

NIRS-IVUS to Predict Long Term Outcome

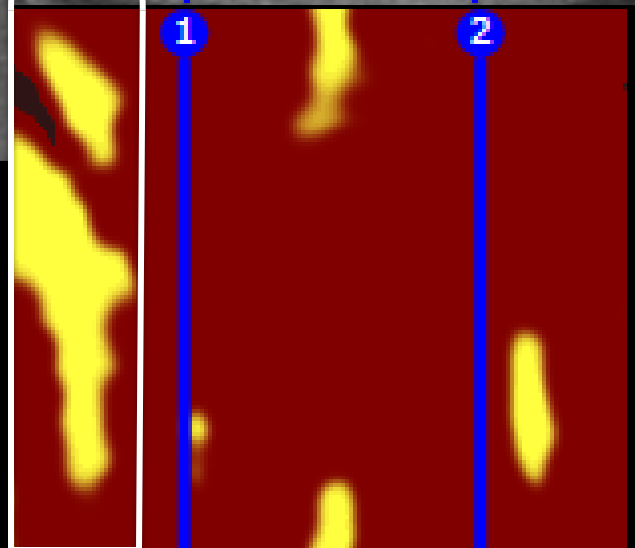
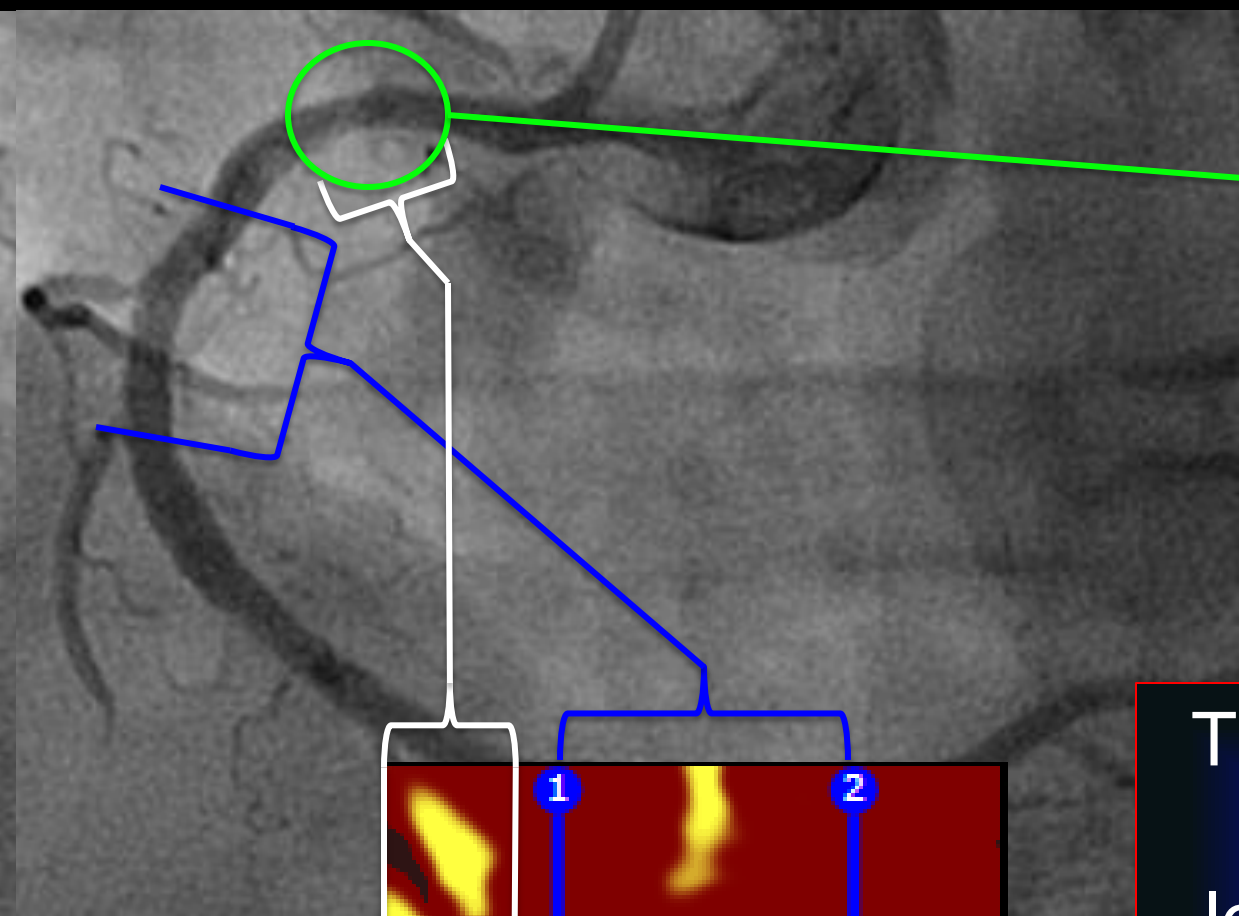
Akiko Maehara, MD

**Cardiovascular Research Foundation
Columbia University Medical Center
New York City, NY**

64 year old presents with STEMI in March 2012



Unstable angina October 2012



maxLCBI_{4mm}
694

This was the only de novo culprit lesion to emerge from the 462 coronary segments imaged at baseline

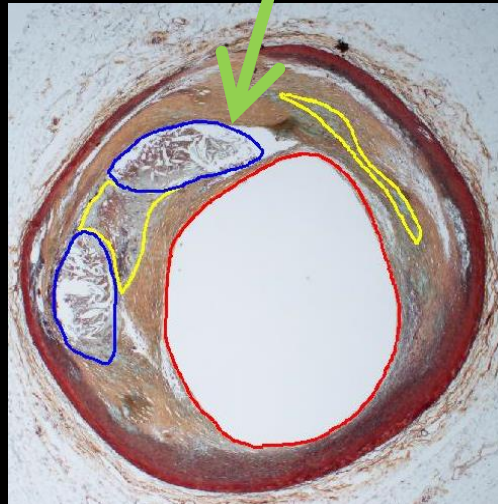
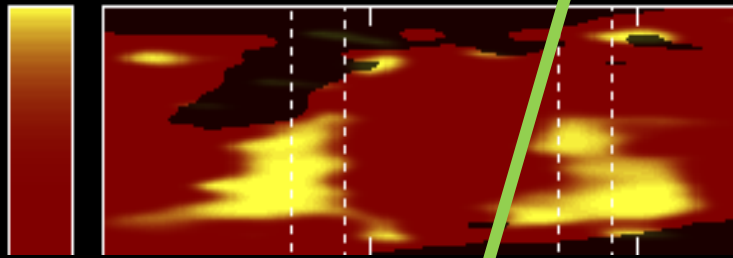
NIRS Collagen-deficient LCP Preliminary Algorithm:

Detection of Thin cap in an Autopsy Specimen

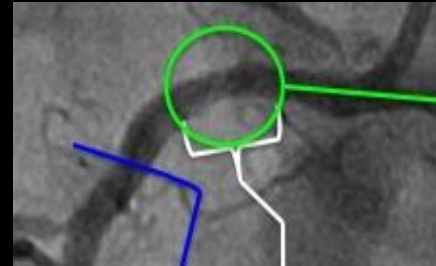
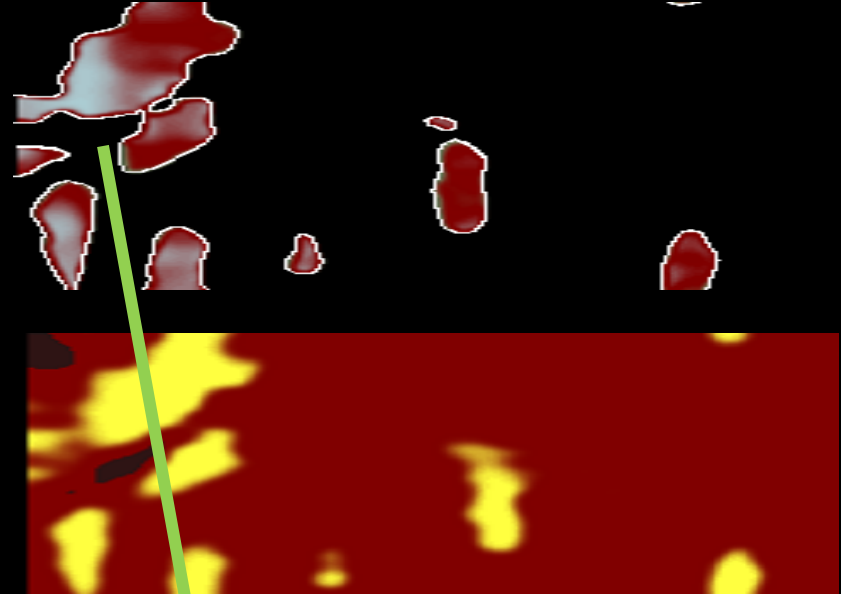
Blue signal indicates collagen-deficient signal over LCP



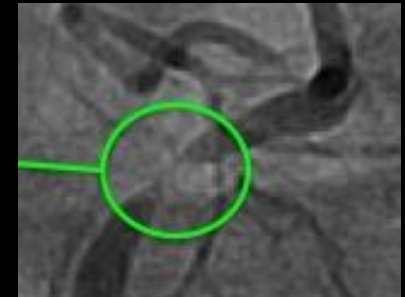
NIR CHEMOGRAM



Detection of Collagen Deficient Signal Over LCP in a Patient Followed by a Coronary Event



7
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Courtesy of Ryan Madder, MD
Sean Madden Ph.D and Joel Raichlen, MD



Frederik Meijer Heart & Vascular Institute



SPECTRUM HEALTH

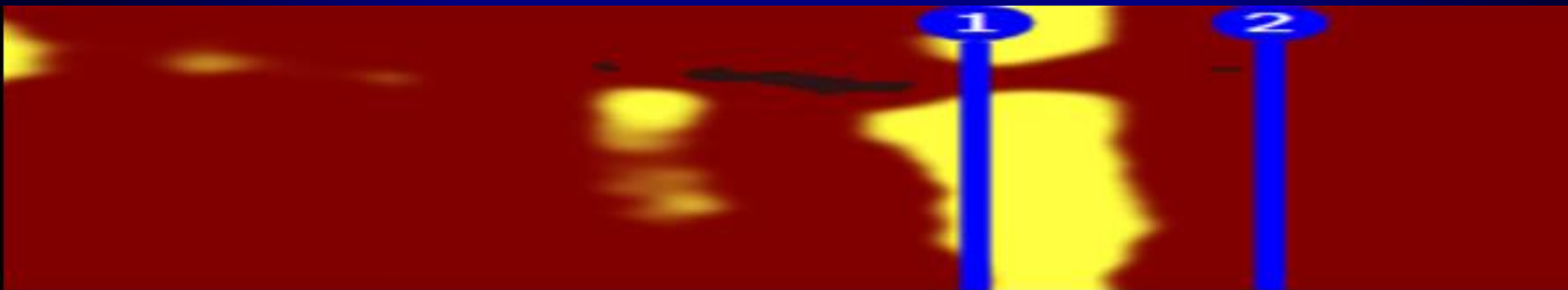
Identification of Vulnerable Patients by Intracoronary Near-Infrared Spectroscopy

Ryan D Madder, MD, FACC

Frederik Meijer Heart & Vascular Institute

Spectrum Health

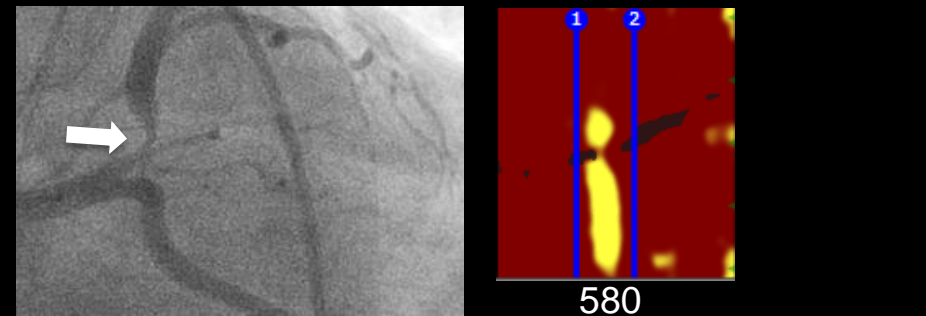
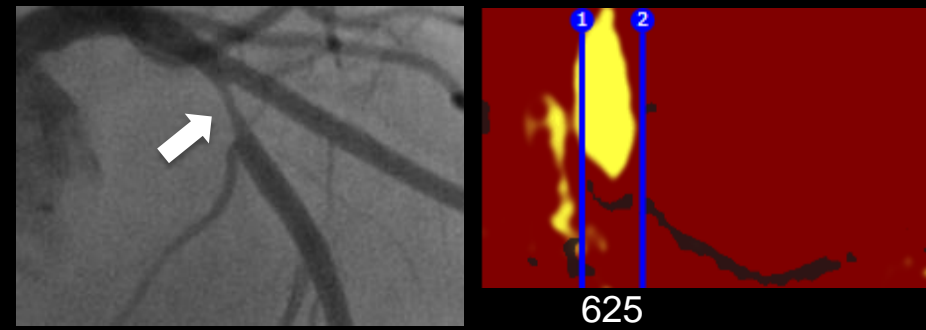
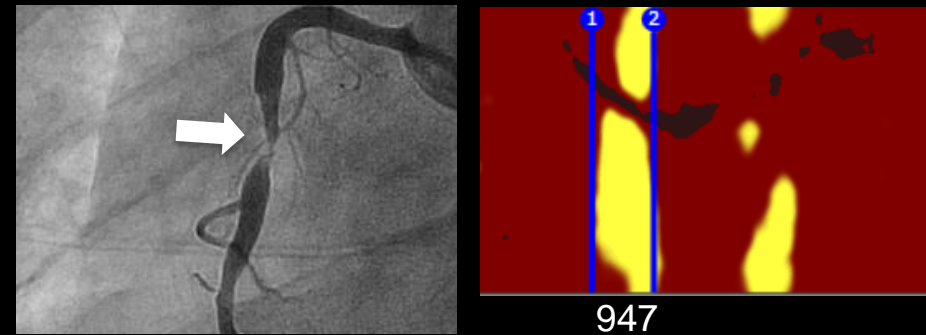
Grand Rapids, Michigan



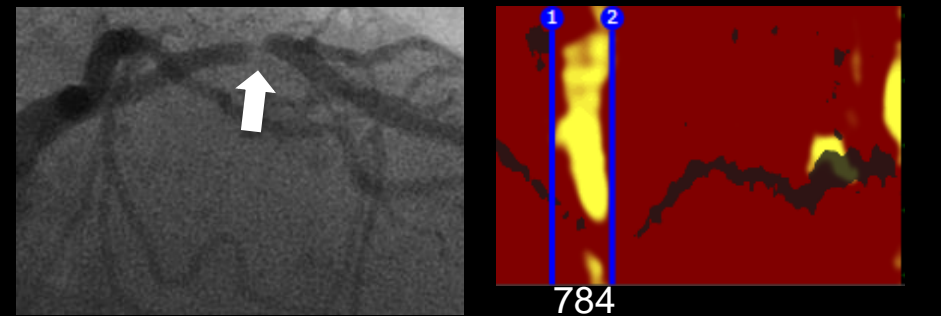
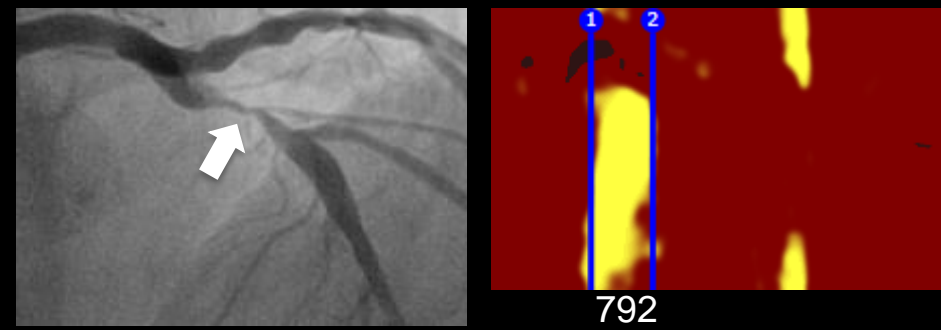
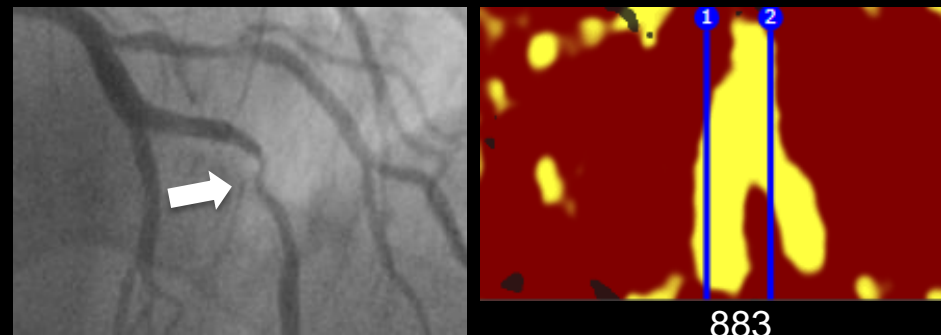


NIRS Findings in NSTEMI and Unstable Angina

NSTEMI



Unstable Angina



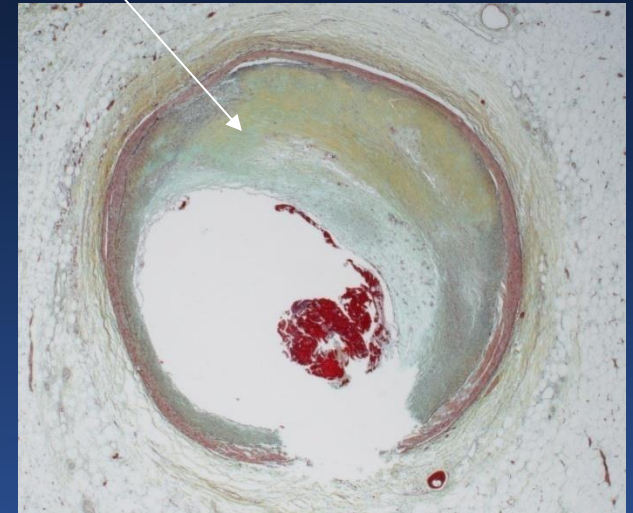
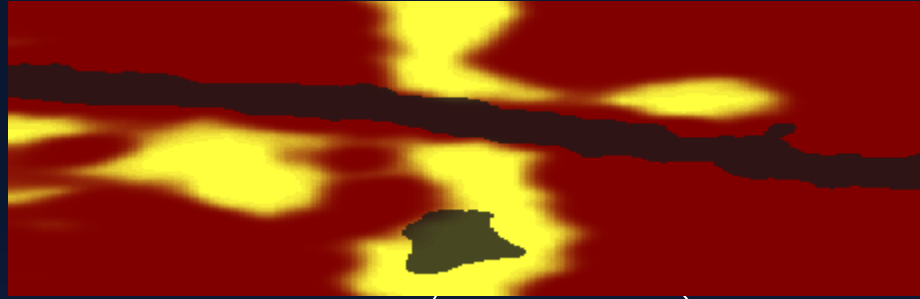


NIRS Findings in Sudden Cardiac Death

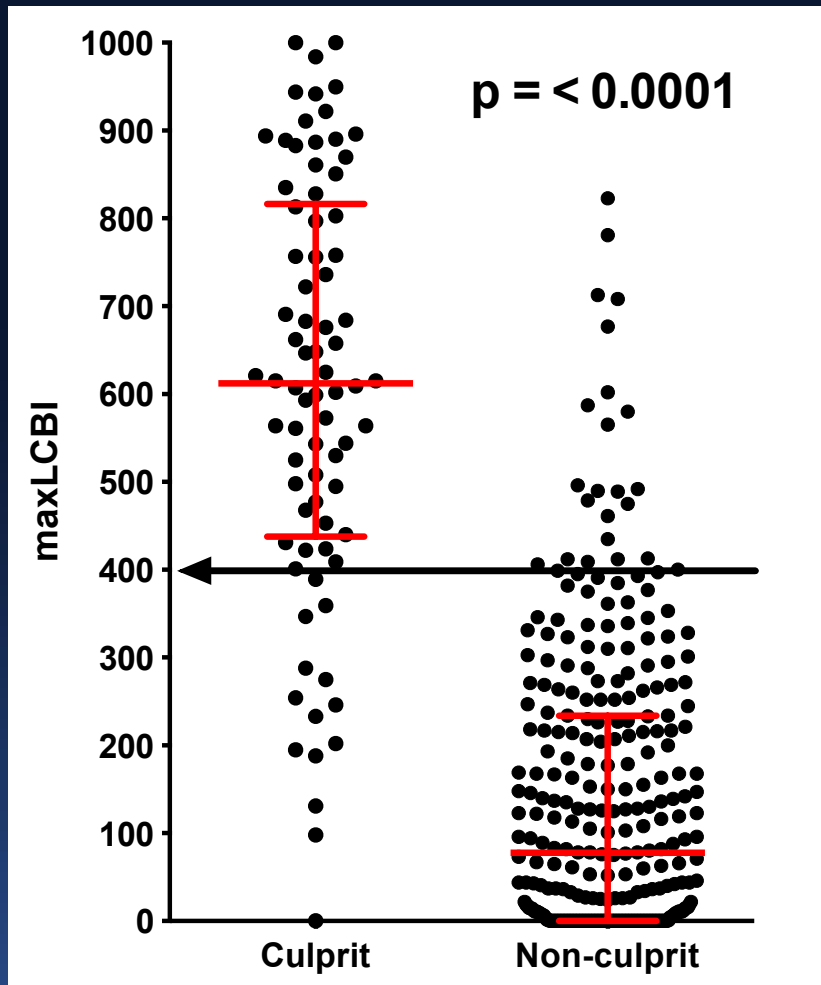
35 year old male with sudden cardiac arrest.



48 yo Male, Sudden Coronary Death



STEMI culprit vs. non-culprit segments



STEMI culprit lesions:
 $maxLCBI_{4mm} = 612 (438-817)$

Non-culprit lesions:
 $maxLCBI_{4mm} = 78 (0-234)$

MaxLCBI_{4mm} >400 was present at the STEMI culprit site in 63 of the 78 cases

MaxLCBI_{4mm} >400 was present at the non-culprit site in 22 of the 304 segments

Mann-Whitney U test
Median \pm interquartile range



Methods

Spectrum NIRS-IVUS Registry

- Single center, observational
- Prospectively enrolled patients undergoing NIRS-IVUS

Inclusion criteria

- Patients completing ≥ 1 year of follow-up

Exclusion criteria

- Prior CABG/referred for CABG
- Uninterpretable NIRS
- NIRS imaging performed only within a stented segment

January 2012 to April 2013

167 patients
NIRS-IVUS imaging
&
 ≥ 1 year of follow-up

→ Excluded

Prior CABG (7)

Referred for CABG (17)

Uninterpretable NIRS (15)

NIRS only in stent (7)

121 patients
included in this analysis

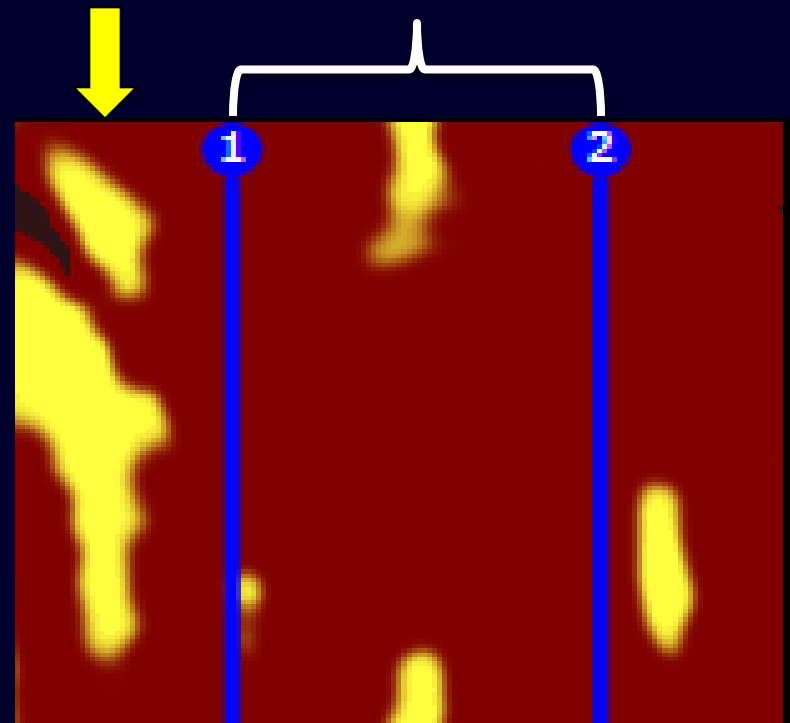


Methods

- Evaluated non-stented coronary segments for large LRP
 - defined as a $\max\text{LCBI}_{4\text{mm}} \geq 500$
- Patients followed for MACCE
 - Composite of all-cause mortality, recurrent ACS requiring revascularization, or acute cerebrovascular events
- Events related to previously stented segments were excluded
- All events adjudicated blinded to the NIRS-IVUS imaging

Large LRP
in
non-
stented
segment

Stented
segment
excluded
from
analysis





Baseline characteristics

Baseline characteristics N = 121

Age	62.5 ± 11.2
Male	83 (68.6)
BMI	30.2 ± 29.3
Ejection fraction	53 ± 12
Hypertension	70 (57.9)
Diabetes	24 (19.8)
History of smoking	79 (65.3)
Dyslipidemia	70 (57.9)
Chronic kidney disease	7 (5.8)
LDL-C	107 ± 38
HDL-C	44 ± 15

Index presentation N = 121

STEMI	45 (37.2)
Non-STEMI	18 (14.9)
Unstable angina	40 (33.1)
Stable symptoms	18 (14.9)

Discharge meds N = 121

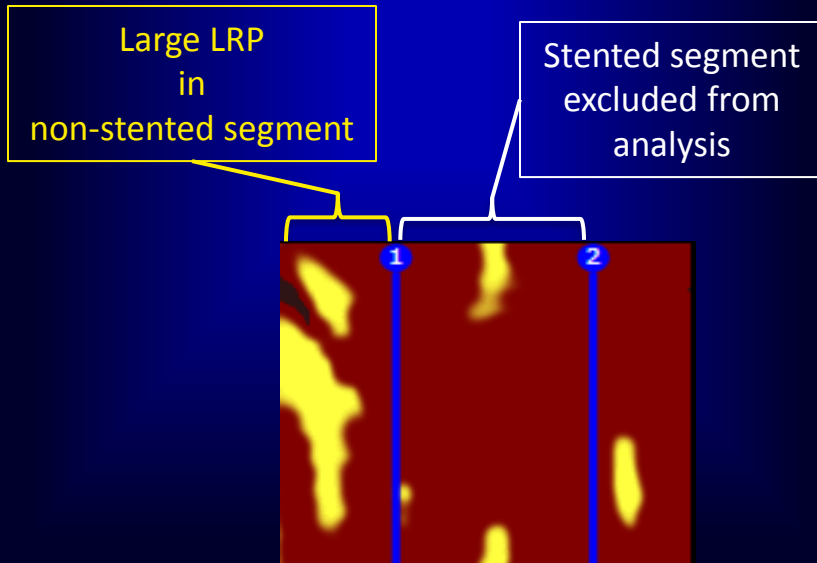
Aspirin	119 (98.3)
P2Y12 inhibitor	111 (91.7)
Beta-blocker	110 (90.9)
ACEI/ARB	86 (71.1)
Statin	115 (95.0)



Results

Baseline NIRS Findings

- 462 non-overlapping 10-mm coronary segments analyzed
- A large LRP was detected in 15 (3.2%) segments & in 12 (9.9%) patients



Follow Up Events

- Average follow-up duration was 603 ± 145 days (1.7 years)
- MACCE (unrelated to previously stented segments) occurred in **11.6%** of patients during follow up
 - ➔ All-cause death 4.1%
 - ➔ ACS requiring revascularization 6.6%
 - ➔ CVA 0.8%



Patient-Level Factors Associated with MACCE

	MACCE N = 14	No MACCE N = 107	P-value
Age	63.9 ± 10.7	62.3 ± 11.3	0.62
Male	9 (64.3)	74 (69.2)	0.76
Ejection fraction	48.9 ± 14.1	53.8 ± 11.3	0.23
Diabetes	5 (35.7)	19 (17.8)	0.15
Chronic kidney disease	2 (14.3)	5 (4.7)	0.19
Statin	13 (92.9)	102 (95.3)	0.53
MI at presentation	9 (64.3)	54 (50.5)	0.50
Large LRP in non-stented segment	7 (50.0)	5 (4.7)	<0.001

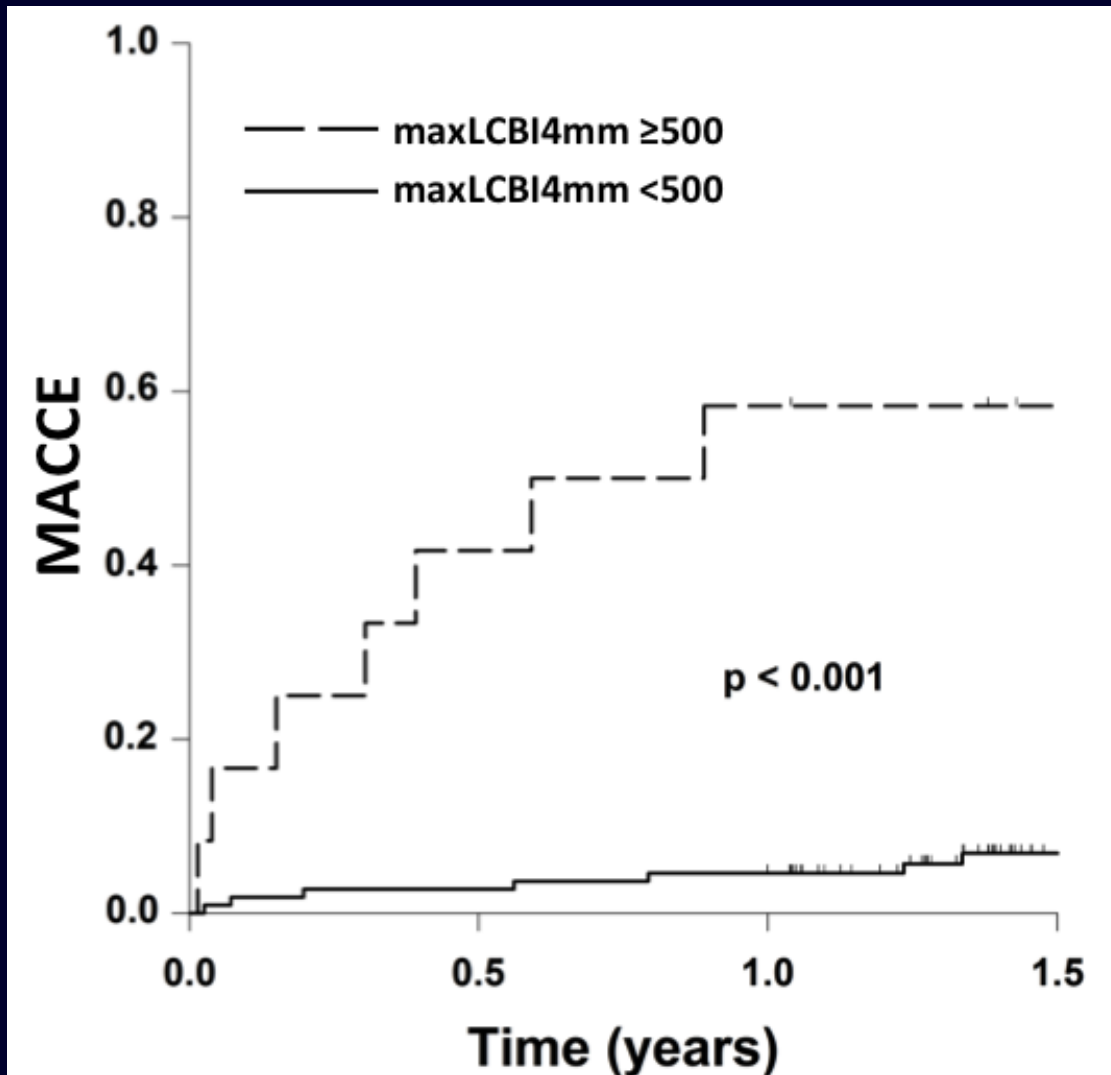
By multivariable analysis, a large LRP in a non-stented segment at baseline was the only independent predictor of:

* **MACCE (HR 13.3, 95% CI 4.6 – 38.3, p<0.001)**

* **ACS requiring revascularization (HR 8.5, 95% CI 2.0 – 35.8, p=0.004)**



Large LRP by NIRS and MACCE



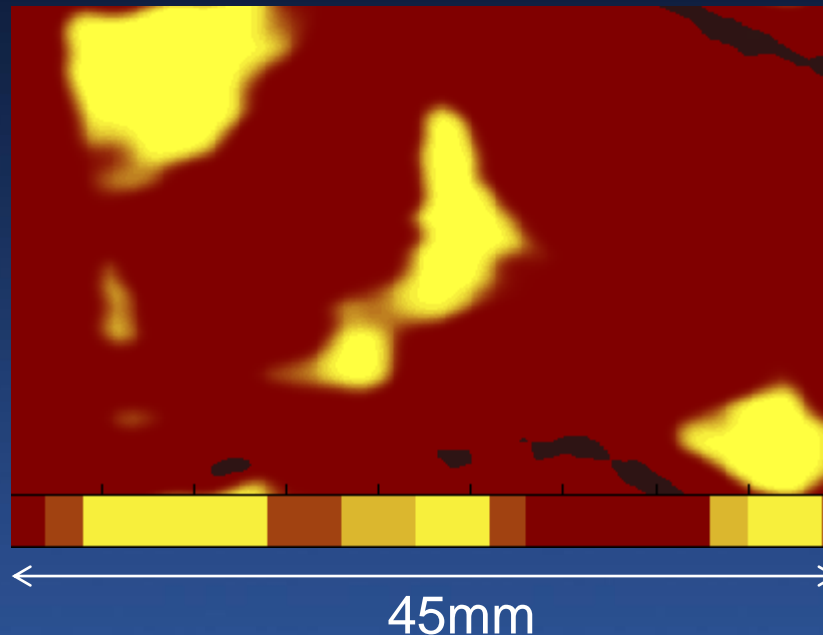
MACCE Rate
Large LRP 58.3%
vs
No large LRP 6.4%
($p < 0.001$)

ACS Requiring Revascularization
Large LRP 25.0%
vs
No large LRP 4.6%
($p < 0.001$)

Relationship between Lipid Rich Plaque detected by NIRS and Outcomes

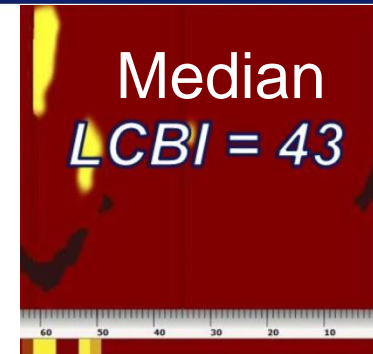
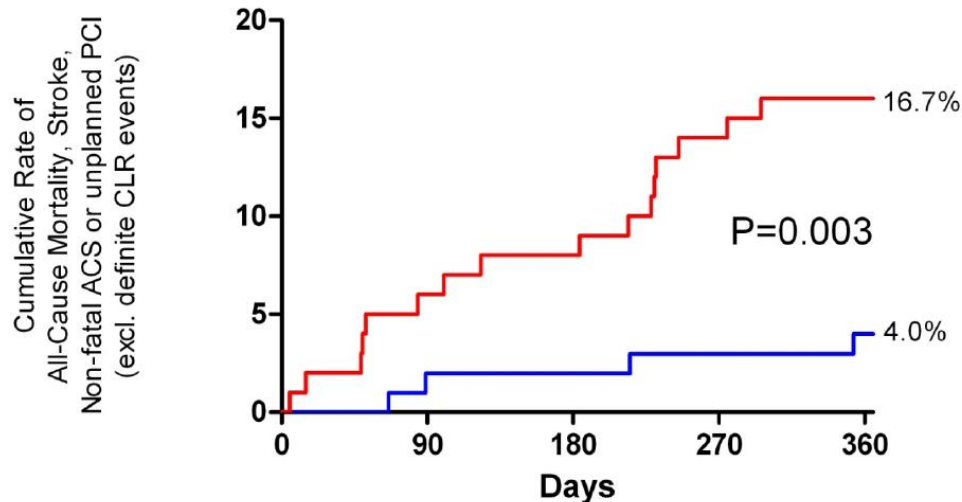
- Prospective Single Center Study, 206 patients (ACS47%)
- Primary Endpoint: Composite of all-cause mortality, non-fatal ACS, stroke and unplanned PCI during one-year FU
- >40mm non culprit segment of NIRS

Lipid Core
Burden Index
(LCBI)=188



Relationship between Lipidic Plaque detected by NIRS and Outcomes

Primary endpoint



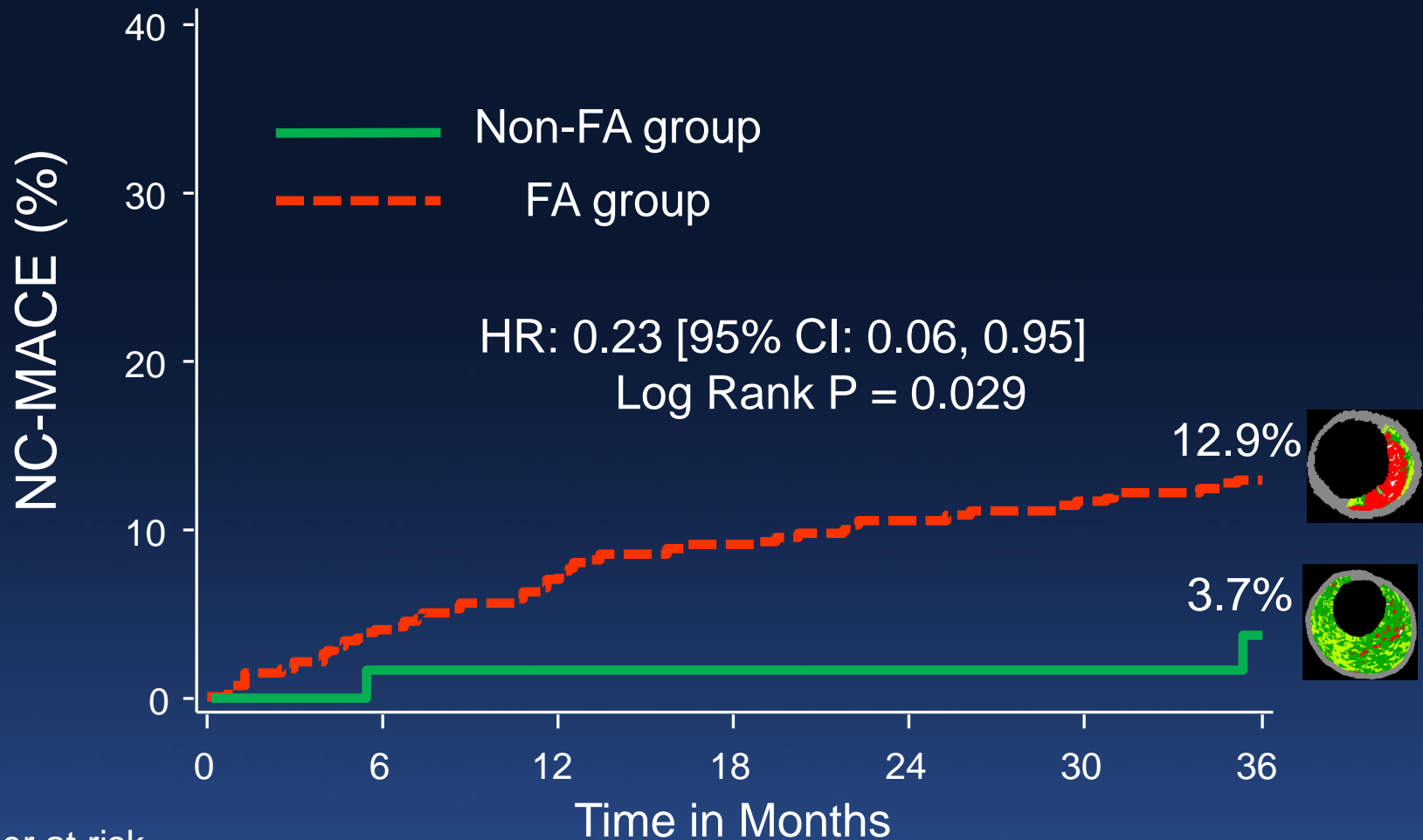
- LCBI ≥ median
- LCBI < median

No. at Risk

LCBI < Median	101	99	99	97	91
LCBI ≥ Median	102	94	92	86	83

Adjusted HR: **4.04** 95% CI: 1.3-12.3 P=0.01

PROSPECT: Non-FA Lesions



Number at risk

Non-FA group	67	62	61	61	60	57	29
FA group	542	485	463	443	424	406	248

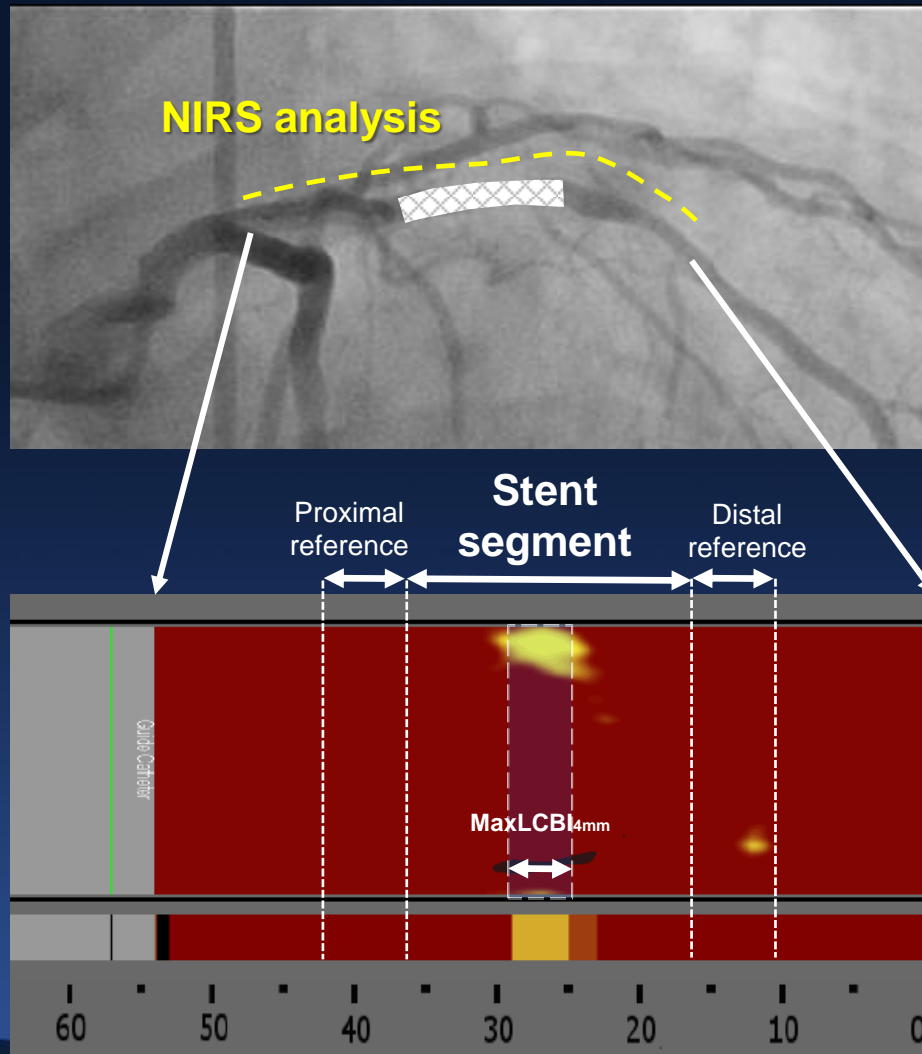
The Extent of Lipid-Rich Plaque Assessed by Near-Infrared Spectroscopy May Predict DES Failure A COLOR Registry Analysis

Tomotaka Dohi, MD, PhD

*Columbia University Medical Center,
The Cardiovascular Research Foundation*

Coregistration of NIRS with Angiogram

Coronary angiography

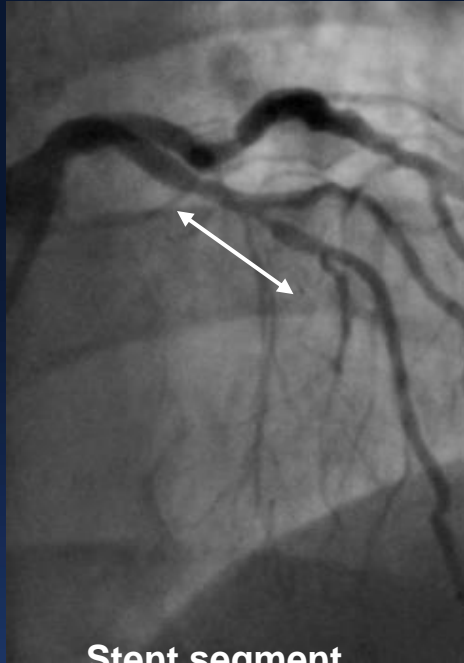


- The stent segment was defined as the length of vessel in which any stent implantation was performed.
- The corresponding stenting zone on the chemogram was identified by colocalized registration marks placed on the chemogram by the treating physician.

Case 1 - **Stent Failure** in Proximal LAD-

Index PCI

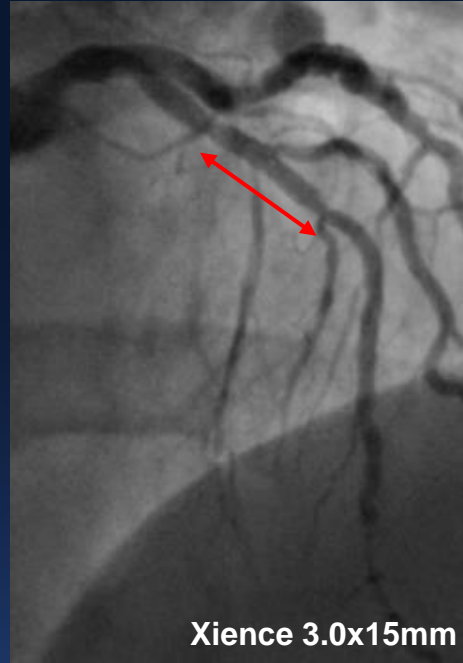
Pre Stenting



Stent segment

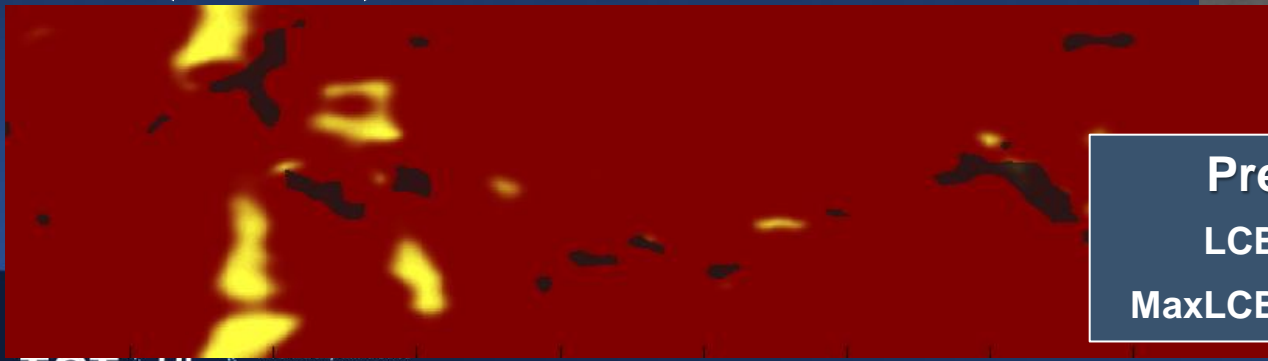
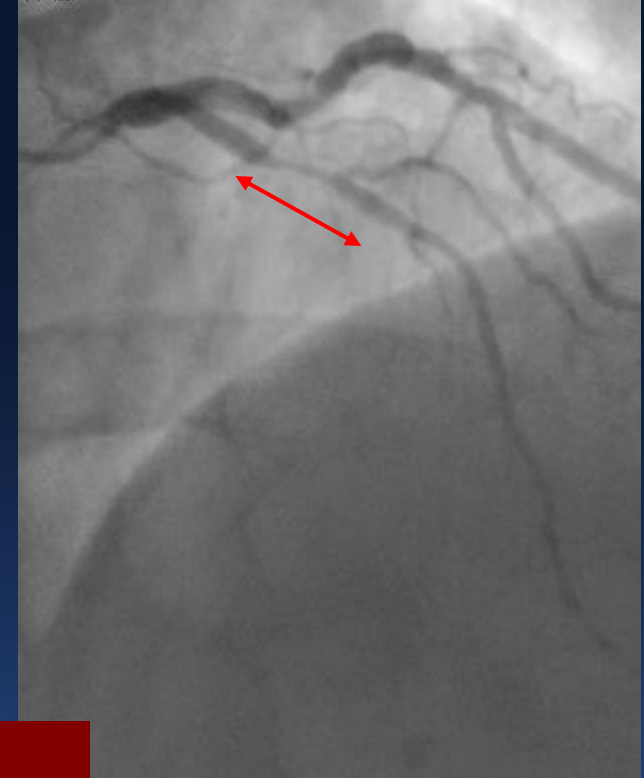


Post Stenting



Xience 3.0x15mm

In-stent Restenosis after 1 year

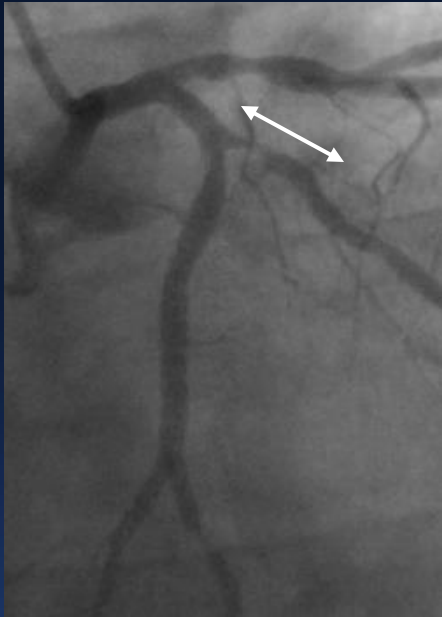


Pre PCI NIRS findings
LCBI in stent segment: **270**
MaxLCBI4mm in stent segment: **547**

Case 2 - Stent Failure in OM1-

Index PCI

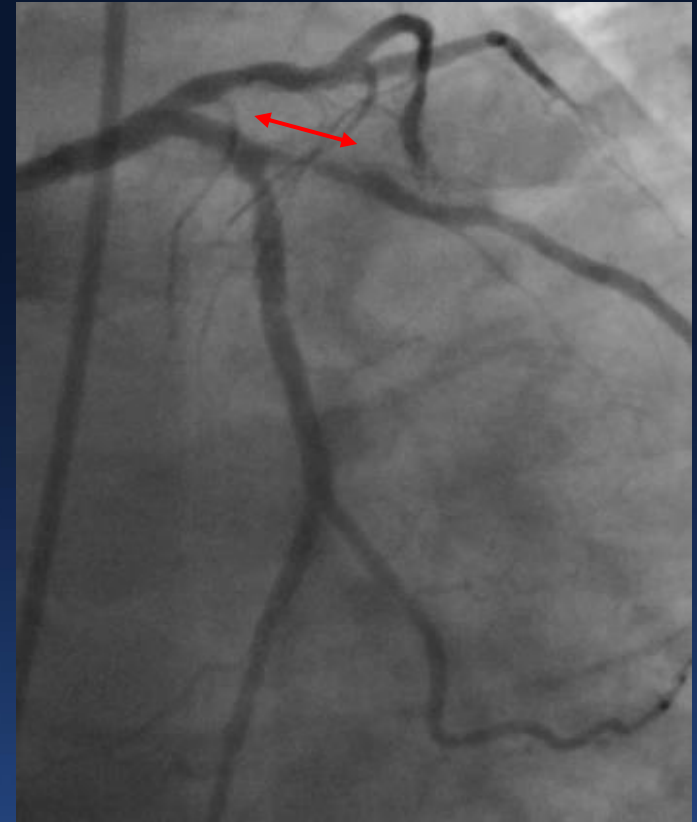
Pre Stenting



Post Stenting



In-stent Restenosis after 8 months



Stent segment



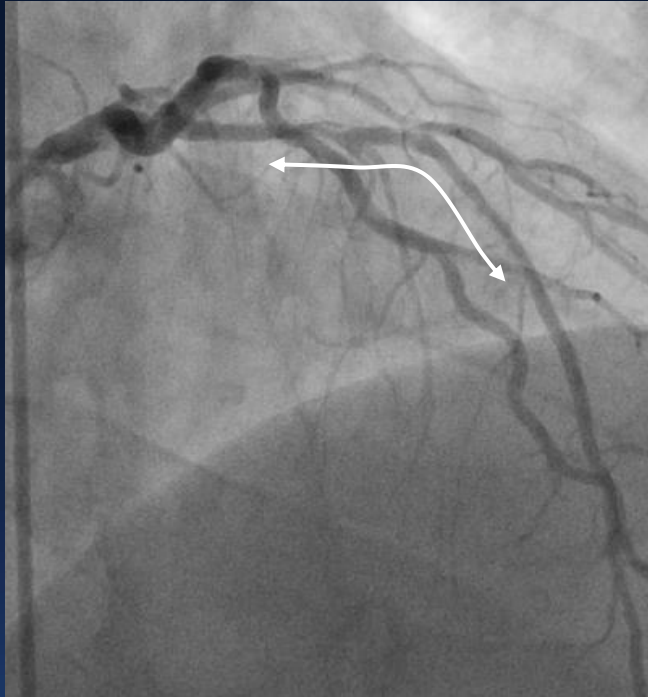
Pre PCI NIRS findings

LCBI in stent segment: **420**

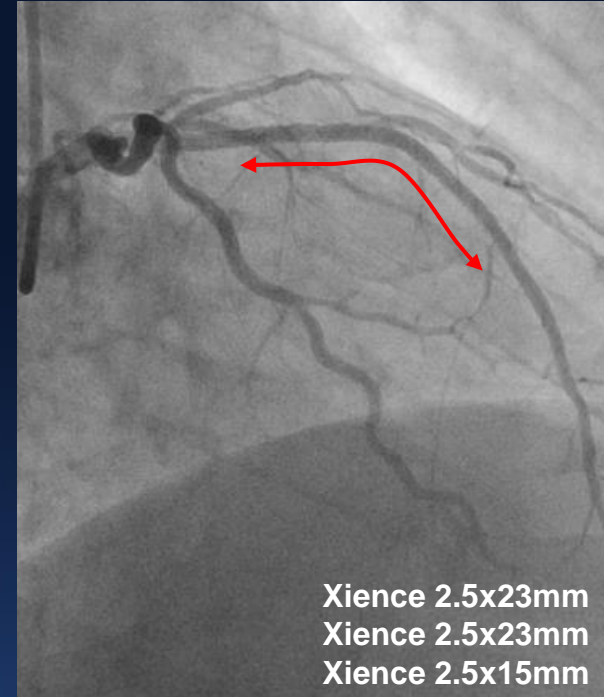
MaxLCBI_{4mm} in stent segment: **936**

Case 3 - **Control case** in Middle LAD-

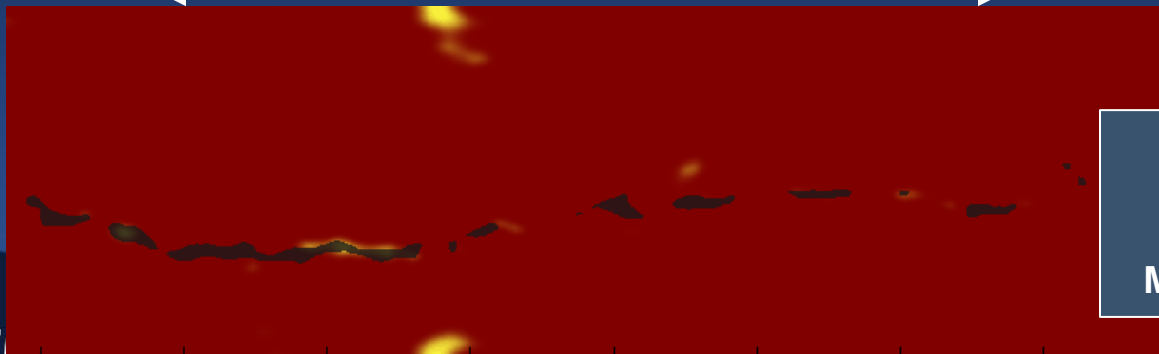
Pre Stenting



Post Stenting



Stent segment



Pre PCI NIRS findings

LCBI in stent segment: **14**

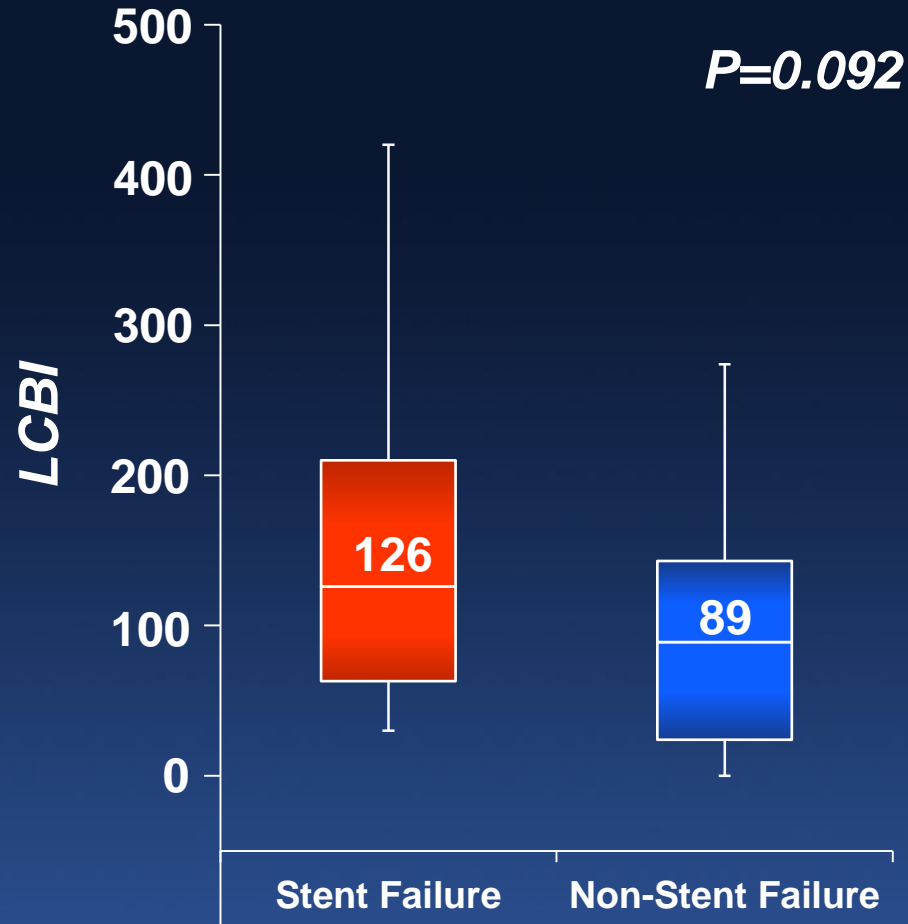
MaxLCBI_{4mm} in stent segment: **157**

Results

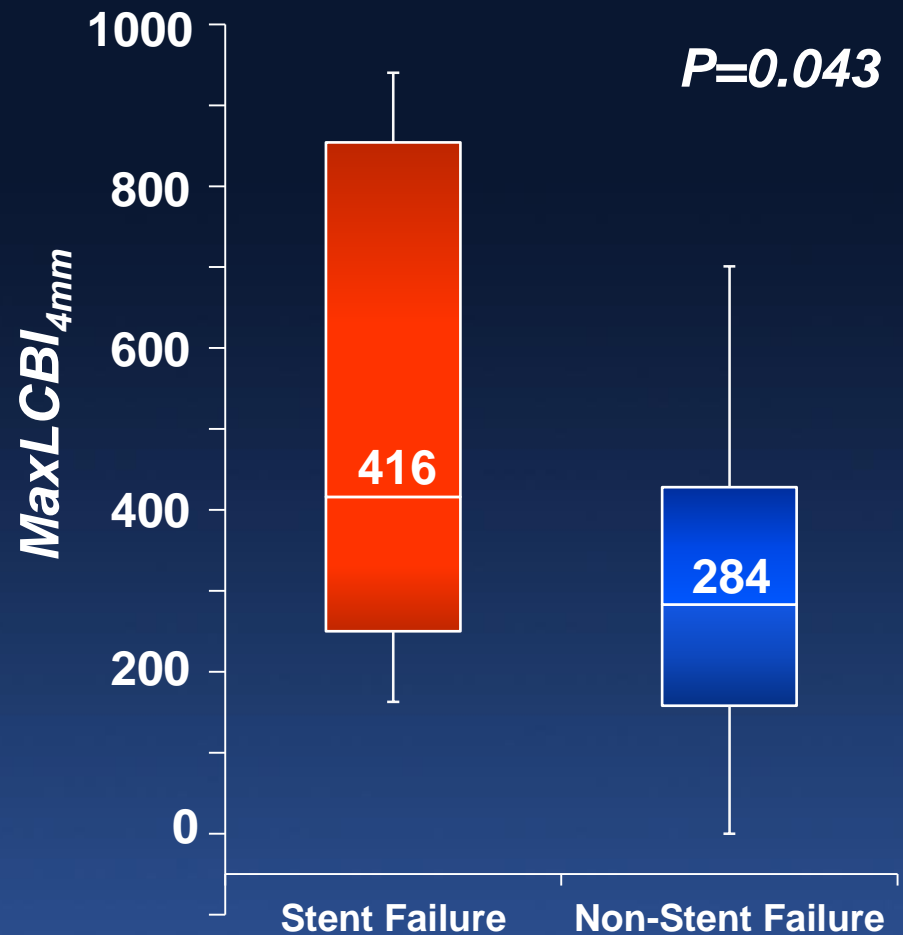
- ◆ From a total of 478 patients with complete data between February 2009 and November 2011, we identified 14 patients with stent failure.
- ◆ Of 14 patients with stent failure, ISR was found in 13 patients (9 focal, 3 diffuse, 1 total occlusion), and proximal edge restenosis was found in 1 patient.
- ◆ All implanted stents were DES, and the median follow-up time was 392 days (IQR: 300 to 418) after index PCI.
- ◆ Thirty case-matched controls were identified.

Box Plot of LCBI and maxLCBI_{4mm} in the Stented Segment Grouped by Occurrence of Stent Failure

Lesion LCBI



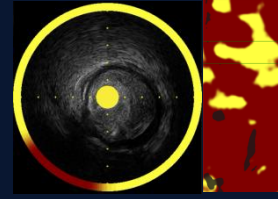
MaxLCBI_{4mm}



Conclusions

- ◆ Pre-intervention NIRS revealed more LRP in lesions that subsequently developed DES failure compared to DES-treated lesions without stent failure.
- ◆ Pre-intervention NIRS evaluation may help to identify lesions at high risk for DES restenosis.

PROSPECT II Study



**900 pts with ACS at up to 20 hospitals
in Sweden, Denmark and Norway (SCAAR)**

NSTEMI or STEMI $>12^{\circ}$

IVUS + NIRS (blinded) performed in culprit vessel(s)

Successful PCI of all intended lesions (by angio \pm FFR/iFR)



Formally enrolled



3-vessel imaging post PCI

Culprit artery, followed by non-culprit arteries

Angiography (QCA of entire coronary tree)

IVUS + NIRS (blinded) (prox 6-8 cm of each coronary artery)



PROSPECT II Study PROSPECT ABSORB RCT

900 pts with ACS after successful PCI

3 vessel IVUS + NIRS (blinded)

≥1 IVUS lesion with ≥70% plaque burden present?

Yes

(N=300)

No

(n=600)

R

1:1

**ABSORB BVS
+ GDMT** (N~150)

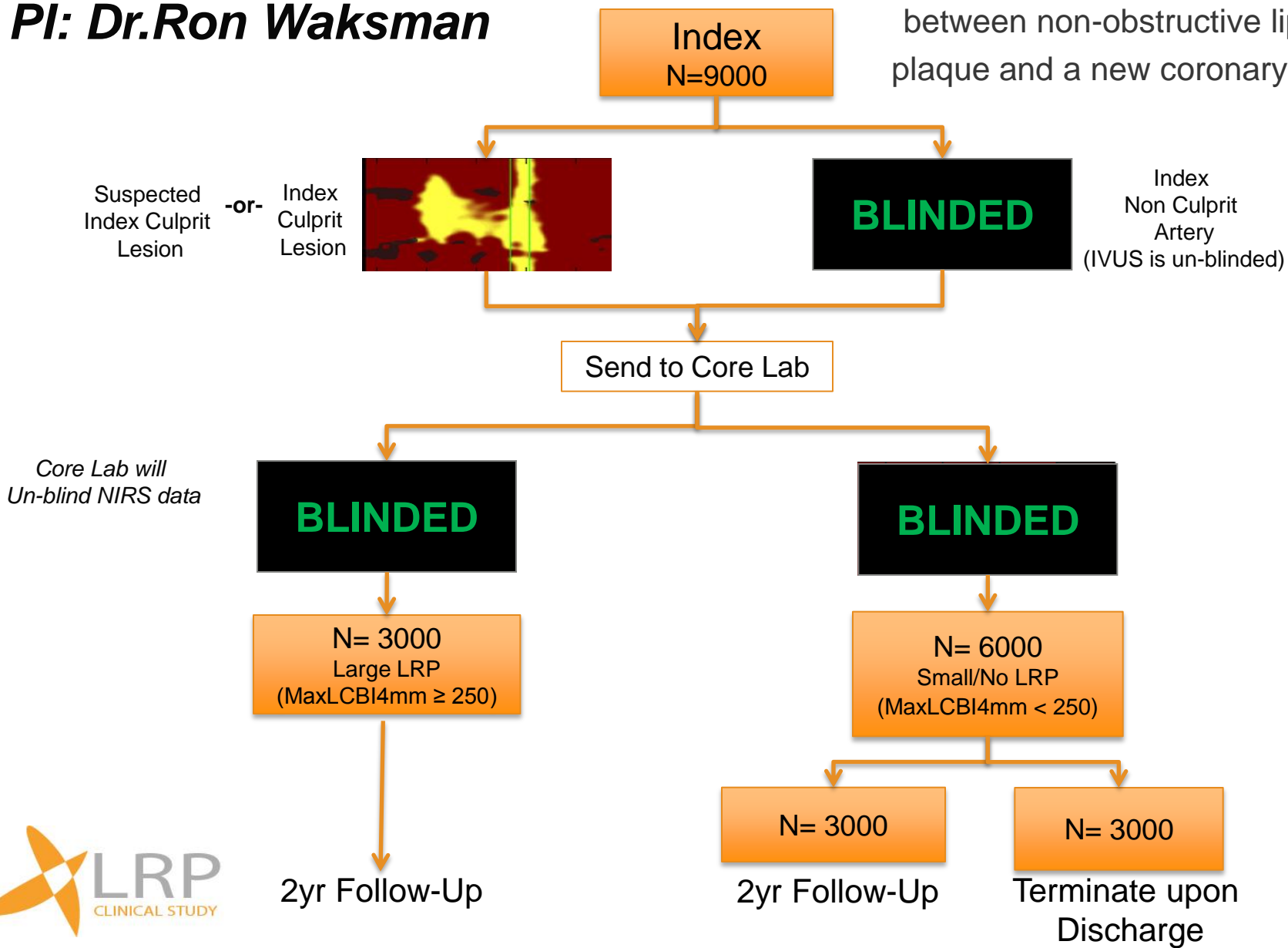
GDMT
(N=150)

Routine angio/3V IVUS-NIRS FU at 2 years

Clinical FU for ≥3 years

PI: Dr. Ron Waksman

“To evaluate the relationship between non-obstructive lipid-rich plaque and a new coronary events”



Summary

- 1. Circumferential large lipid rich plaque (LRP) was found as a unique feature of culprit lesions in the patients with sudden death, STEMI, or unstable angina.**
- 2. Small studies showed baseline LRP correlated to the worse clinical outcomes.**
- 3. Large prospective studies are on-going to evaluate the natural history of LRP and feasibility of aggressive therapy for these lesions.**