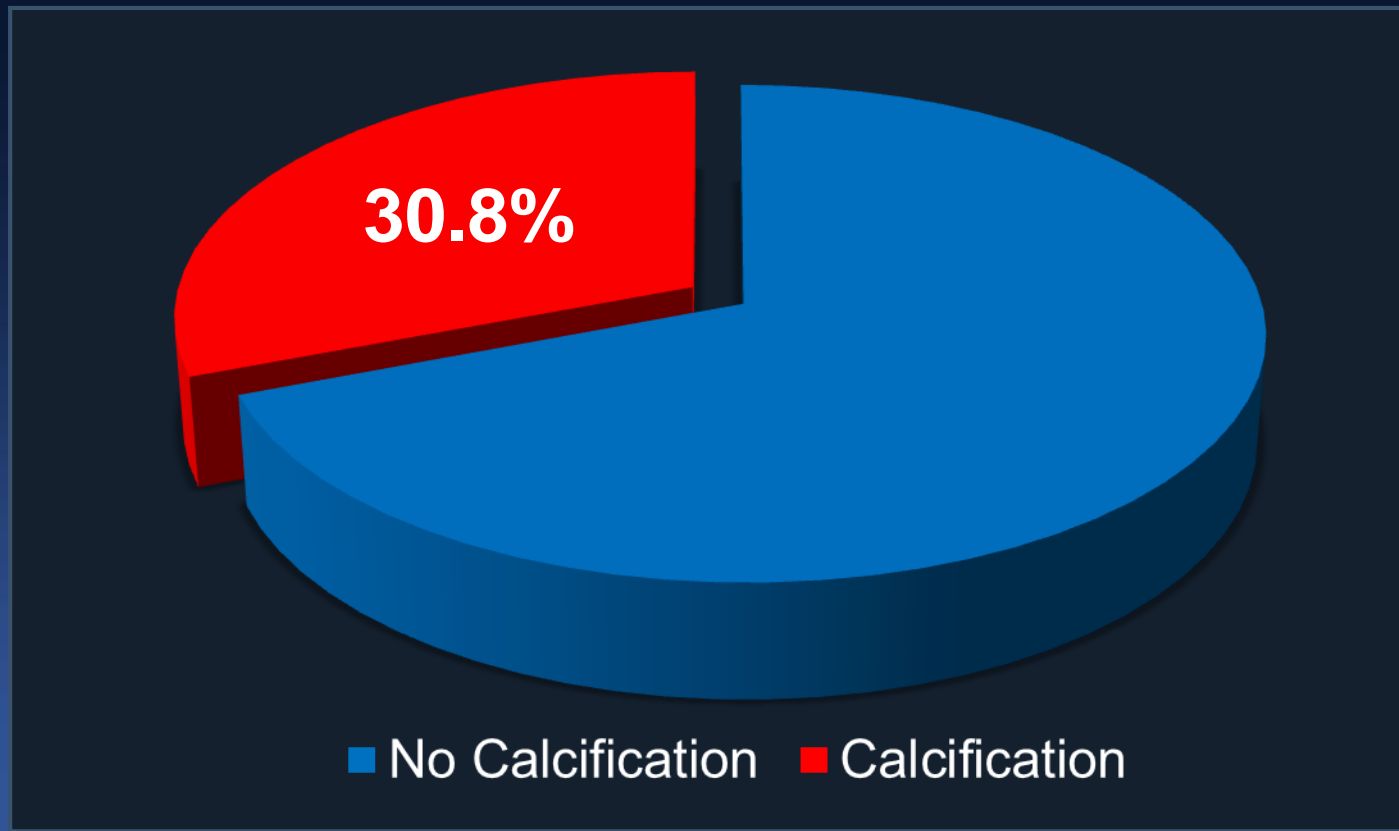


POC MLA 3.2 mm²

Frequency and Detection of Coronary Calcification

ADAPT-DES (11 center all-comers registry): Site-reported Mod/Sev Calcification

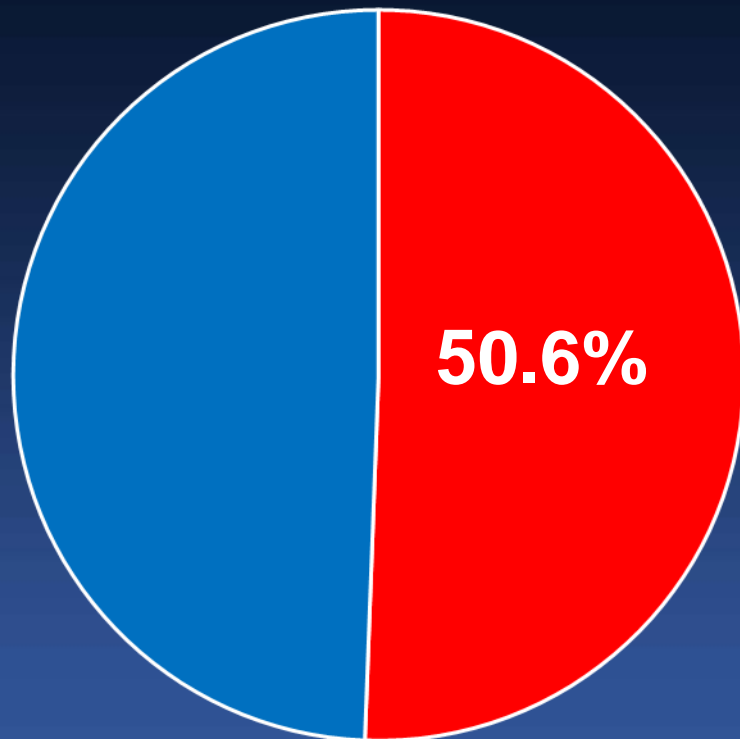
N = 8,582 pts



Frequency of “heavy” calcification in the SYNTAX trial: Randomized + Registry

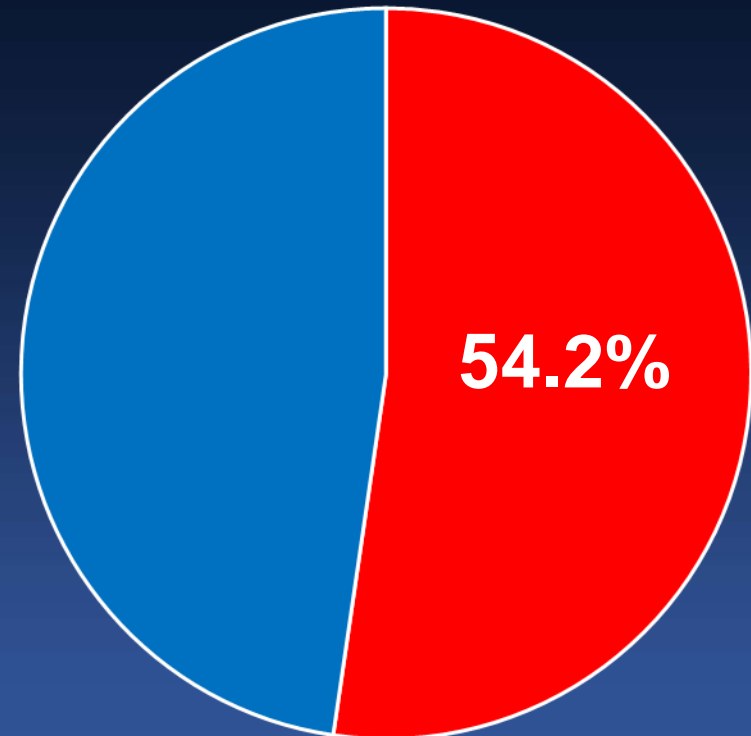
N=2,636 pts with LM or 3VD

PCI (n=1,095)



■ Heavy calcification
□ No heavy calcification

CABG (n=1,541)



■ Heavy calcification
□ No heavy calcification

Imaging Coronary Calcification

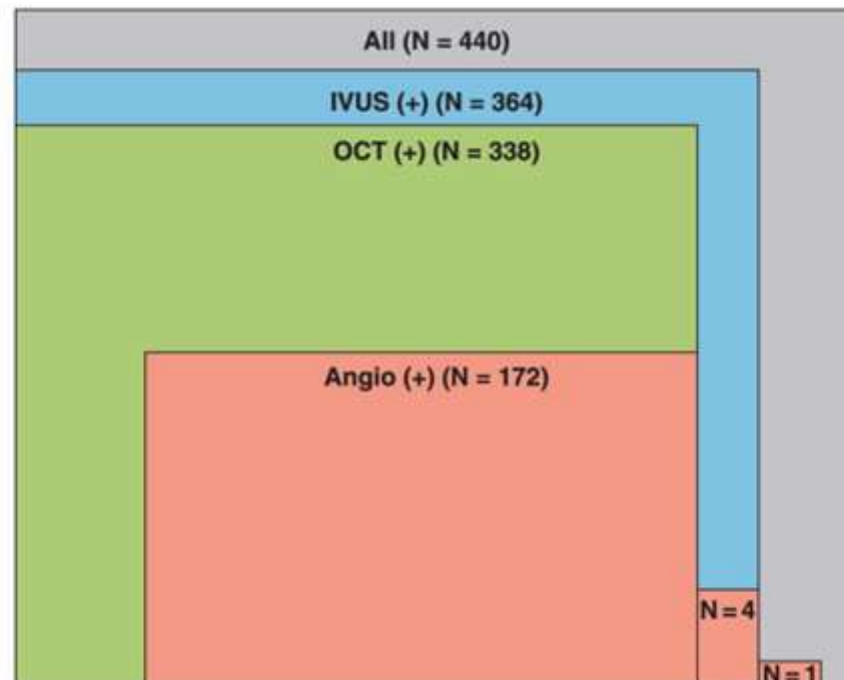
- Fluoroscopy/cineangiography
- Intravascular ultrasound (gray-scale and radiofrequency)
- Optical coherence tomography

Detection of Coronary Calcium by Angiography, IVUS, OCT

440 lesions with IVUS and OCT-guided stent implantation

Disagreement between angiography and other modalities was due to thinner layers of calcium that importantly did NOT appear to affect stent expansion

	IVUS (+)	IVUS (-)		OCT (+)	OCT (-)		OCT (+)	OCT (-)
Angio (+)	176	1	Angio (+)	172	5	IVUS (+)	338	26
Angio (-)	188	75	Angio (-)	166	97	IVUS (-)	0	76

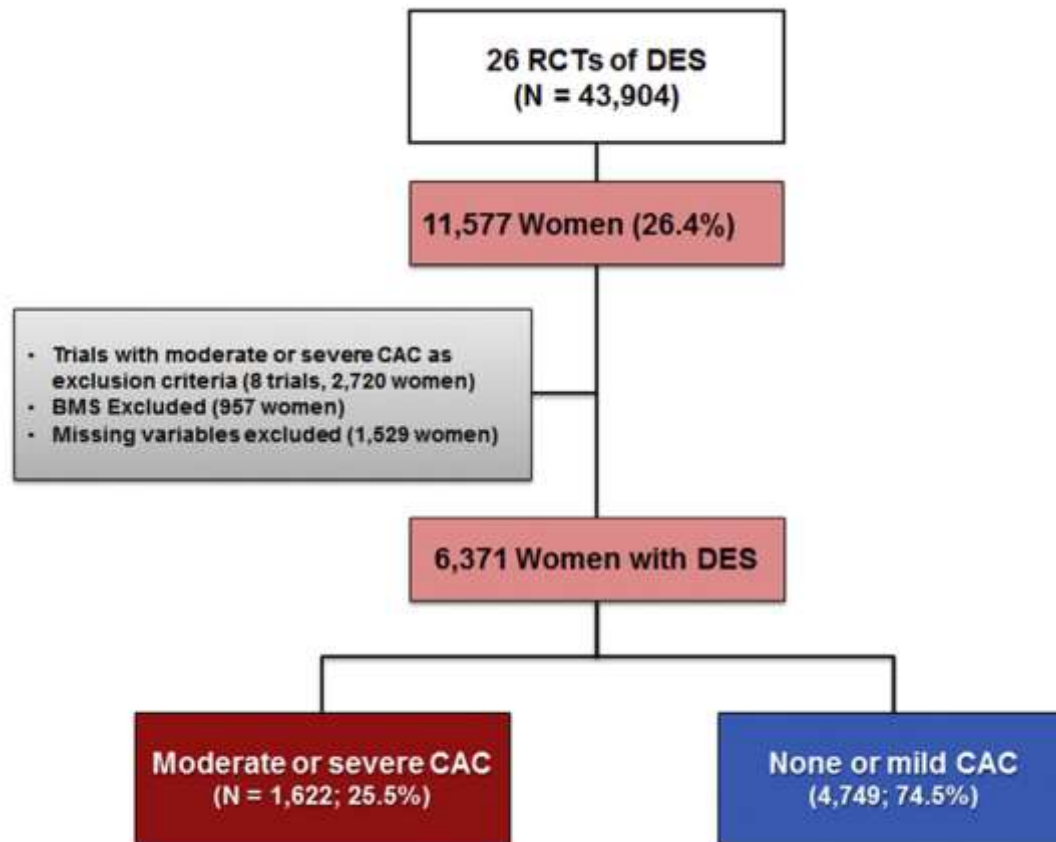


Impact of Coronary Calcium in DES era

Correlates and Impact of Coronary Artery Calcifications in Women Undergoing Percutaneous Coronary Intervention With Drug-Eluting Stents



From the Women in Innovation and Drug-Eluting Stents (WIN-DES) Collaboration

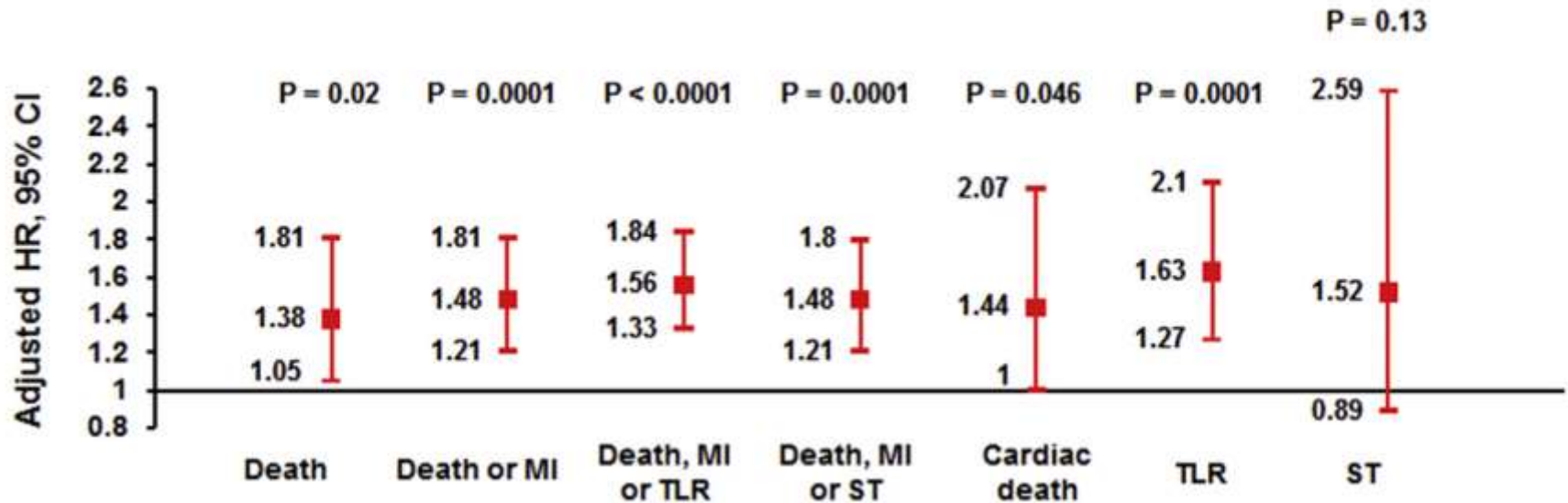


Women with coronary artery calcifications (CAC) requiring PCI



- Clinical Correlates**
- Older age
 - Arterial hypertension
 - Smoking
 - Previous CABG
 - Stable clinical presentation
 - Lower left ventricular function
 - Impaired renal function

3-year outcomes for moderate or severe CAC (N = 1,622) versus mild or none CAC (N = 4,749)



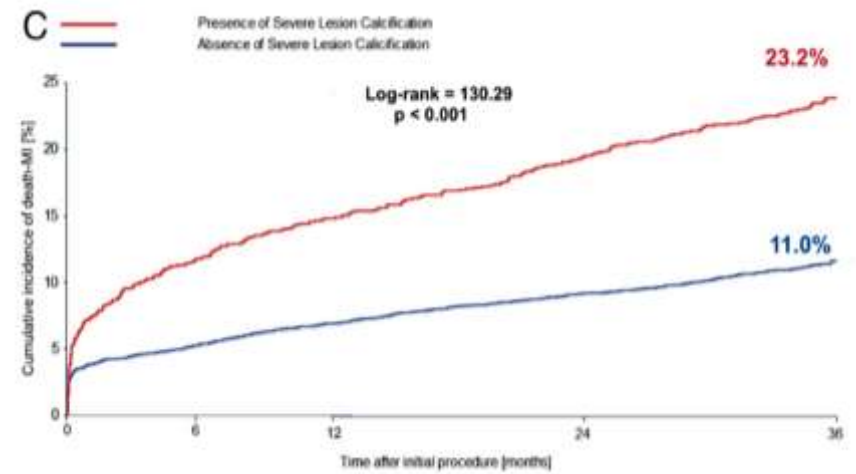
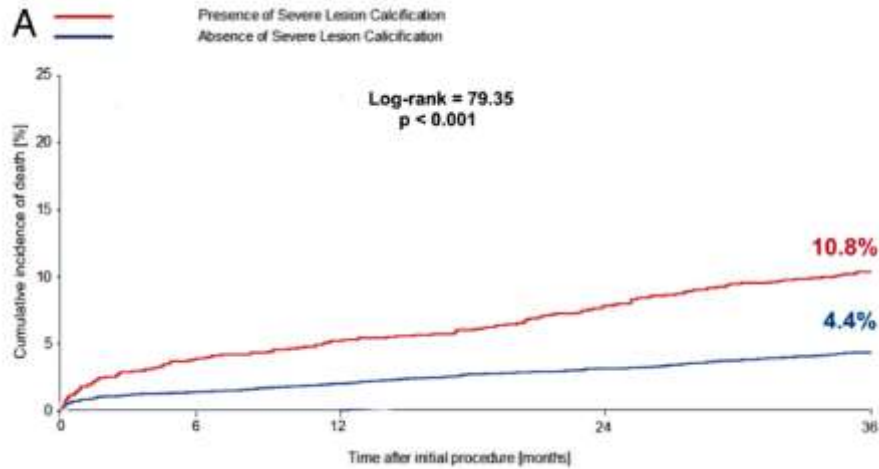
Prognostic implications of coronary calcification in patients with obstructive coronary artery disease treated by percutaneous coronary intervention: a patient-level pooled analysis of 7 contemporary stent trials

Christos V Bourantas,¹ Yao-Jun Zhang,¹ Scot Garg,² Javaid Iqbal,¹ Marco Valgimigli,¹ Stephan Windecker,³ Friedrich W Mohr,⁴ Sigmund Silber,⁵ Ton de Vries,⁶ Yoshinobu Onuma,¹ Hector M Garcia-Garcia,¹ Marie-Angele Morel,⁶ Patrick W Serruys^{1,7}

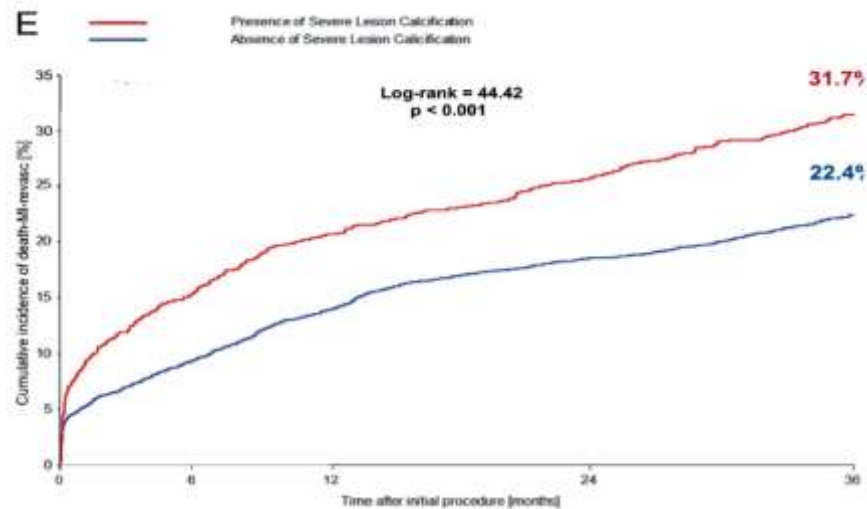
- 6296 patients from 7 DES RCTs
- Severe calcification: 20%
- Patients with severe lesion calcification were less likely to have undergone complete revascularization (48% vs 55.6%, $p < 0.001$)

Death

Death/MI

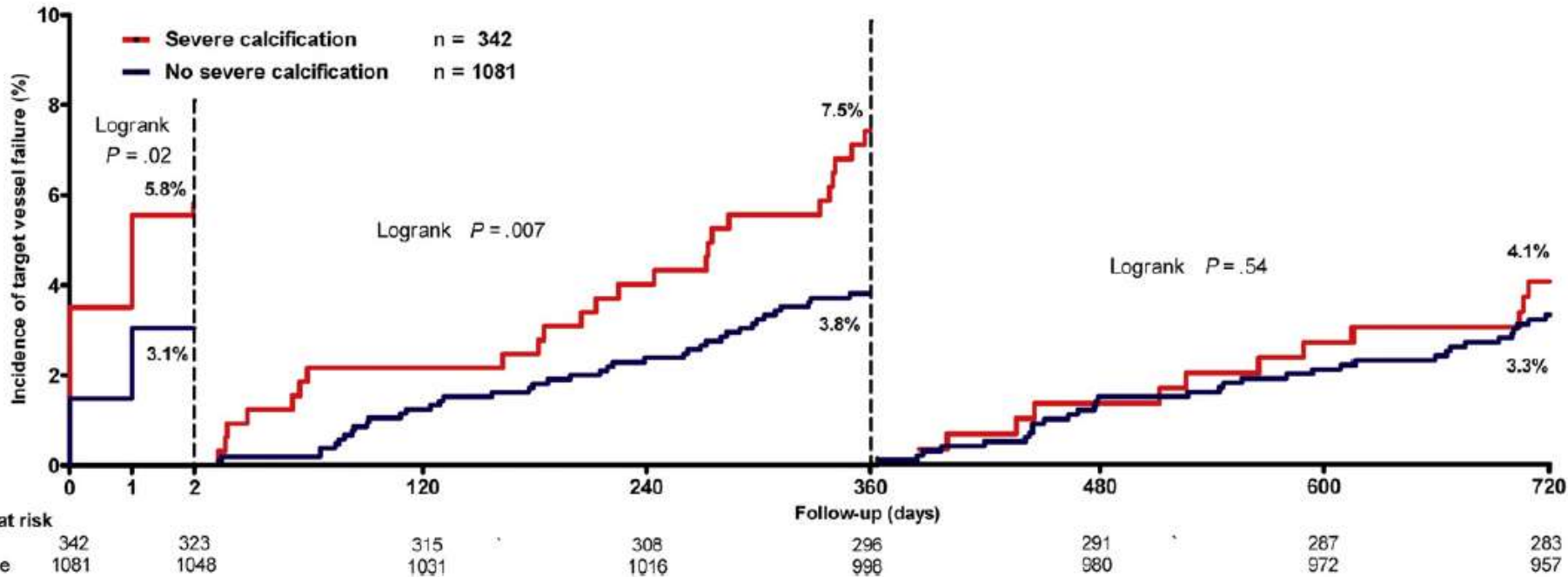


Death/MI/any revascularization



TWENTE and DUTCH PEERS (TWENTE II): Impact of Severe Calcification with 2nd Generation DES

1,423 pts with stable angina; 342 with severe calcification (24%)



At 2 years, TVF was 16.4% vs. 9.8%, $p=0.001$
predominantly driven by events in the first 48 hours and up to 1 year

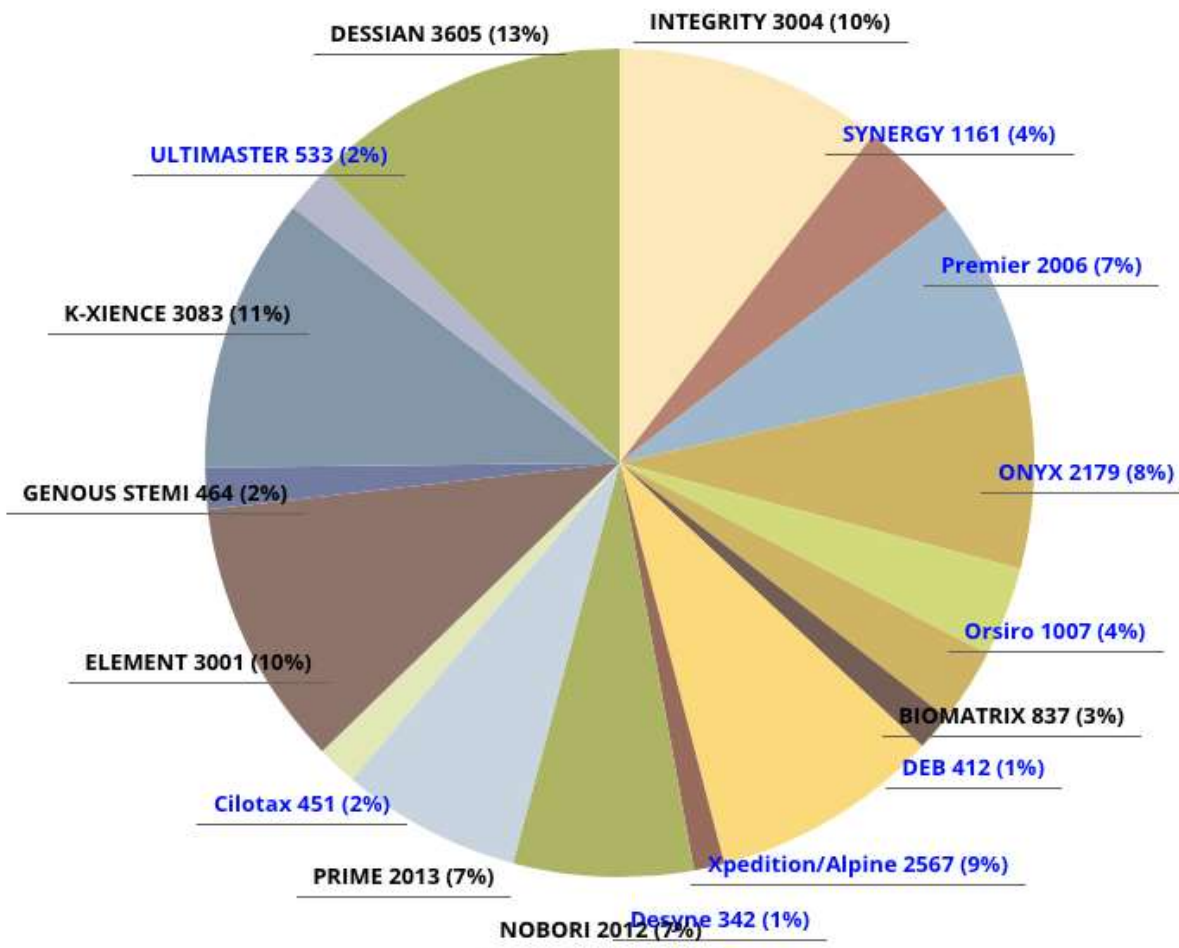
Of note, 2 year definite ST was 1.8% vs. 0.4%, $p=0.02$

Impact of Coronary Calcification in Real-World PCI

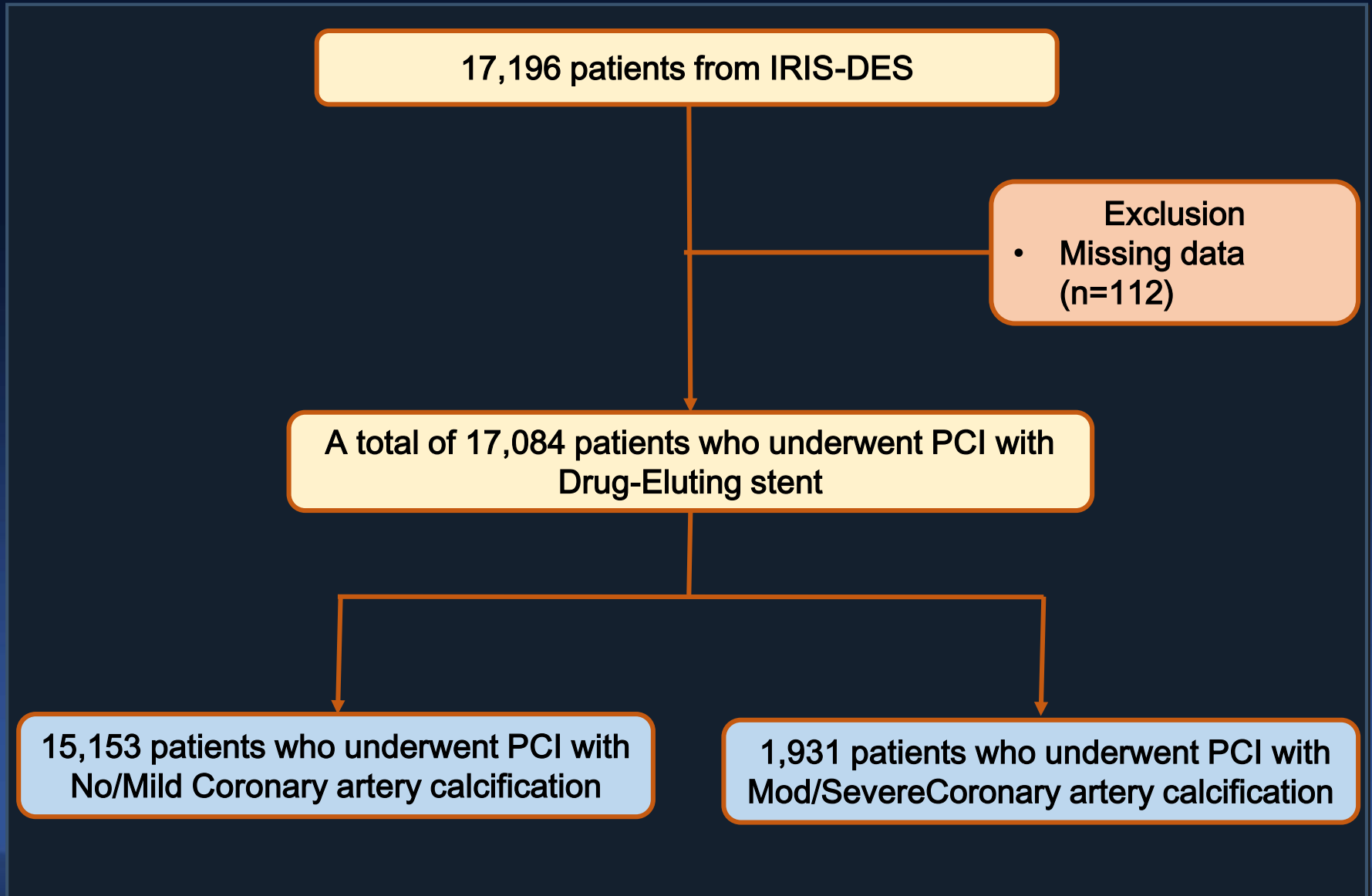
Insights from the IRIS-DES registry

IRIS-DES,Total 28,677

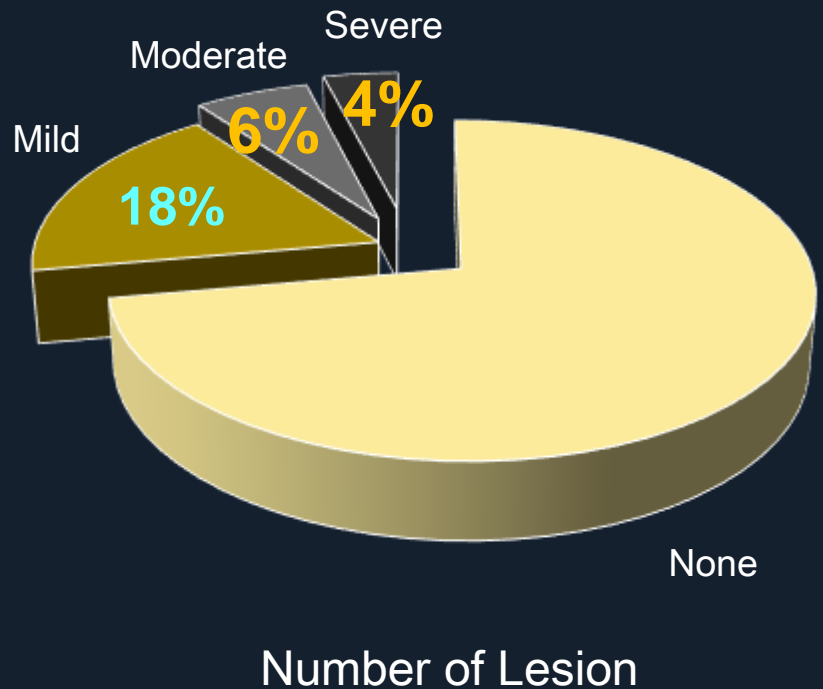
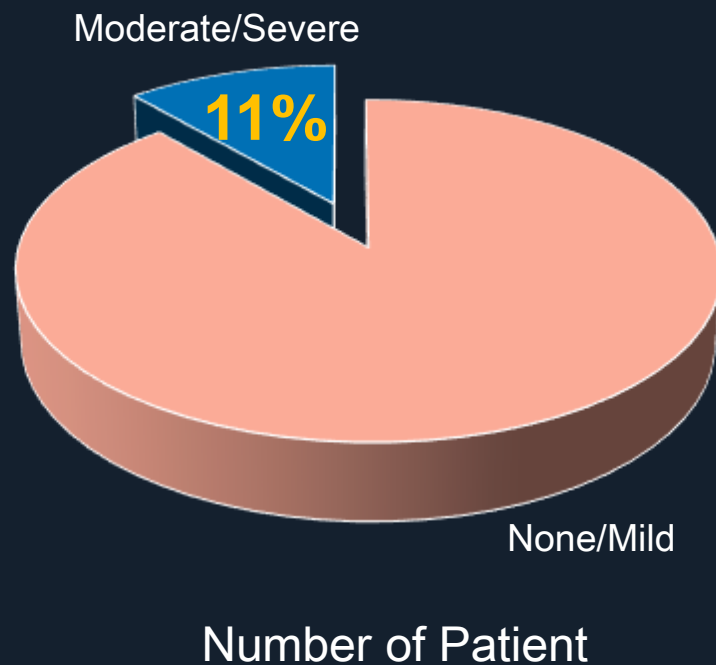
연구별 등록현황



Our Data from Large Registry



Prevalence of calcium according to severity

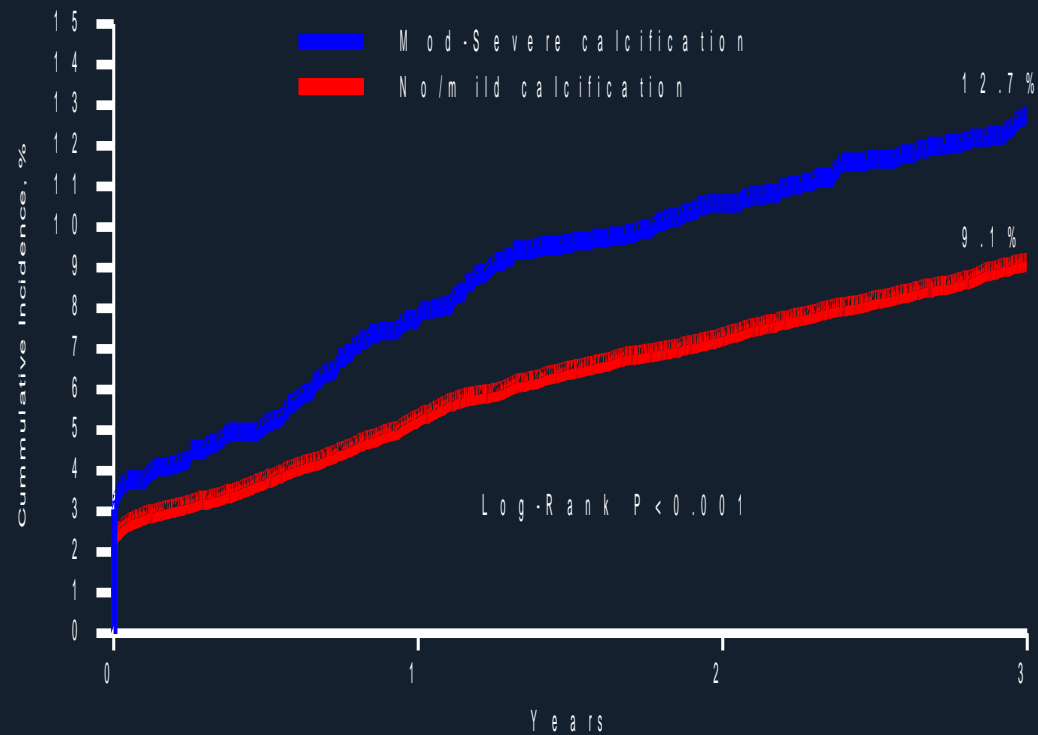


Baseline Characteristics

	No/Mild CAC (N=15153)	Mod/Sev CAC (N=1931)	P value
Age (years)	63.4 ± 10.8	66.5 ± 10.2	<0.001
Male sex	10615 (70.1%)	1223 (63.3%)	<0.001
BMI, kg/m ²	24.7 ± 3.1	24.3 ± 3.4	<0.001
Hypertension	9139 (60.3%)	1368 (70.8%)	<0.001
Diabetes mellitus	4934 (32.6%)	774 (40.1%)	<0.001
Hypercholesterolemia	5897 (38.9%)	759 (39.3%)	0.76
Current smoker	4463 (29.5%)	482 (25.0%)	<0.001
Previous PCI	1935 (12.8%)	256 (13.3%)	0.57
Previous CABG	271 (1.8%)	52 (2.7%)	0.008
Chronic renal failure	469 (3.1%)	116 (6.0%)	<0.001
LVEF, %	58.9 ± 10.3	58.1 ± 11.6	0.002
Stable angina	6276 (41.4%)	801 (41.5%)	0.977
ACS presentation	8877 (58.6%)	1130 (58.5%)	0.977

IRIS-DES, 3-year Target-vessel failure (cardiac death, target vessel MI, ischemic driven TVR)

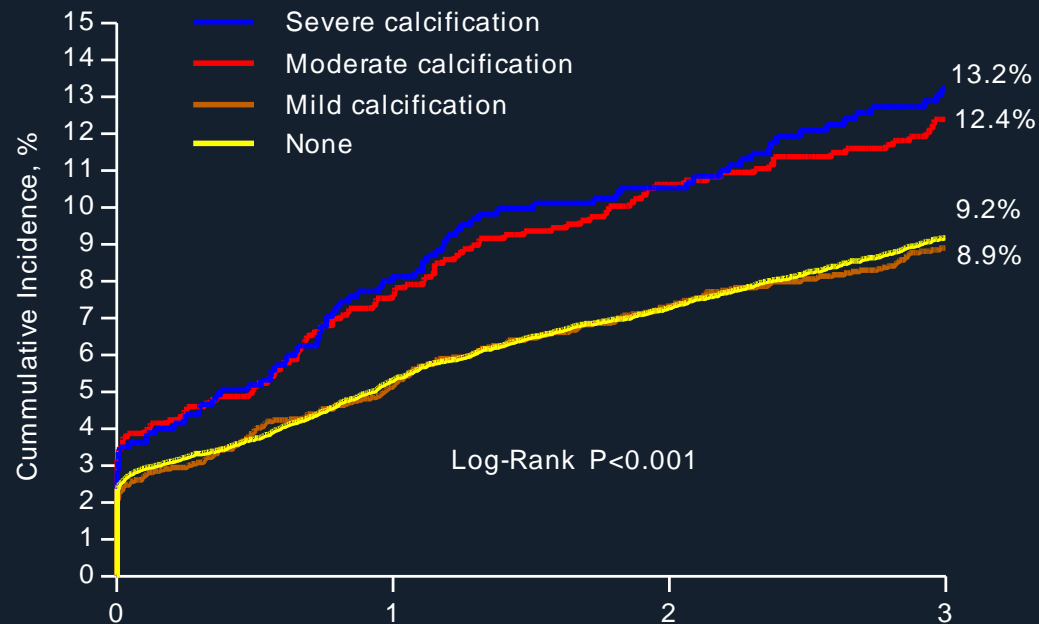
(A) Target-vessel failure



No. at Risk	0	1	2	3
Mod-Severe	2022	1969	1959	1954
No/mild	25938	25808	25758	25728

IRIS-DES, 3-year Target-vessel failure

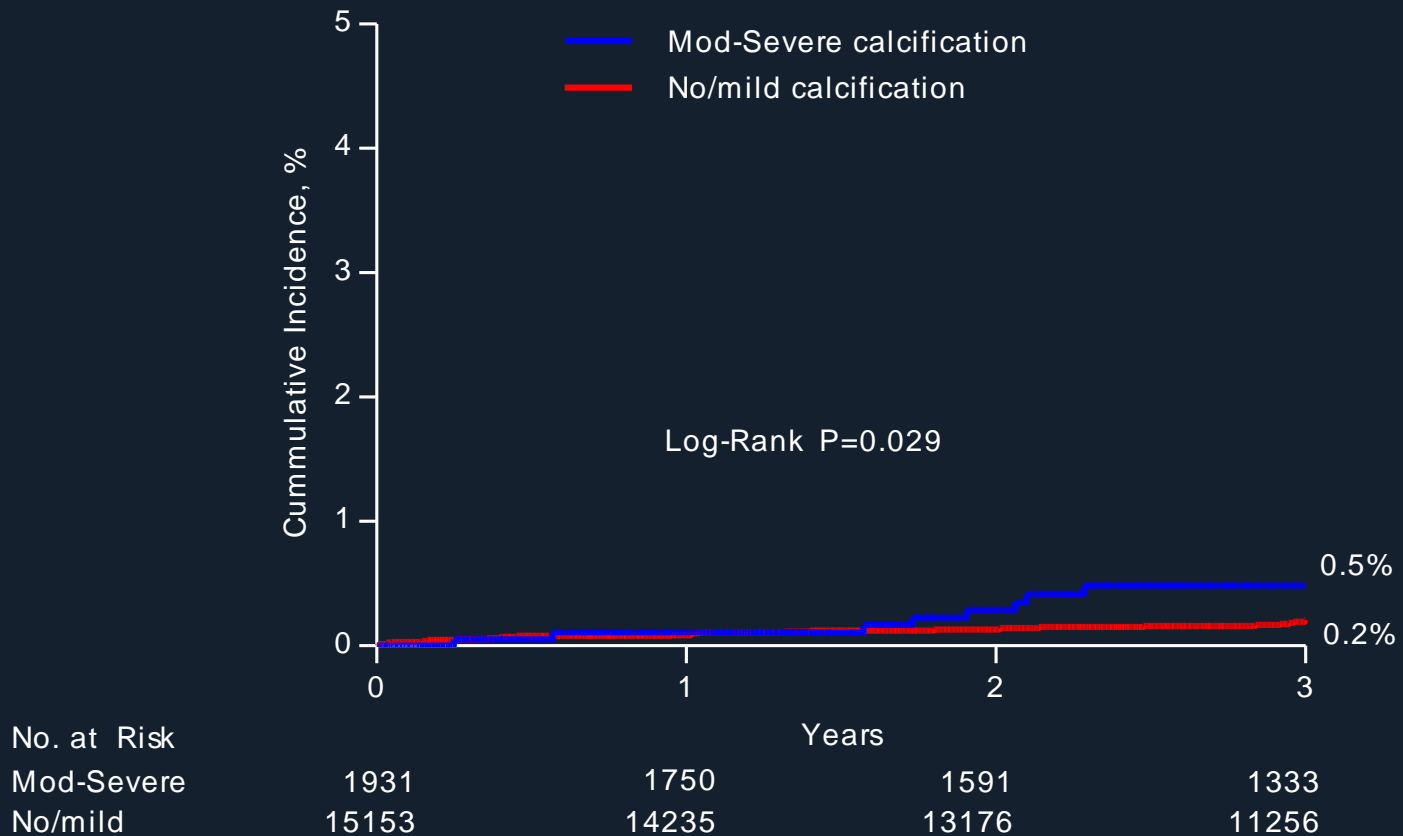
(A) Target-vessel failure



No. at Risk	0	1	2	3
Severe	798	664	604	497
Moderate	1133	986	885	735
Mild	3016	2733	2502	2197
None	12137	10925	10024	8375

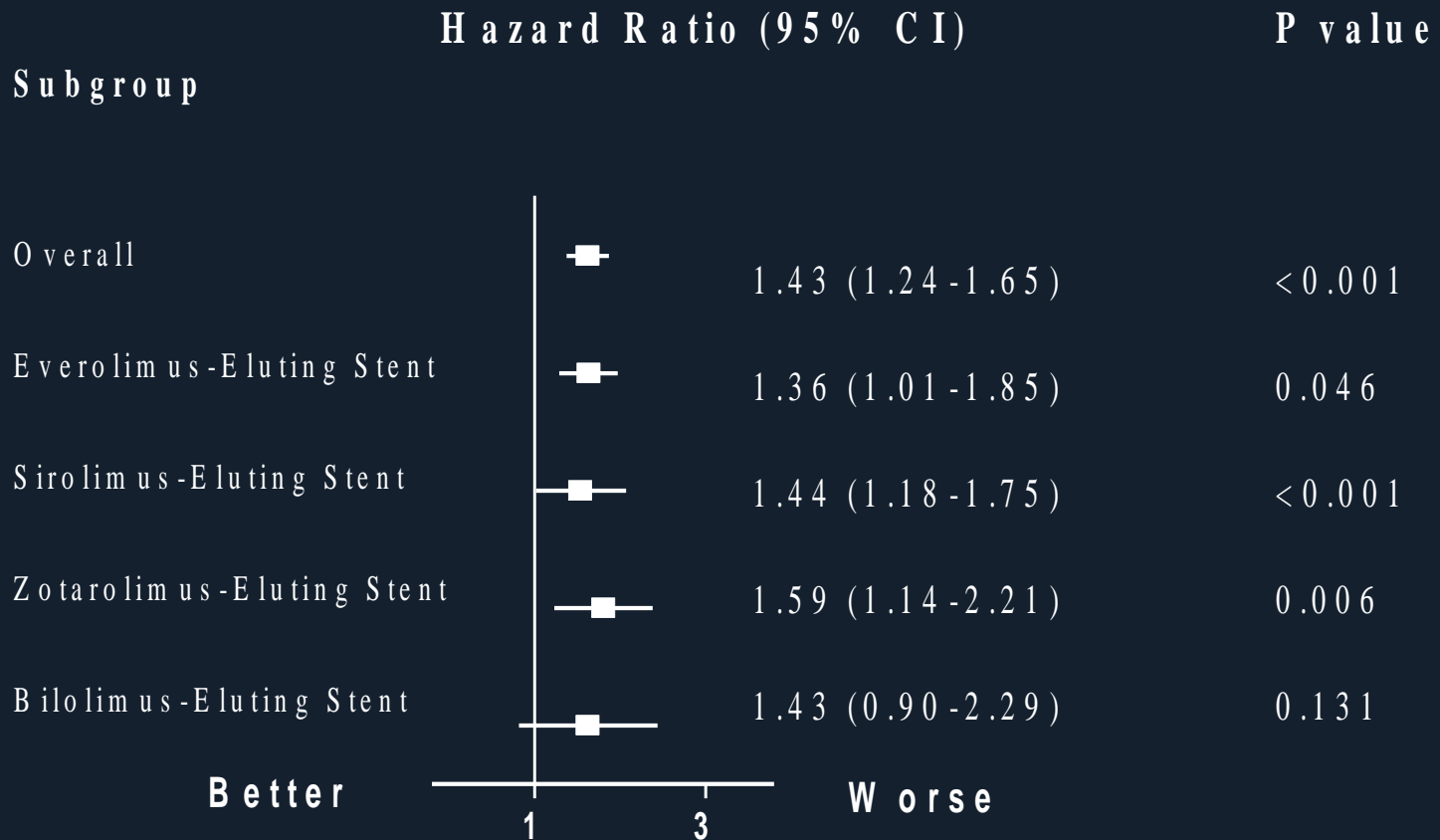
IRIS-DES, 3-year Definite or probable stent thrombosis

(D) Definite or probable stent thrombosis



Hazard ratio for TVF

Subgroup Analysis by Stent-Types



Treatment of coronary calcification

Why Calcium Lesion Preparation?

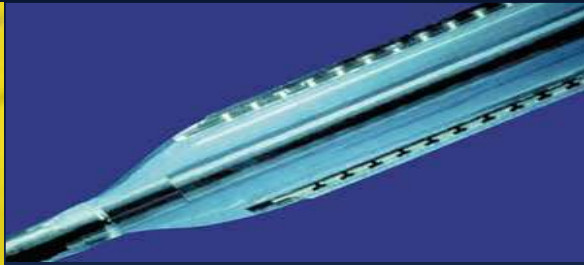
- **Facilitates procedural success**
 - lumen expansion
 - enables lesion access for balloons and especially stents
- **Plaque modification**
 - changing lesion compliance
 - minimizes vessel “trauma” (severe dissections)
 - creates a larger MLD

Toolkits for Calcified Lesion

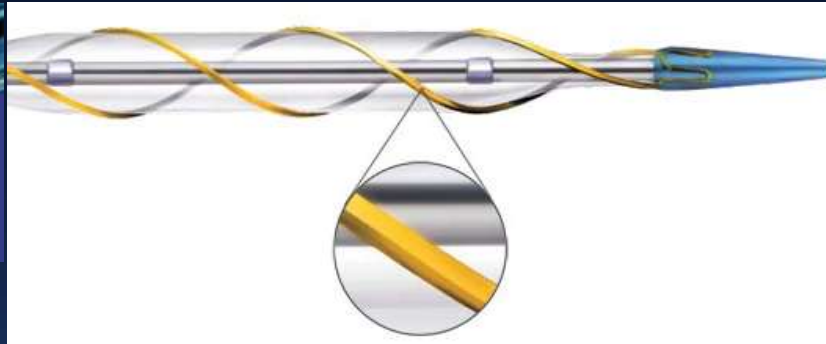
NC balloons



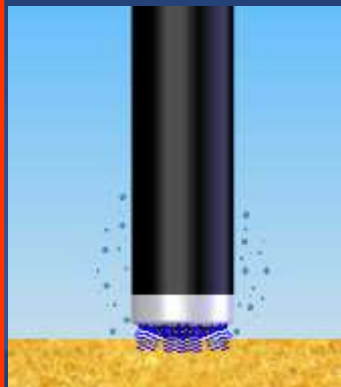
Cutting balloon



Angiosculpt



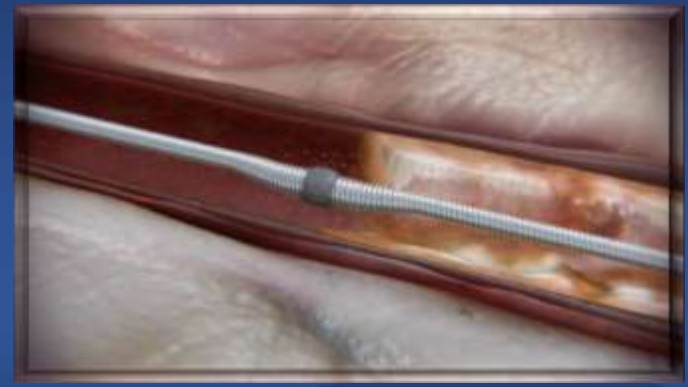
Laser



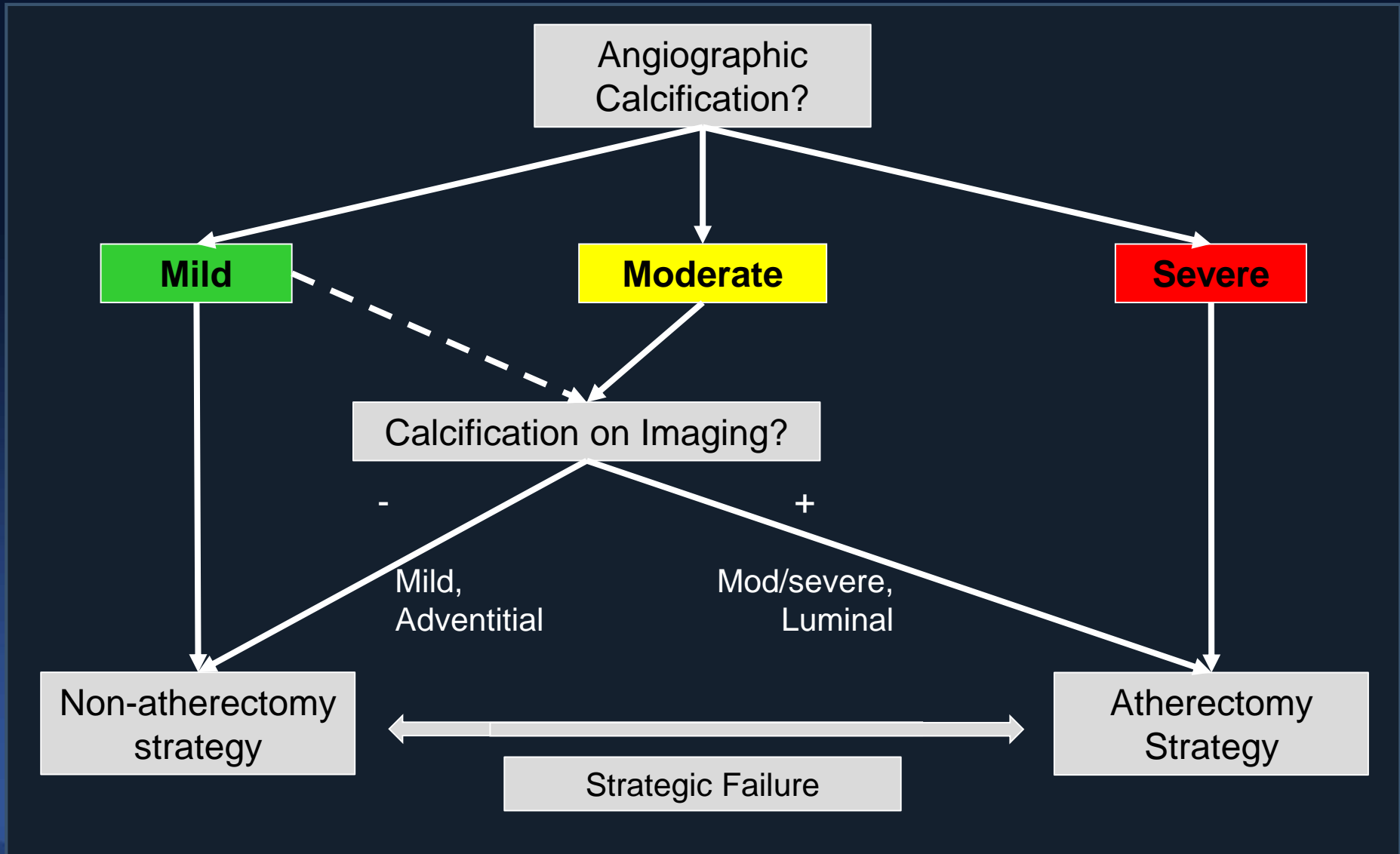
Rotational atherectomy



Orbital atherectomy



Strategy for Approaching Calcified Lesions



WHAT NEXT?

Time for Drill ?



Treatment of Calcified Lesions: PCI guidelines

Device	ACCF/AHA/SCAI 2011	ESC/EAPCI 2014
Cutting/scoring balloon angioplasty	<ul style="list-style-type: none"> Might be considered to avoid slippage induced coronary artery trauma during PCI for in-stent restenosis or ostial lesions in side branches (Class IIb-C) Should not be performed routinely during PCI (Class III-A) 	May be useful in highly calcified, rigid ostial lesions (also applies to scoring).
Rotational atherectomy	<ul style="list-style-type: none"> Reasonable for fibrotic or <i>heavily calcified lesions</i> that might not be crossed by a balloon catheter or adequately dilated before stent implantation (Class IIa-C) Should not be performed routinely for de novo lesions or in-stent restenosis (Class III-A) 	Might technically be required in cases of tight and calcified lesions, to allow subsequent passage of balloons and stents.
Laser angioplasty	<ul style="list-style-type: none"> Might be considered for fibrotic or moderately calcified lesions that cannot be crossed or dilated with conventional balloon angioplasty (Class IIb-C) Should not be used routinely during PCI (Class III-A) 	(Laser not mentioned for calcification)

RCT for Calcified Lesion Treatment

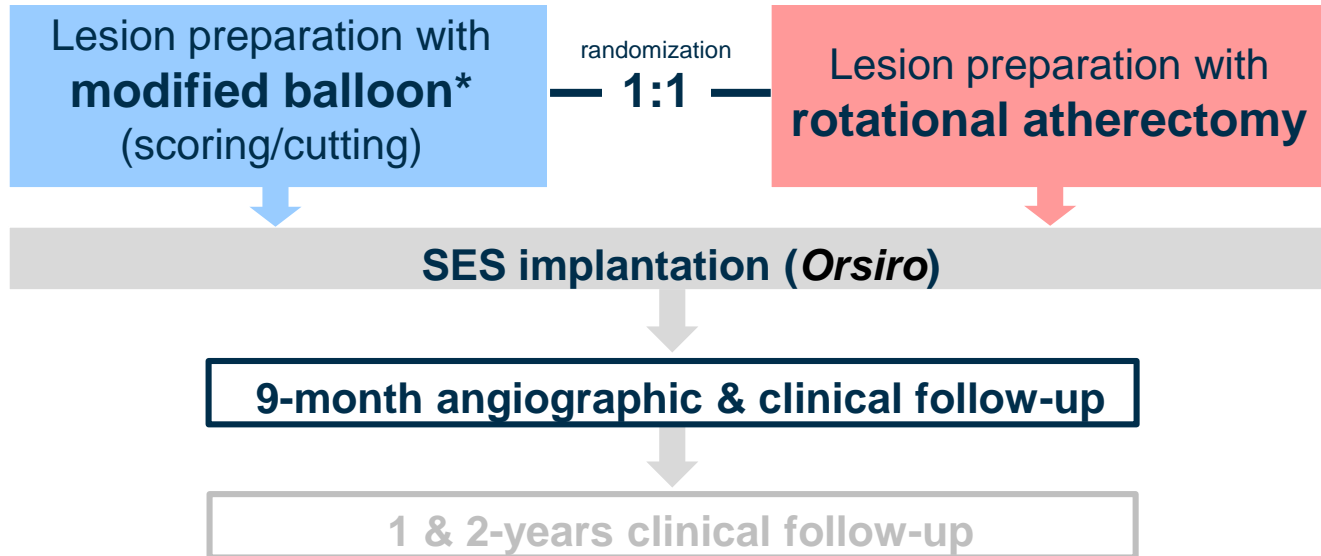
PREPARE-CALC Trial



Prospective, randomized, active-controlled clinical trial in two German centers

PCI in 200 patients with severely calcified lesions

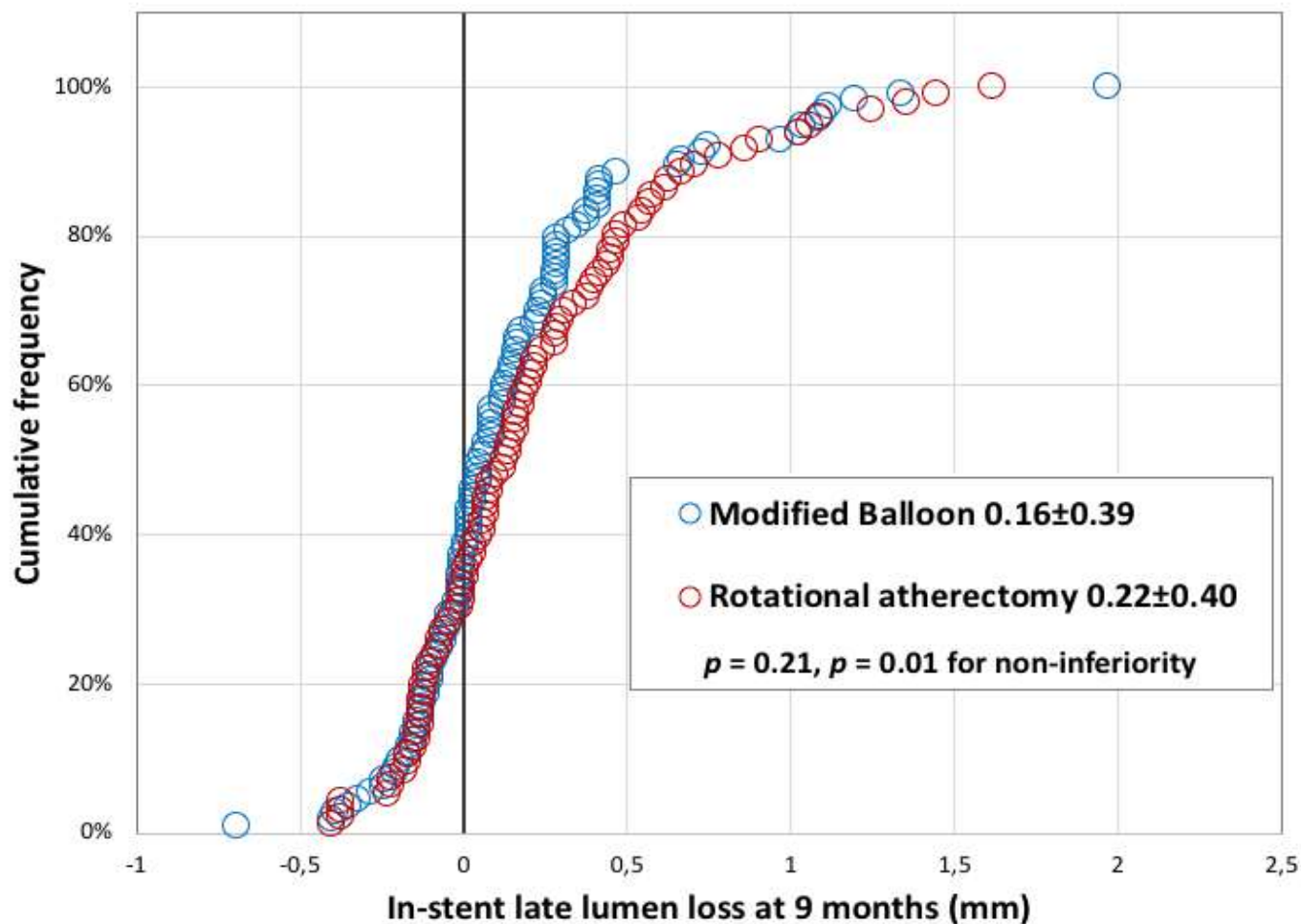
* Predilatation with standard balloons was allowed to facilitate delivery of modified balloons



Primary Endpoint – Strategy Success

	Modified balloon (n = 100 pts.)	Rotational atherectomy (n = 100 pts.)	p-value
Strategy success	81 (81%)	98 (98%)	0.0001
Final TIMI flow < III	0 (0%)	1 (1%)	0.99
Residual stenosis >20%	2 (2%)	0 (0%)	0.49
Stent failure	4 (4%)	1 (1%)	0.36
Crossover	16 (16%)	0 (0%)	<0.0001

Co-Primary Endpoint – In stent LLL at 9 Month



Clinical Outcome at 9 Month

	Modified balloon (n = 100 pts.)	Rotational atherectomy (n = 100 pts.)	p-value
Death	2 (2%)	2 (2%)	1.00
Cardiac death	1 (1%)	1 (1%)	1.00
Non-cardiac death	1 (1%)	1 (1%)	1.00
Myocardial infarction	3 (3%)	2 (2%)	1.00
Target vessel MI	1 (1%)	2 (2%)	1.00
Periprocedural MI	1 (1%)	2 (2%)	1.00
Spontaneous MI	2 (2%)	0 (0%)	0.50
Stent thrombosis (def./prob.)	0 (0%)	0 (0%)	1.00
TVR	8 (8%)	3 (3%)	0.21
Target vessel failure	8 (8%)	6 (6%)	0.78



ECLIPSE

Evaluation of Treatment Strategies for Severe **C**alcific Coronary Arteries: Orbital Atherectomy vs. Conventional Angioplasty **P**rior to Implantation of Drug Eluting **S**tents

~2000 pts with severely calcified lesions; ~60 US sites

Randomize

1:1

Orbital Atherectomy Strategy

(1.25 mm Crown followed by non-compliant balloon optimization)

Conventional Angioplasty Strategy

(conventional and/or specialty balloons per operator discretion)

2nd generation DES implantation and optimization

2nd generation DES implantation and optimization

1° endpoints: 1) Post-PCI in-stent MSA (N~400 in imaging study)
2) 1-year TVF (all patients)

2° endpoint: Procedural Success (stent deployed w/RS<20% & no maj complications)

Principal investigators: Ajay J. Kirtane, Philippe Généreux; **Study chairman:** Gregg W. Stone

Sponsor: Cardiovascular Systems Inc.

Take-Home Message

- The ability to manage severe coronary calcium is a key cornerstone to the complex PCI interventionist.
- Imaging is a key component of vessel assessment and optimization and is a natural adjunct to PCI in calcified anatomy.
- In the contemporary PCI, several toolkits for treating severe calcification are available, but still underused, particularly in low-volume operator hospital.
- More RCT data are needed to fully understand the efficacy and safety of an atherectomy-first approach