PREVENT Trial:
Update and Interesting Cases

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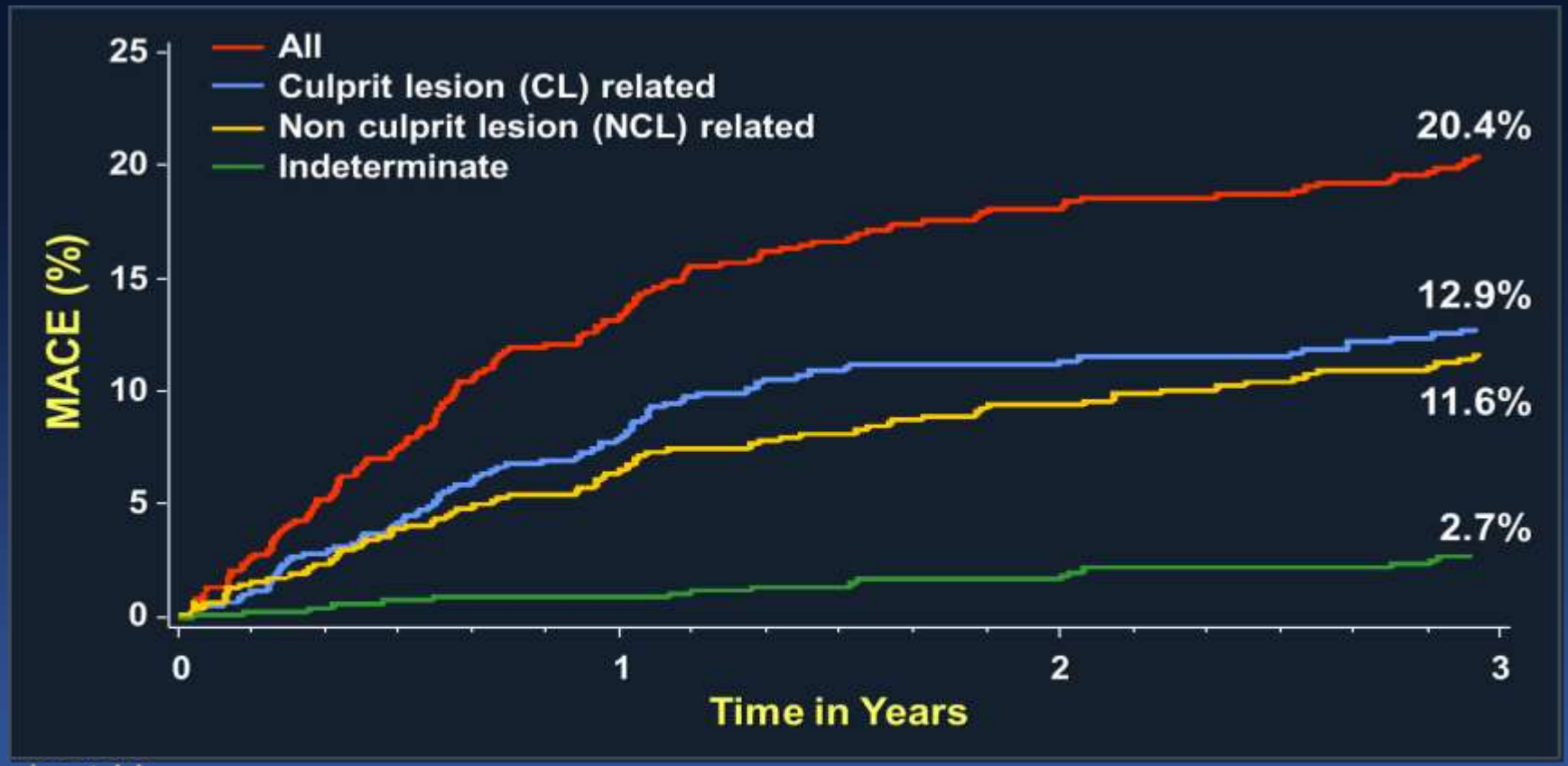
To Treat or Not Tot Treat ?

Functionally Insignificant Vulnerable Plaque

PROSPECT: MACE

(N=700, ACS, 3-Vessel Imaging after PCI)



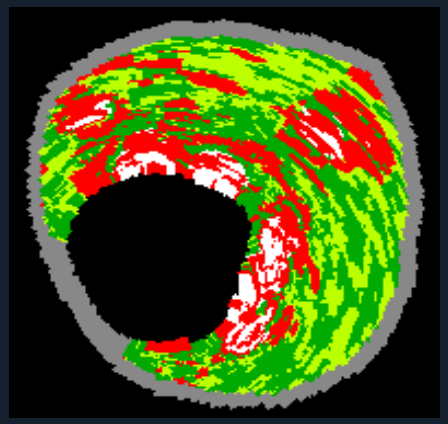
Number at risk

ALL	697	557	506	480
CL related	697	590	543	518
NCL related	697	595	553	521
Indeterminate	697	634	604	583

Stone GW et al. NEJM 2011;364:226-35

Vulnerable Plaque
Defined by VH-IVUS

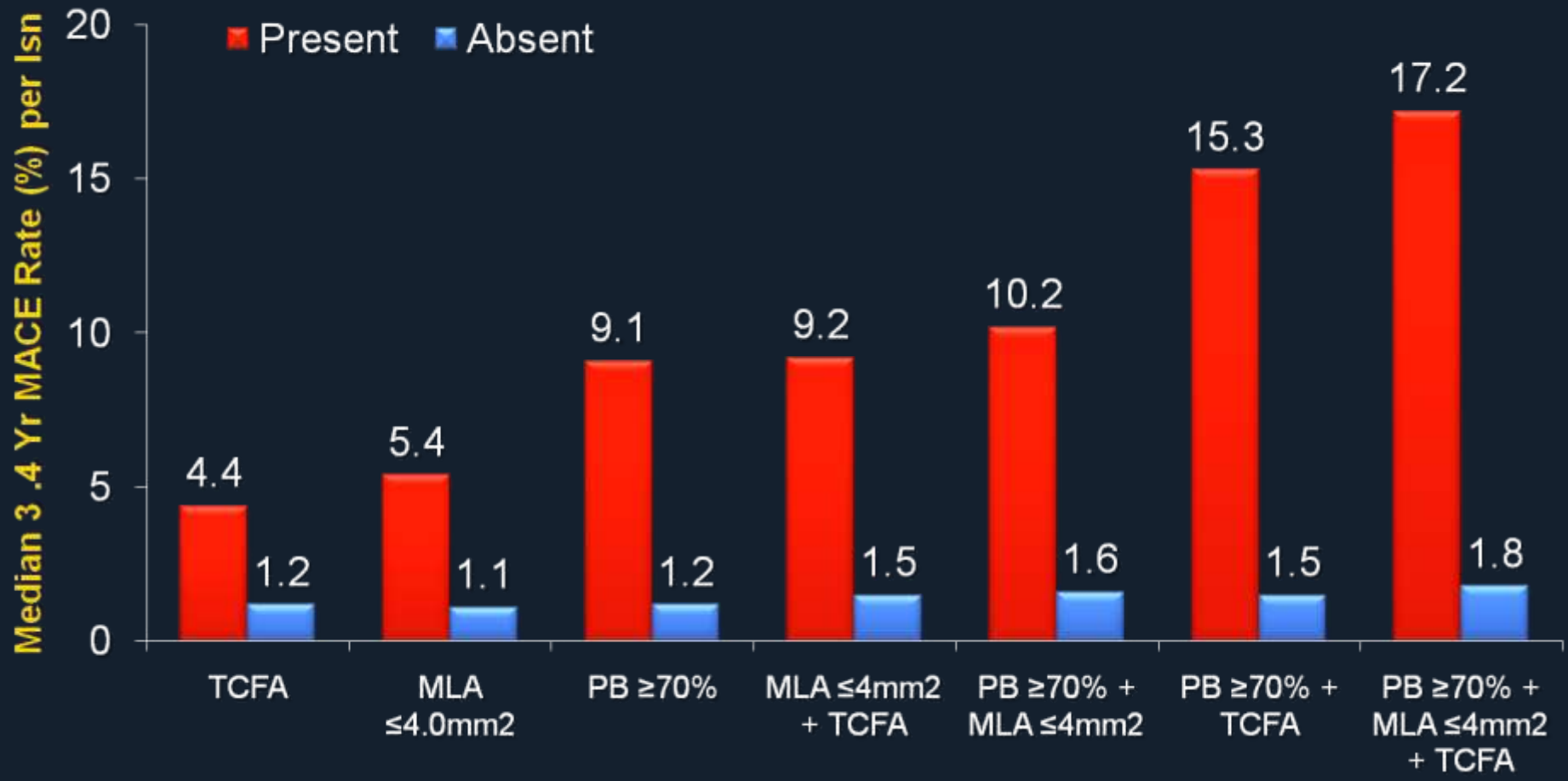
Independent Predictors of Non-Culprit Lesion Events



	HR [95% CI]	P value
PB_{MLA} ≥70%	5.03 [2.51, 10.11]	<0.0001
VH-TCFA	3.35 [1.77, 6.36]	0.0002
MLA ≤4.0 mm^2	3.21 [1.61, 6.42]	0.001

Stone GW et al. NEJM 2011;364:226-35

PROSPECT: Correlates of Non Culprit Lesion Related Events

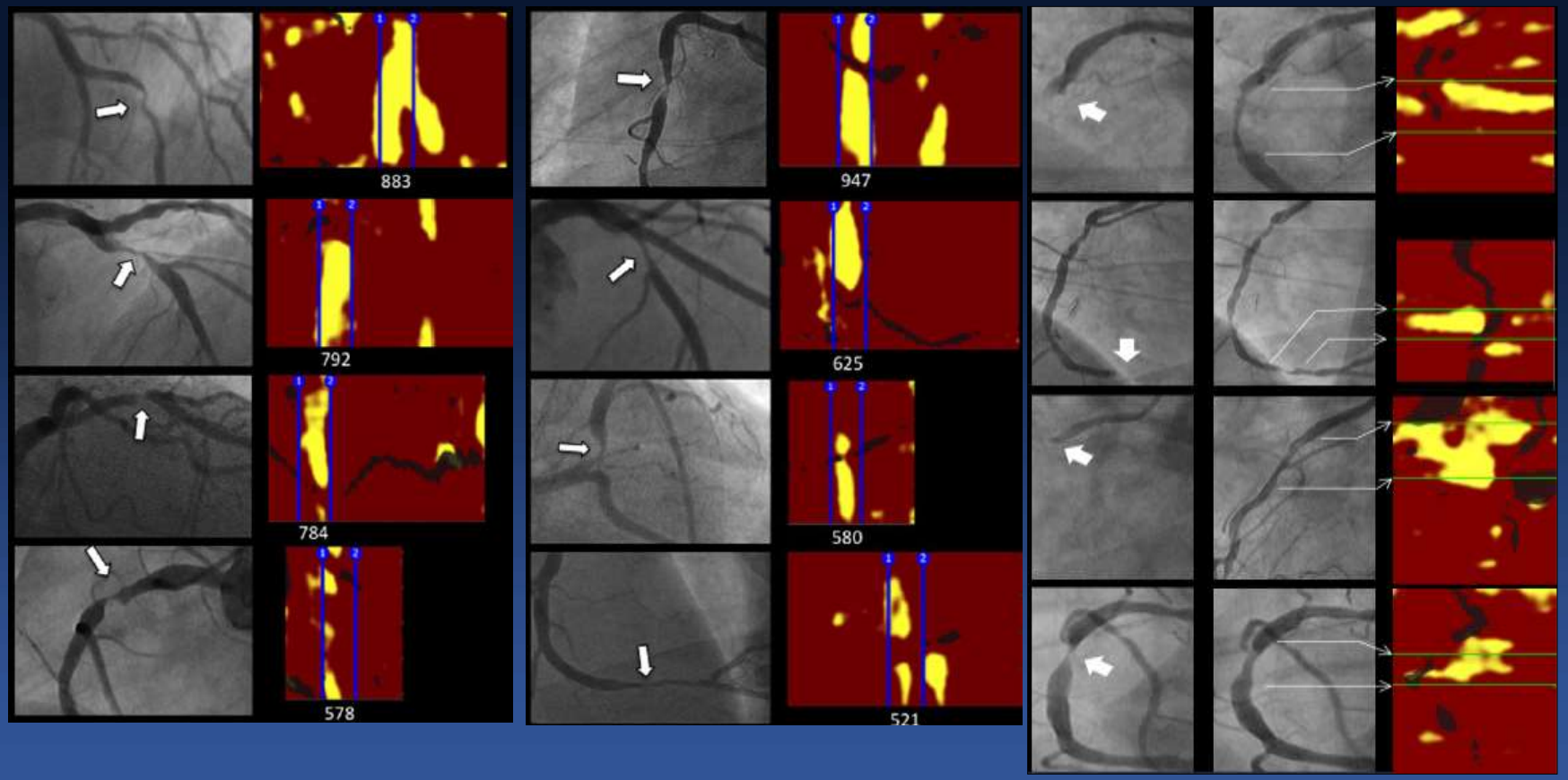


	TCFA	MLA ≤4.0mm2	PB ≥70%	MLA ≤4mm2 + TCFA	PB ≥70% + MLA ≤4mm2	PB ≥70% + TCFA	PB ≥70% + MLA ≤4mm2 + TCFA
Prevalence*	51.2%	49.1%	30.7%	17.4%	15.4%	11.0%	4.6%
Lesion HR	3.8 (2.2, 6.6)	5.0 (2.9, 8.7)	7.9 (4.6, 13.8)	6.4 (3.4, 12.2)	6.7 (3.4, 13.0)	10.8 (5.5, 21.0)	10.8 (4.3, 27.2)
P value	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001

*Likelihood of one or more such lesions being present per patient. PB = plaque burden at the MLA

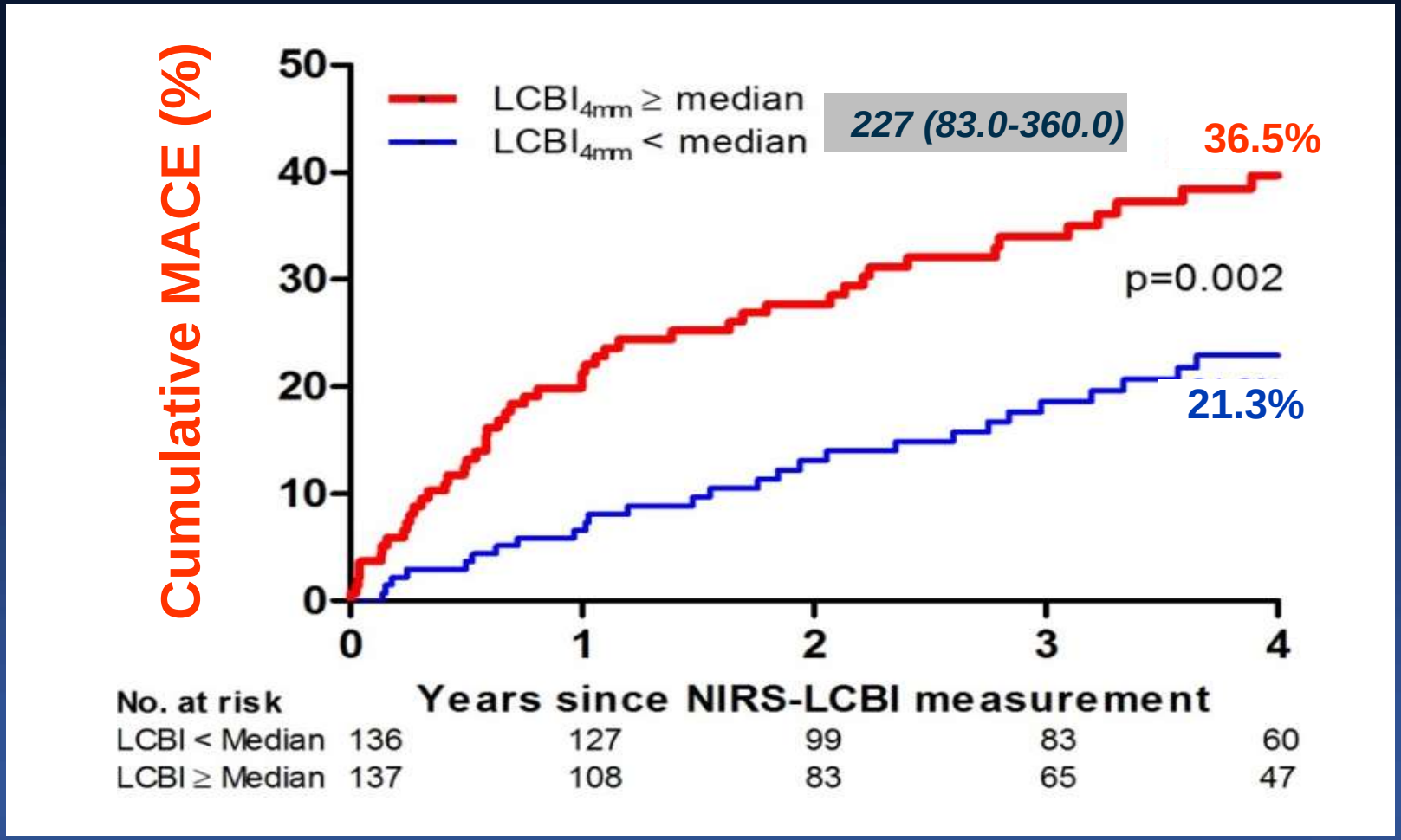
Near-infrared spectroscopy (NIRS)

UAP NSTEMI STEMI



Madder RD, Erlige, JACC Interv 2013, Cather Cardiovasc Interv 2015, Euro Atheroscl Soc 2013

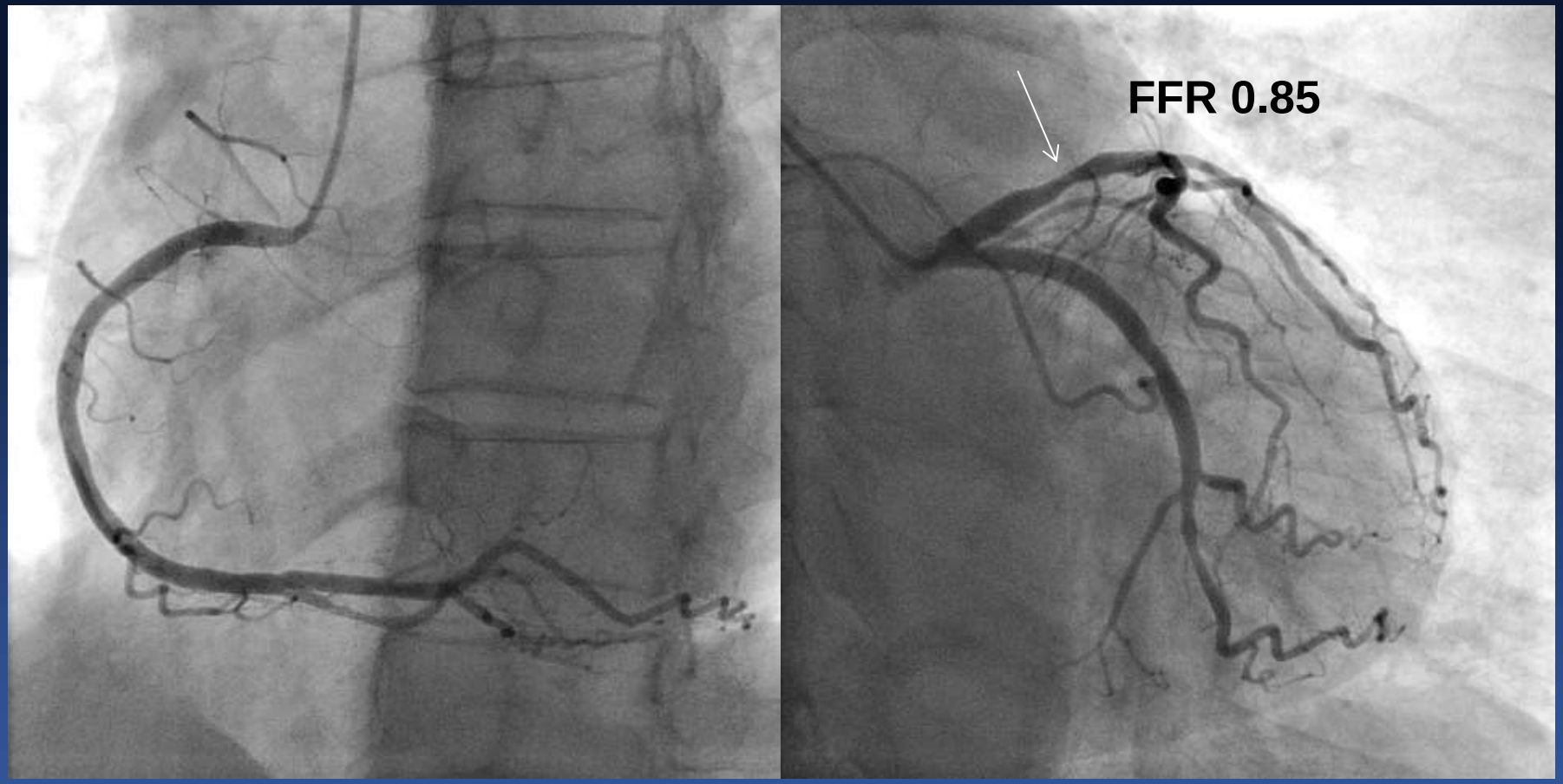
Lipid Core Burden Index (LCBI) Predicts MACE !



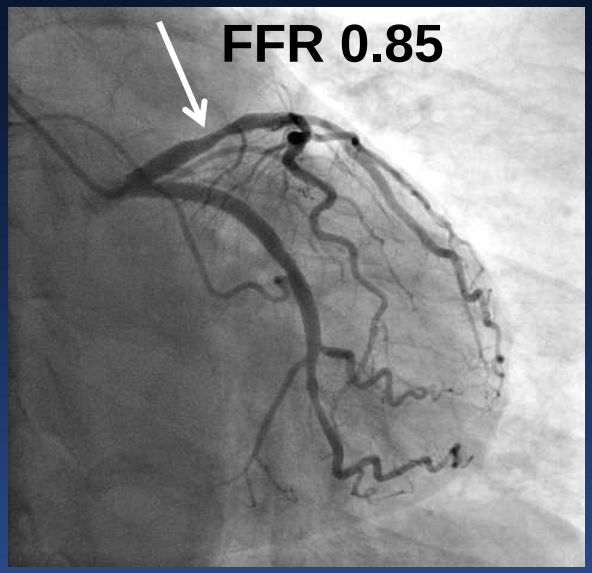
Schuurman et al. EHJ 2017 in press.

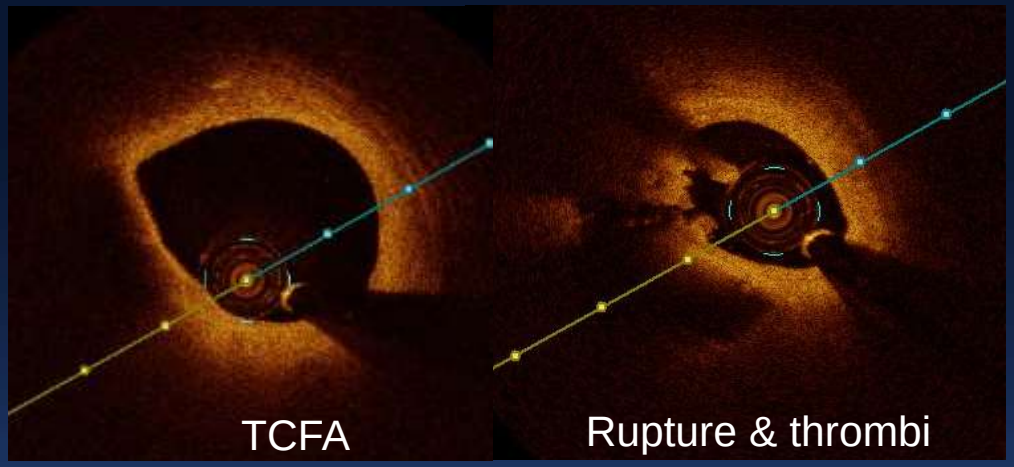
Cases

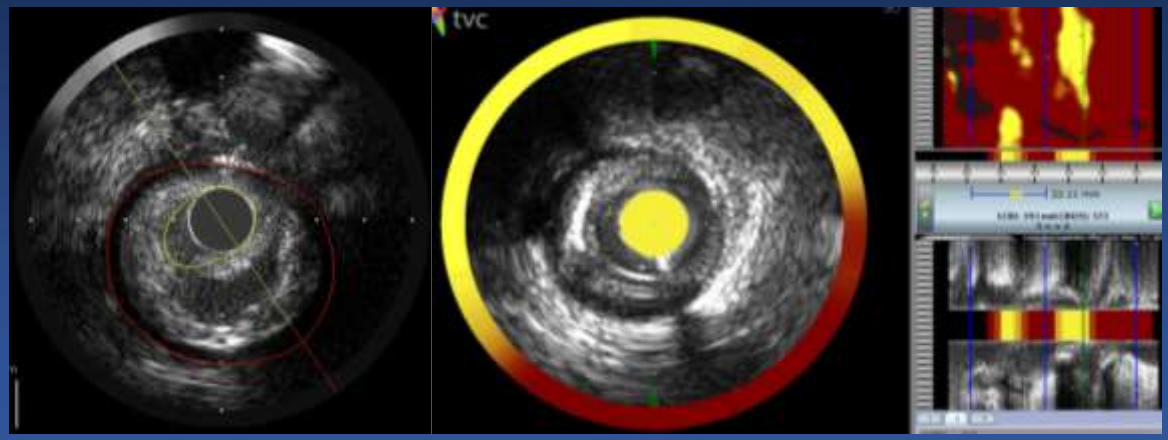
57 y/o Female,
Atypical Chest Pain



Vulnerable Plaque
by OCT & NIRS





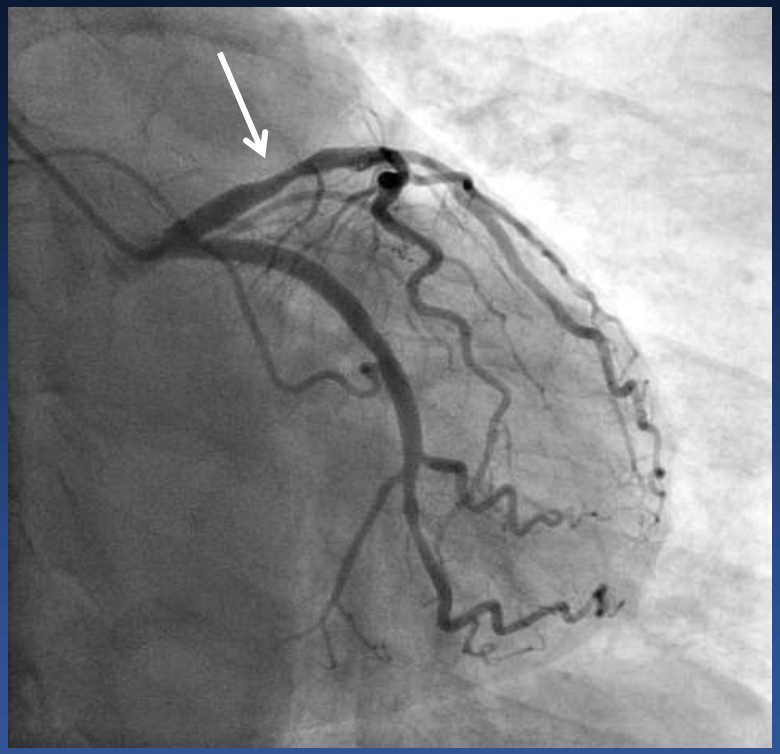


MLA 2.7 mm^2
Plaque burden 73%

maxLCBI 4mm : 571

To Treat or Not Tot Treat ?

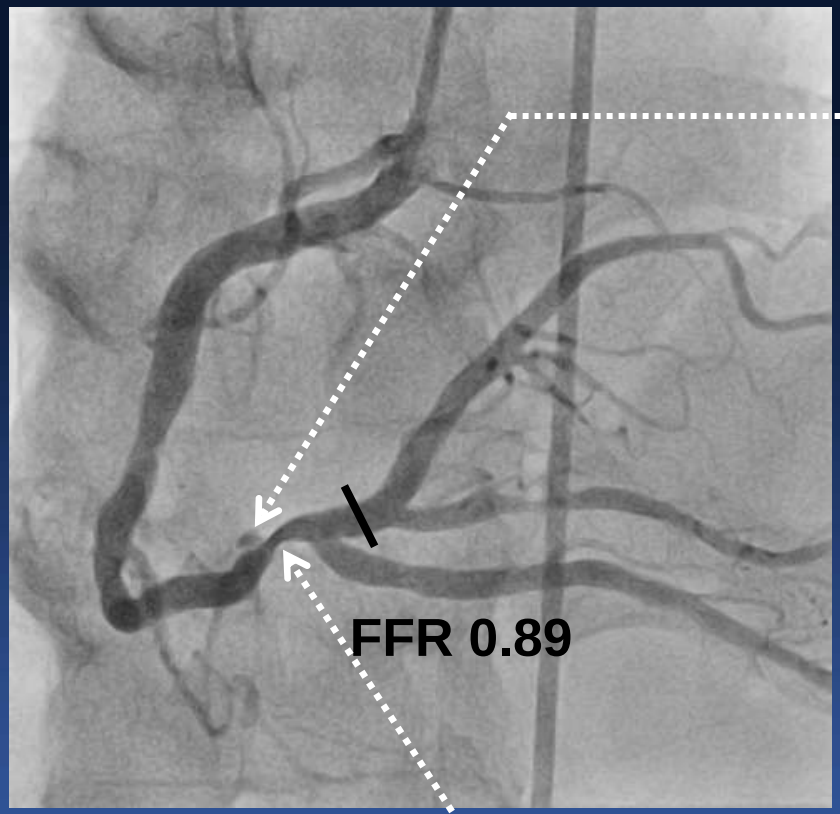
Functionally Insignificant Vulnerable Plaque

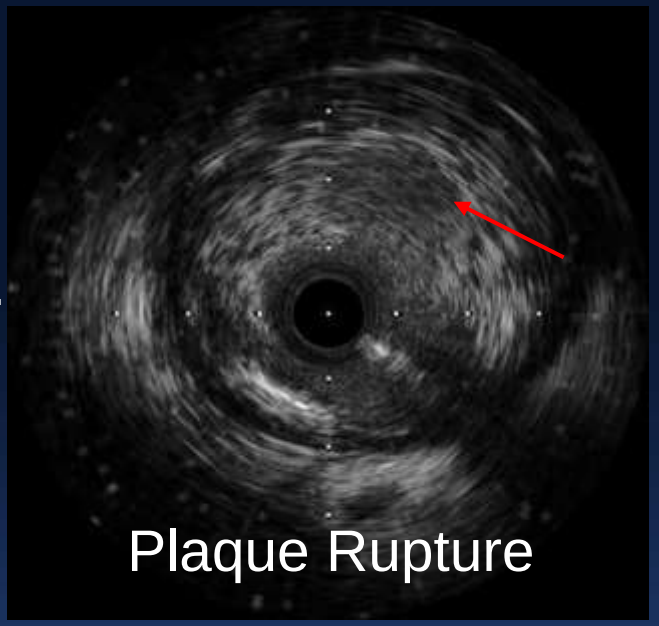


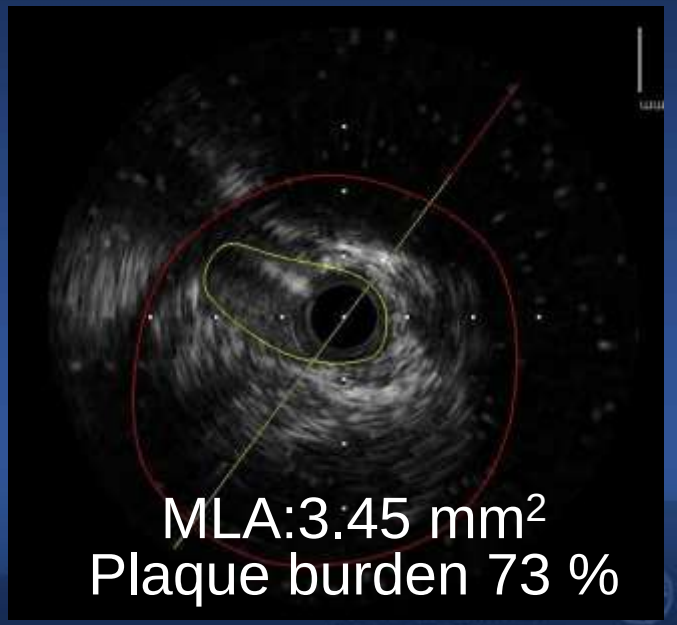
FFR : 0.85
Non-ischemic

IVUS MLA : 2.7 mm^2
Plaque burden : 73%
$_{max}LCBI_{4mm}$: 571
TCFA (+)

55 y/o male,
Atypical Chest Pain



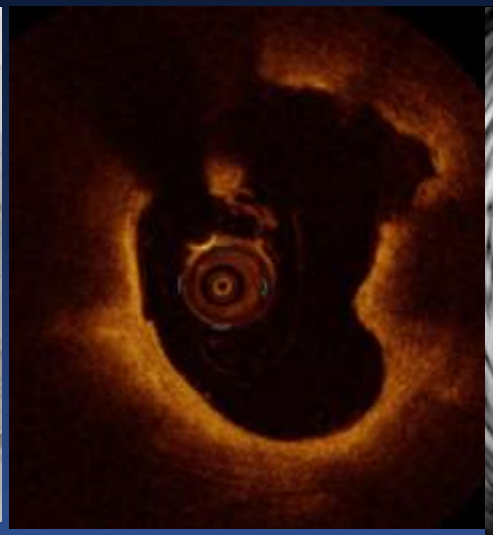


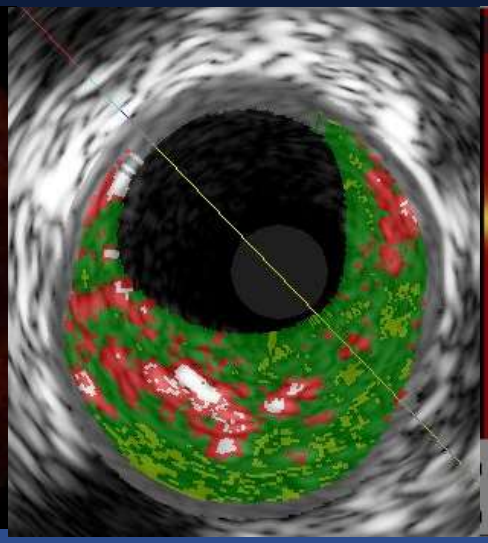


Vulnerable Plaque
by OCT, VH-IVUS & NIRS

Rupture, TCFA

$_{max}LCBI_{4mm}$= 404

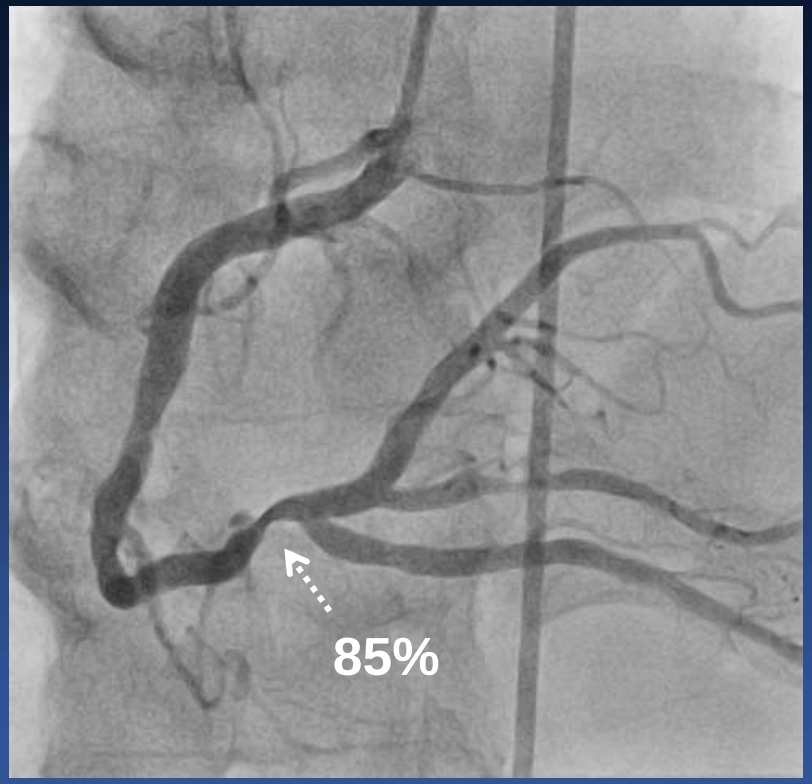




Necrotic Core 25%

To Treat or Not Tot Treat ?

Functionally Insignificant Vulnerable Plaque



No Chest Pain
FFR : 0.89
Non-ischemic

IVUS MLA : 3.45 mm^2
Plaque burden : 73%
$_{max}LCBI_{4mm}$: 404
TCFA (+)

Background

Q1,

Can Optimal Medical Treatment Stabilize Plaque Vulnerability ?

STABLE Trial

(*ST*atin and *A*theroma Vulnera*B*i*L*ity *E*valuation)
Double-blinded, Prospective, Randomized, Controlled Trial

290 patients with
Deferred native coronary artery lesion

2:1 randomization, double-blinded

Rosuvastatin 40mg

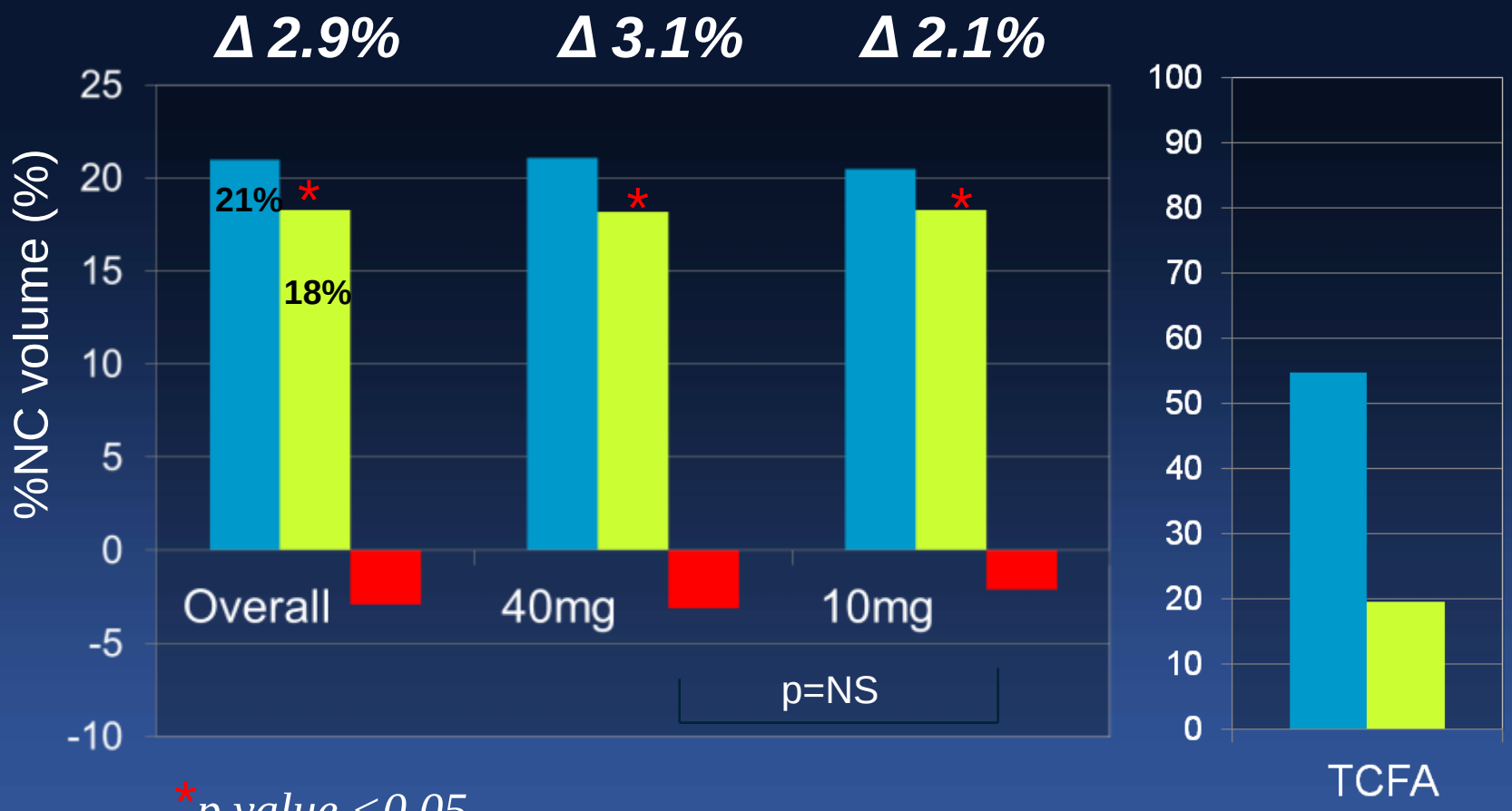
Rosuvastatin 10mg

Primary efficacy endpoint; Change in %NC volume within target segment by VH-IVUS at 1 year

Secondary endpoint: change in %NC volume comparing rosuvastatin 40mg vs. 10mg.

Park SJ, Kang SJ et al, JACC 2016;67(15):1772-1783

Primary Endpoint
%NC Volume Changes at 1 Year



*p value <0.05

Park SJ, Kang SJ et al, JACC 2016;67(15):1772-1783

Q2,

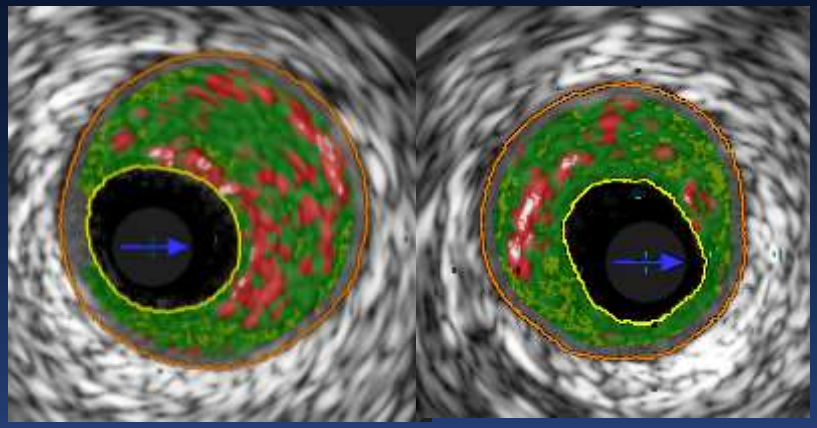
Can BVS
Stabilize Plaque Vulnerability and
Make an Any Difference ?

BRS Concept Is Perfect !

Disappeared,
Plaque Stabilization,
Lumen Enlargement,
Restored Vasomotor tone

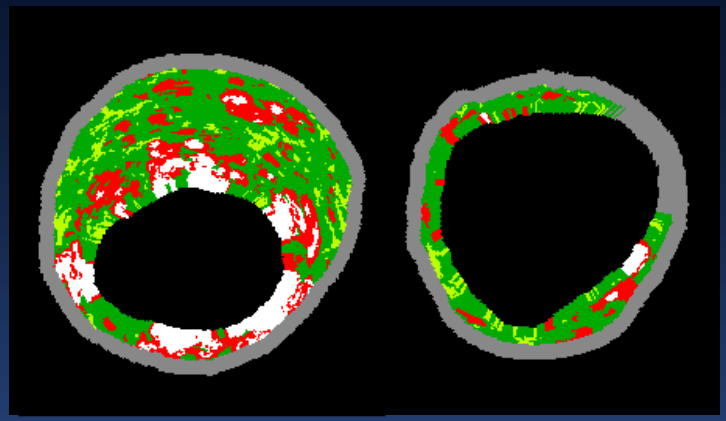
What's the Difference ?

Optimal Medical Treatment



Stabilized Plaque Vulnerability
Decreased Plaque Volume
Decrease Vessel Size
Decreased Lumen

BVS

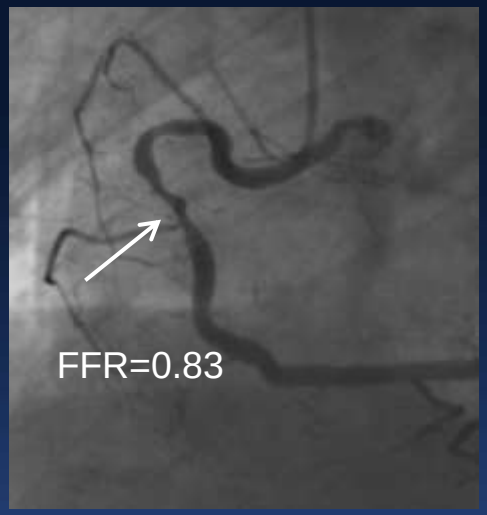


Local Treatment
Stabilized Plaque Vulnerability
Decreased Plaque Volume
Decrease Vessel Size
Increased Lumen

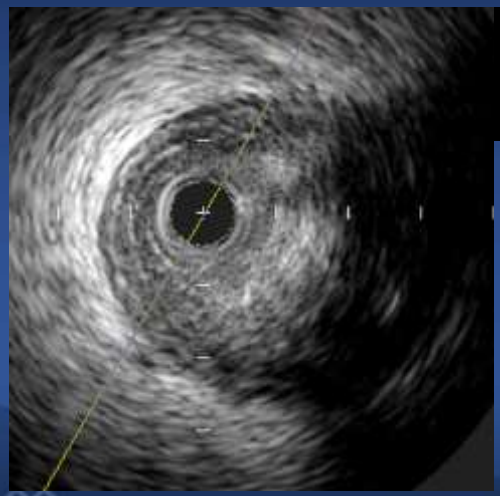
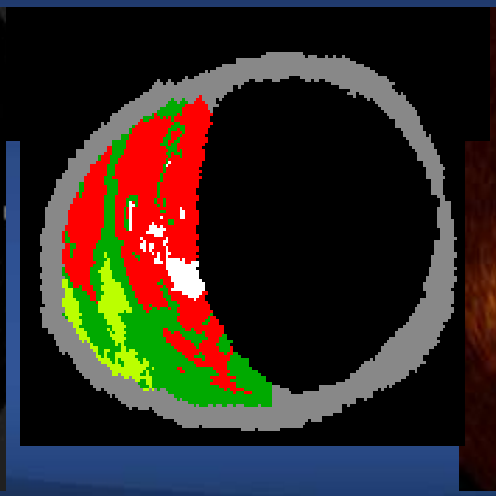
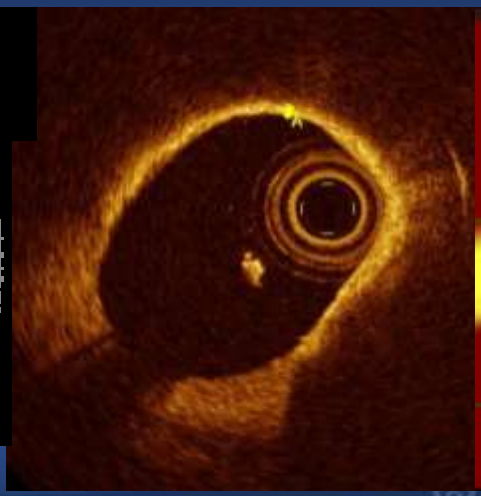
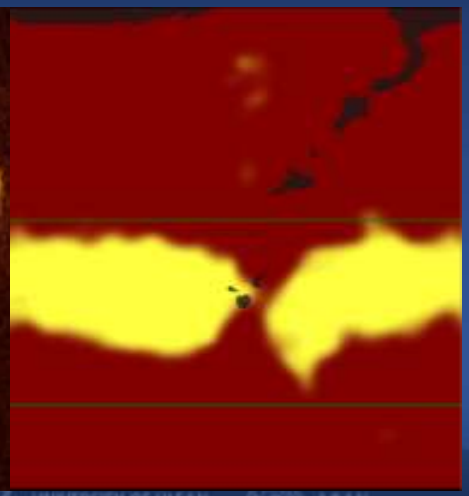
PREVENT Study,

The ***PREVENT***ive Implantation of BVS on Stenosis With Functionally Insignificant Vulnerable Plaque Compared to Optimal Medical treatment.

Defining, Functionally Insignificant Vulnerable Plaque



1. PB_{MLA} ≥70%
2. MLA ≤4.0 mm^2
3. TCFA by OCT or VH-IVUS
4. LRP on NIRS ($_{max}LCBI_{4mm}$>315)

PREVENT Trial

Any Epicardial Coronary Stenosis (≤ 40 mm) **with** ***FFR ≥0.80*** **and with** ***Two*** **of the following**

1. Plaque Burden >70%
2. MLA ≤4.0mm^2
3. TCFA by OCT or VH-IVUS
4. Lipid-Rich Plaque on NIRS ($_{max}LCBI_{4mm}$>315)

R

BVS+OMT
N=800

OMT
N=800

Primary endpoint *at 2 years*:
CV death, MI, Hospitalization d/t unstable angina

OCT sub-study/ NIRS sub-study, (300 patients in each arm at 2 years)

BRS Is Gone !

Disappeared in Our Practice.

PREVENT Trial

Any Epicardial Coronary Stenosis (≤ 40 mm) **with** ***FFR ≥0.80*** **and with** ***Two*** **of the following**

1. Plaque Burden >70%
2. MLA ≤4.0mm^2
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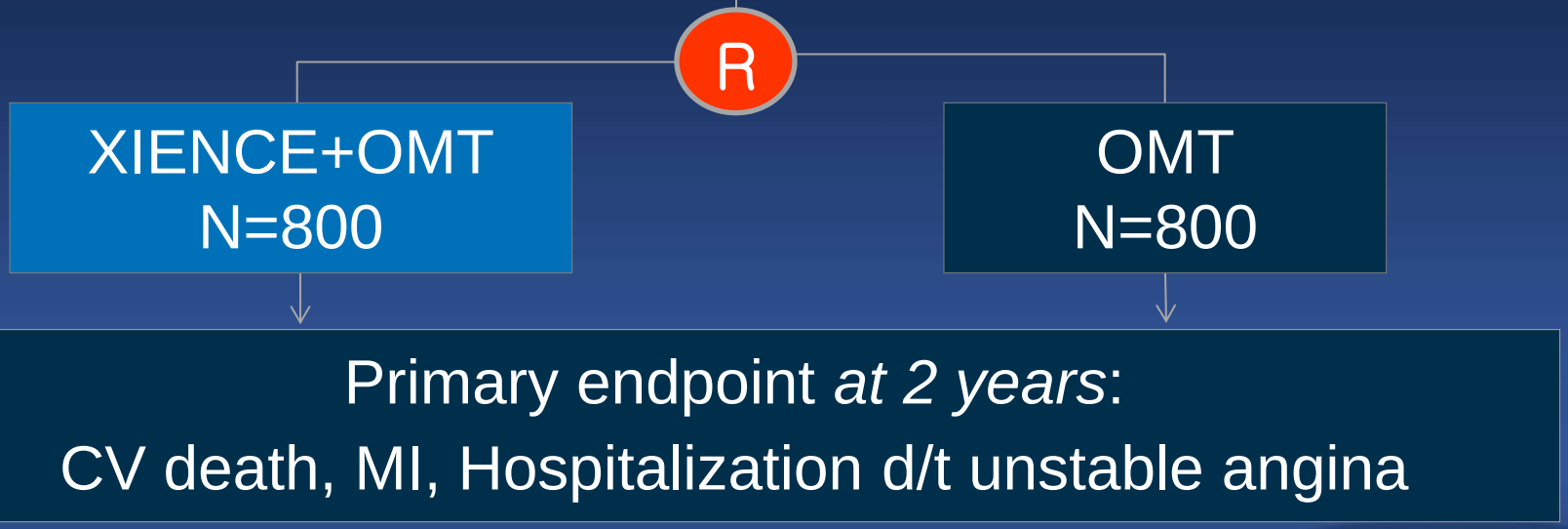


OCT sub-study/ NIRS sub-study, (300 patients in each arm at 2 years)

Inclusion Criteria

Age 18 years or older,
Symptomatic or asymptomatic coronary stenosis,
Eligible lesions for PCI (≤ 40 mm), with
FFR >0.80 and met the two of the following

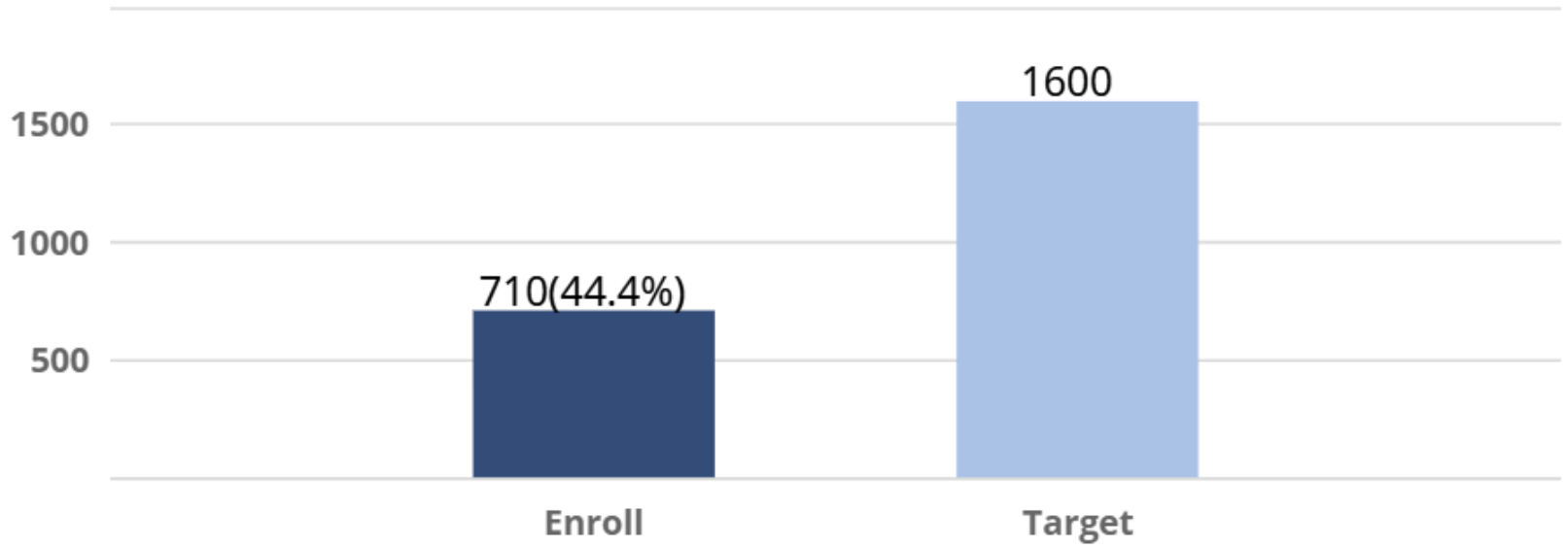
1. Plaque burden>70%
2. MLA<4mm2
3. TCFA by OCT or VH-IVUS
4. Lipid-rich plaque on NIRS ($_{max}LCBI_{4mm}$>315)

Primary and Major Secondary End Point,

The primary endpoint is the 2-year MACE (cardiovascular death, nonfatal MI, unplanned rehospitalization due to unstable angina).

The secondary endpoints include overall MACE, non-urgent revascularization, and rate of cerebrovascular event.

Current Patients Enrollment 2018 April.



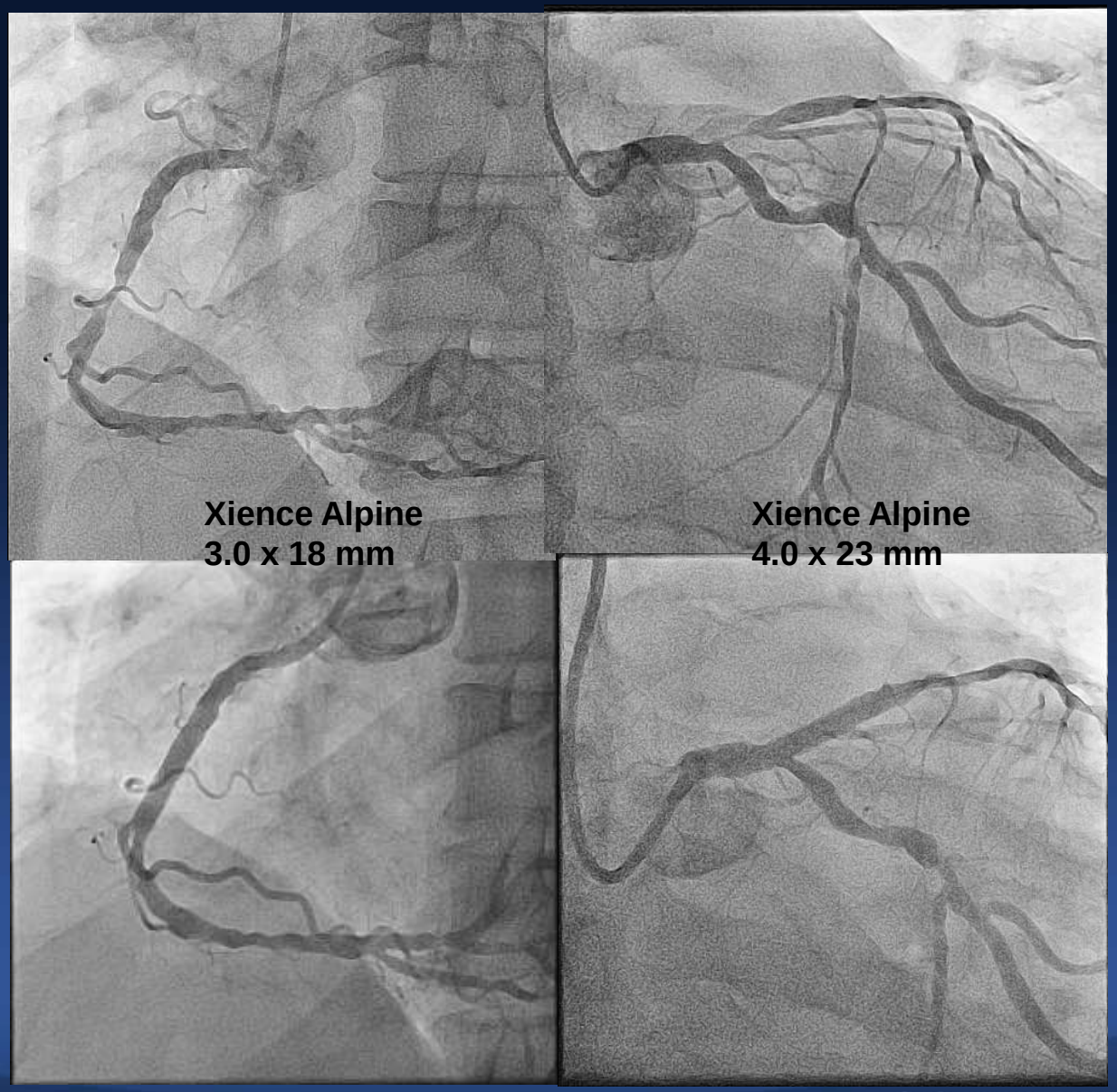
Event Cases During Follow-up

55 y/o male,
Unstable Angina

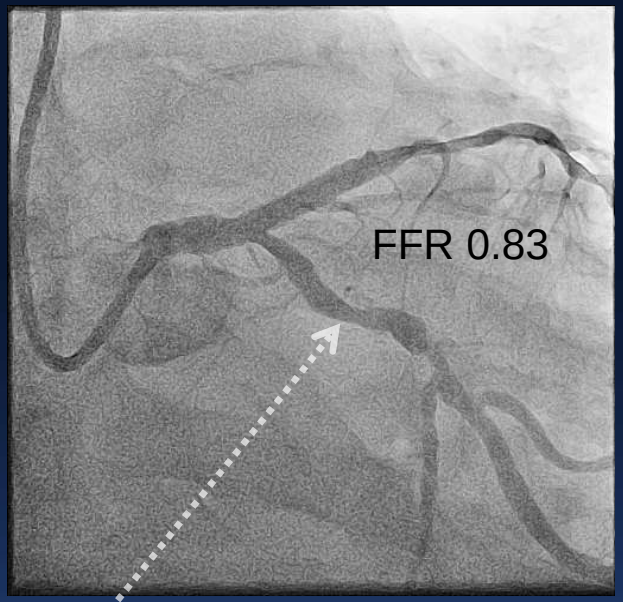
Culprit PCI for RCA and LM-pLAD

Pre

Post PCI

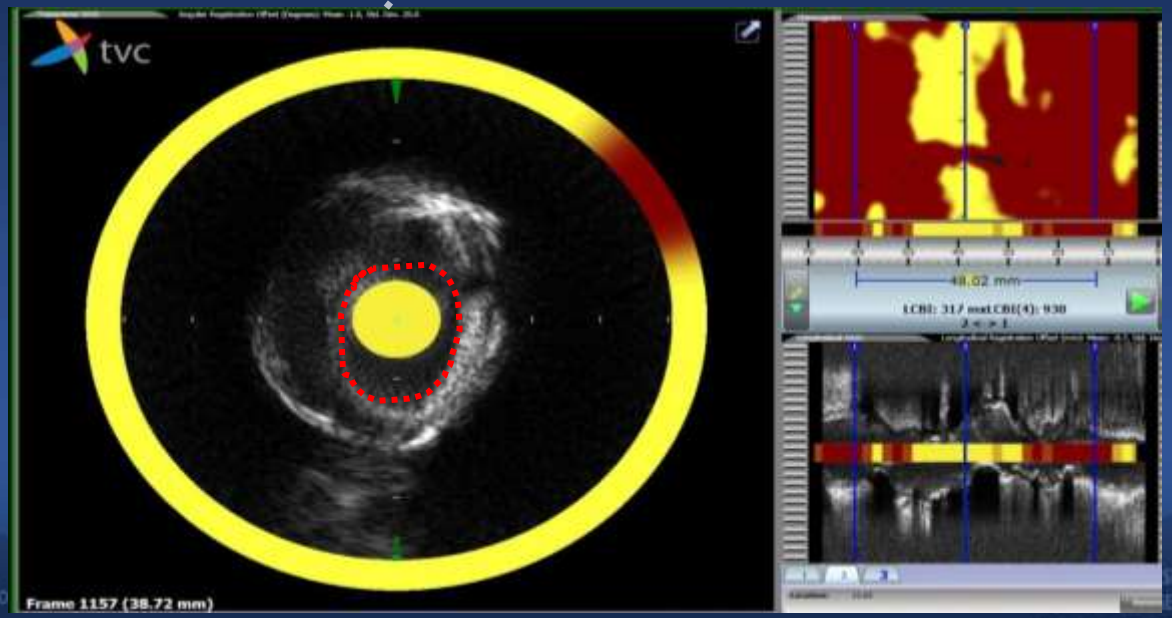


Non-Culprit LCX,
Randomized to OMT Group

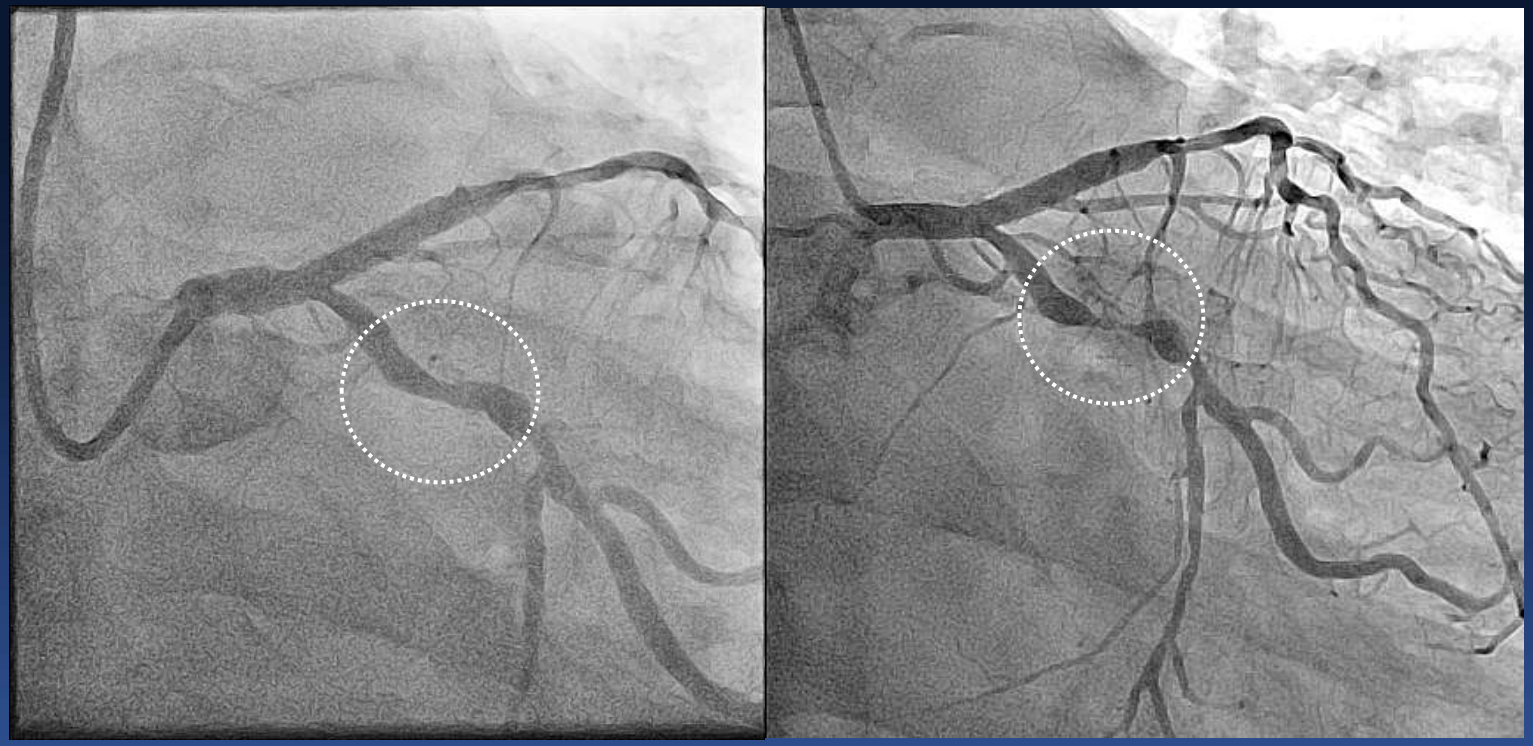


MLA 2.8 mm^2
Plaque burden 81%

max$LCBI_{4mm}$: 930

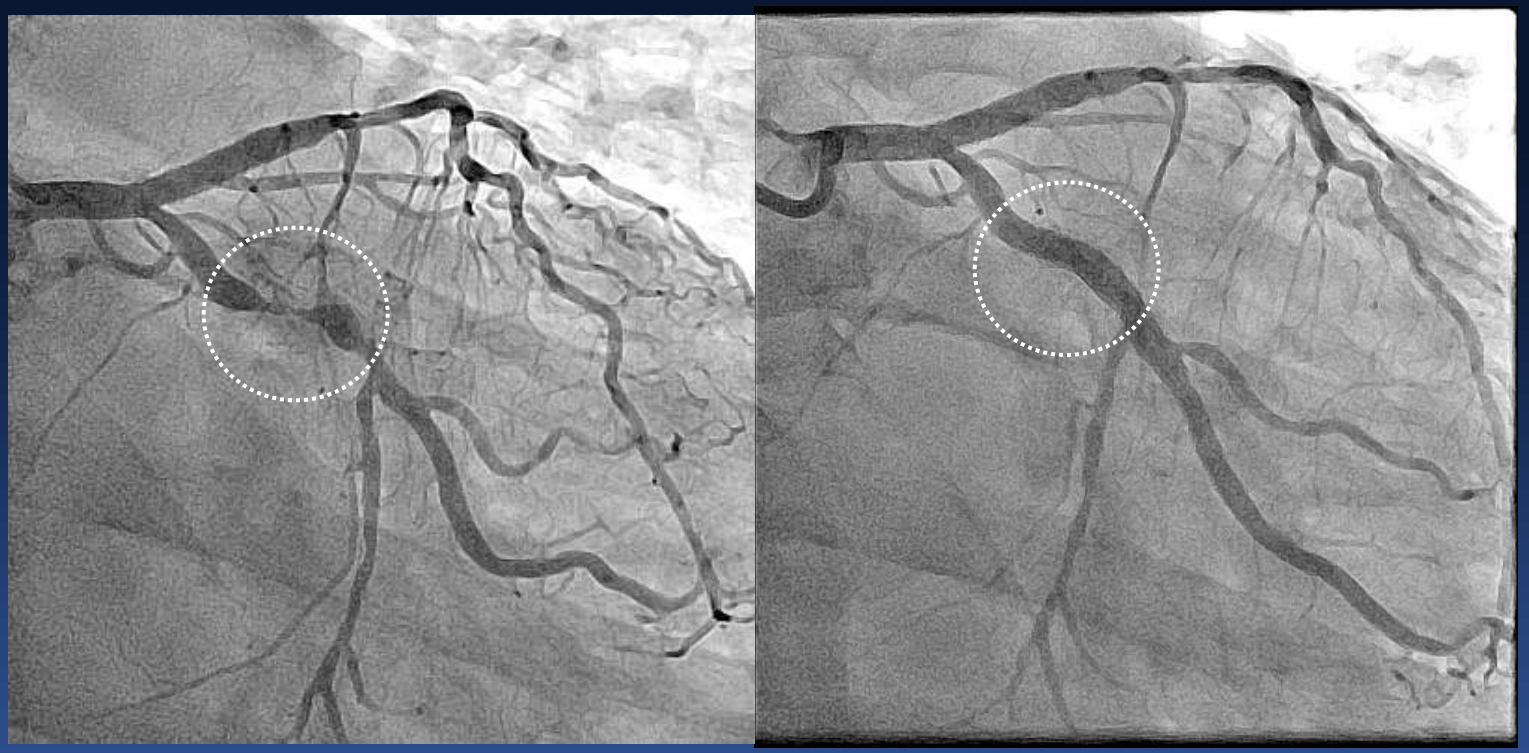


11 months later,
Recurred Chest Pain



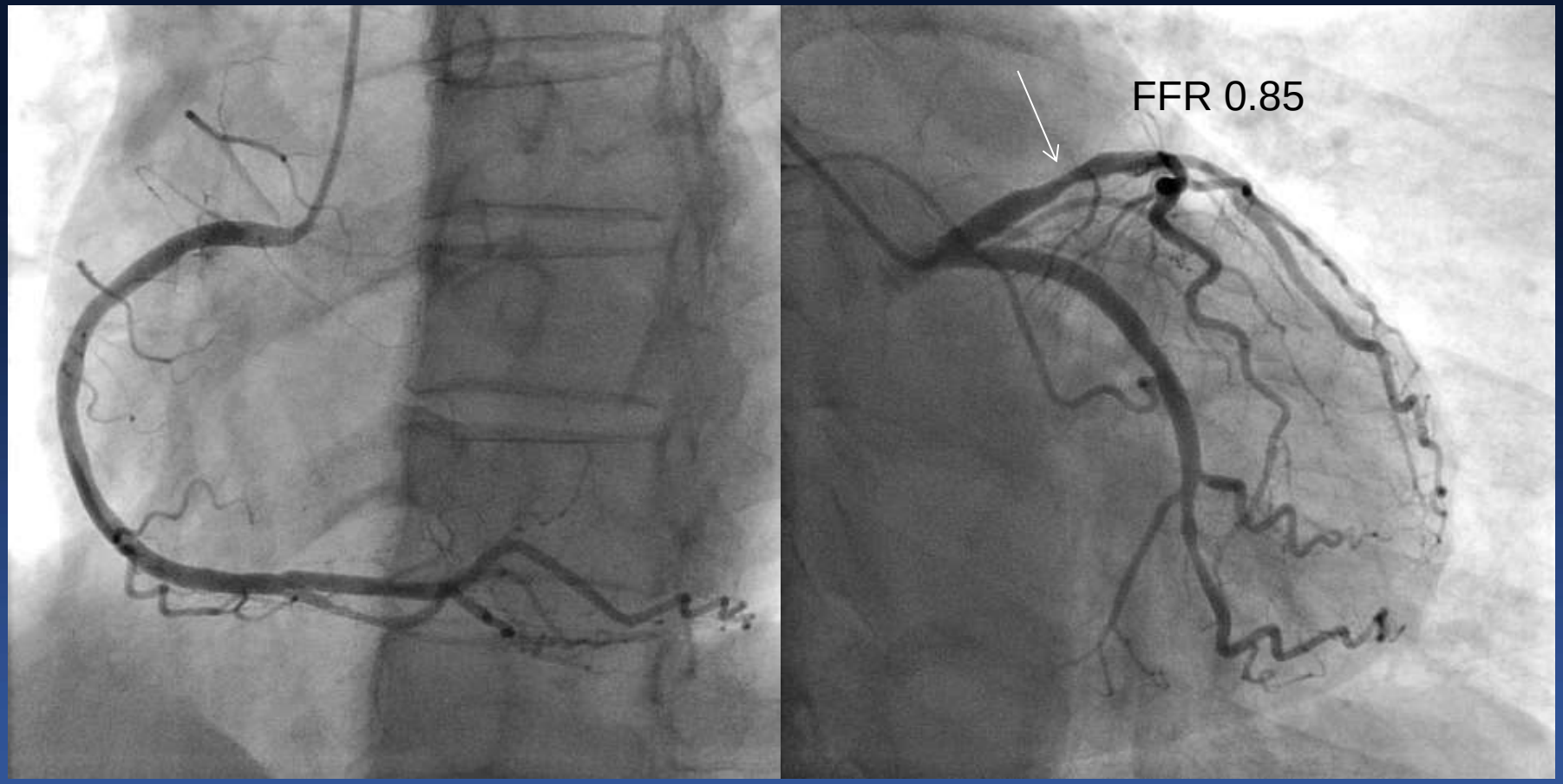
Disease Progression !

OMT group, PCI

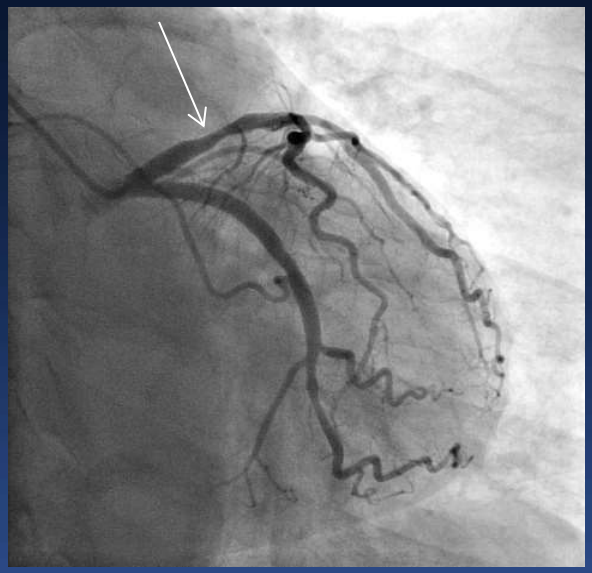


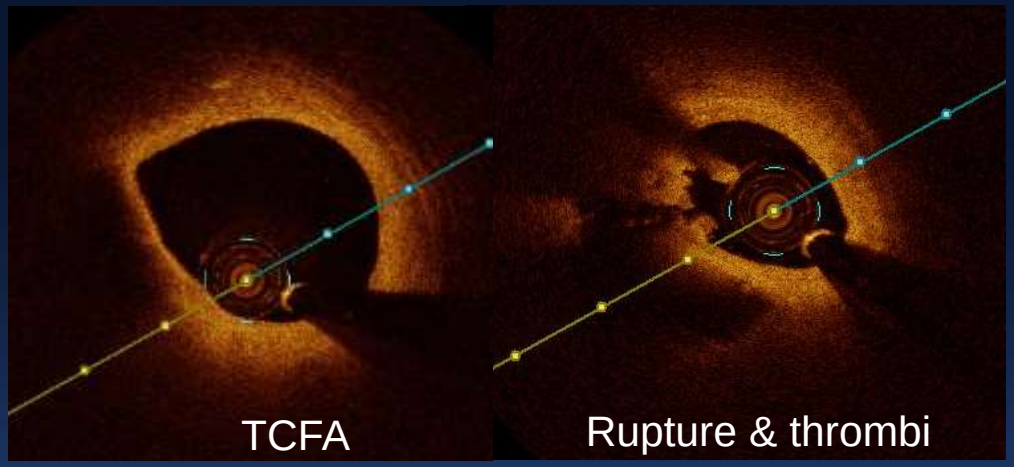
Xience Alpine
3.5 x 23mm

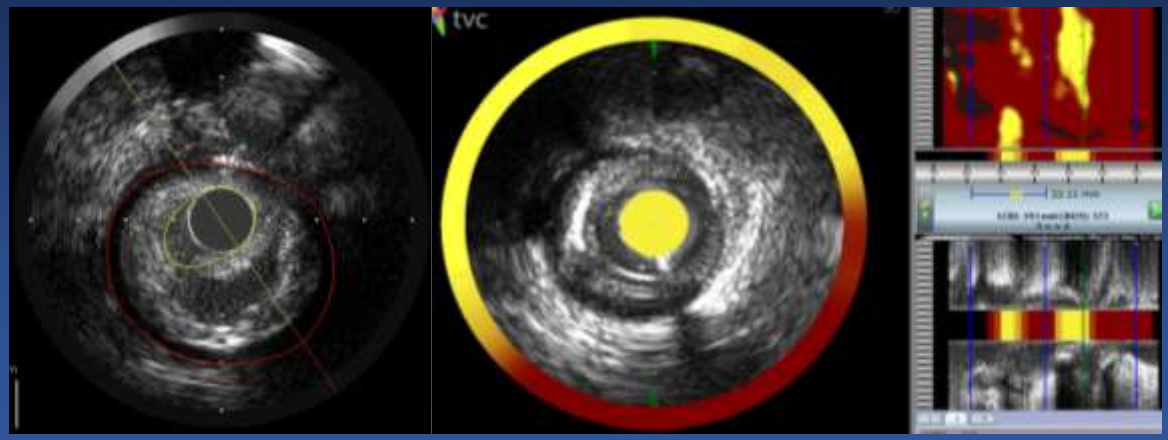
57 y/o Female,
Atypical Chest Pain



Vulnerable Plaque
by OCT & NIRS



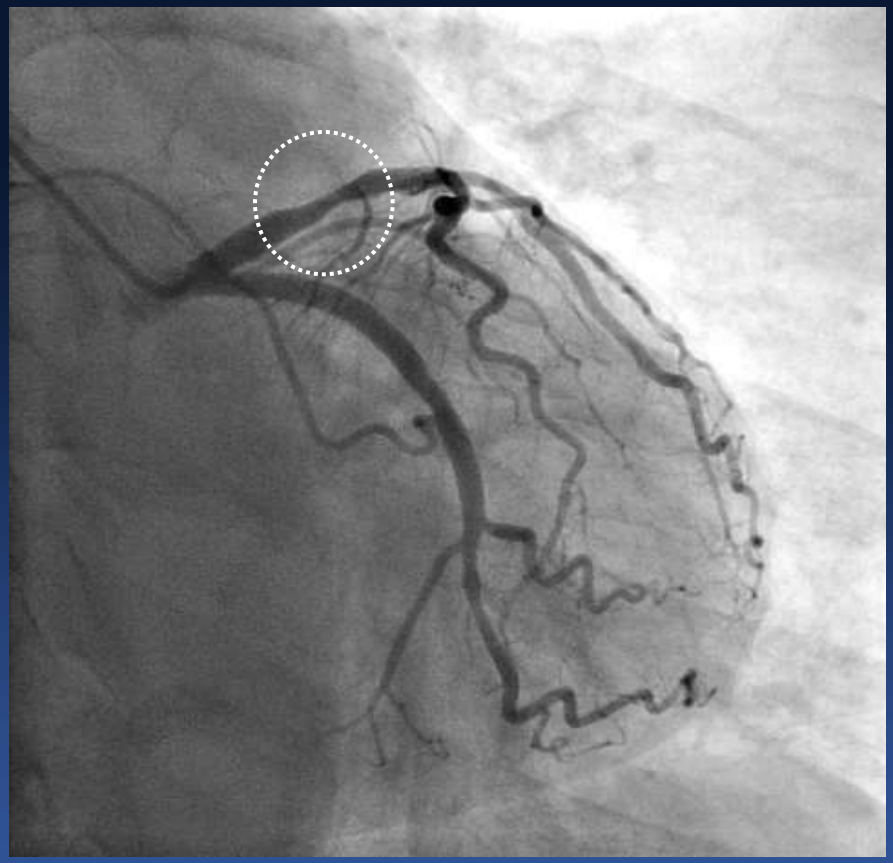




MLA 2.7 mm^2
Plaque burden 73%

maxLCBI 4mm : 571

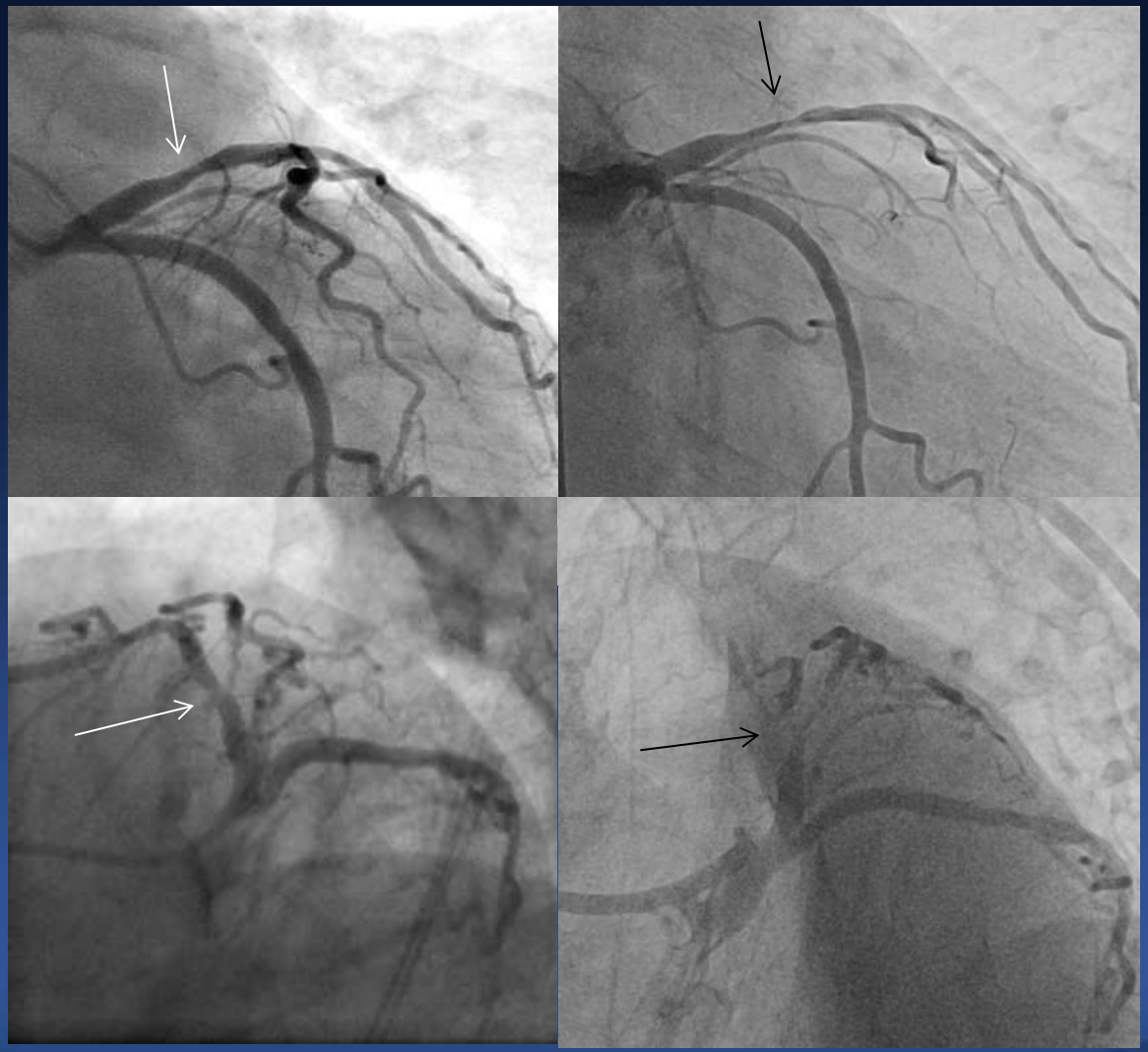
Randomized to OMT



FFR : 0.85
Angiographic DS : 50%
IVUS MLA : 2.7 mm^2
Plaque burden : 73%
$_{max}LCBI_{4mm}$: 571
TCFA (+)

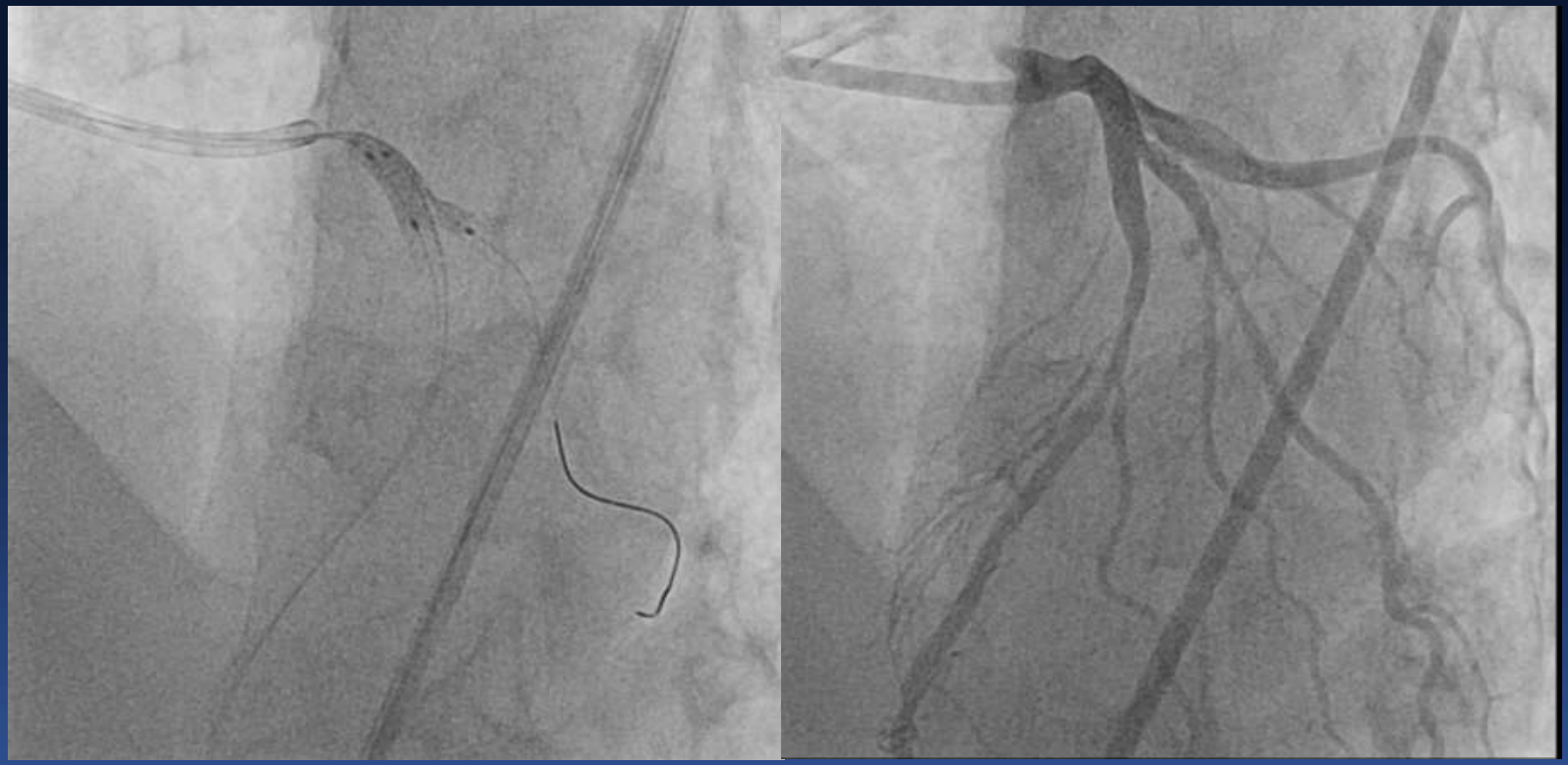
Functionally Insignificant Vulnerable Plaque

7 months later, Rest Chest Pain



Disease Progression !

OMT group, PCI



Resolute Onyx
3.5 x 18 mm
2.5 x 15 mm

To Treat or Not Tot Treat ?

Functionally Insignificant Vulnerable Plaque

Thank You !!

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