CLINICAL STUDIES

LRP

PROSPECT II

PACMAN-AMI

Two Large, Independent Studies. Same Result.

MaxLCBI$_{4mm}$ ≥400

With the help of IVUS+NIRS imaging, results from both the PROSPECT II and LRP clinical studies identify non-obstructive high-risk plaques and conclude that the most vulnerable plaque contains both high PB and high lipid content.

39x

more likely to have an event within 4 years.[1,5]

NIRS has succeeded in observing the process of change to a more stable plaque composition[2] where other techniques were unable[4].

~70%

of the patients exhibited a vulnerable plaque substrate in the non-culprit vessel.[1]

A significant reduction in ischemia-driven revascularization (non-TLR) in the treatment group.

We have the ability to identify non-obstructive high-risk plaque, allowing physicians to be more **proactive** with their method of care.

Intravascular imaging and NIRS research have come a long way over the past decade. **PACMAN-AMI, PROSPECT II, LRP** are groundbreaking all-inclusive studies that build on this progress. The results deliver new insights that can safely transform treatment options by clinically proving patients remain at risk of MACE even after their interventions when on statin therapy alone; **more can be done.**

THE PROSPECT II STUDY

902
Patients Enrolled

Principal Investigator:
David **Erlinge**

> ***We (Interventional Cardiologists) always forget that our words have high weight with patients, we are responsible for initiating and then also convincing the patient to take these medicines long term.***
>
> ***– Lorenz Räber, M.D.***

- After successful treatment of all flow-limiting lesions in patients with recent MI (STEMI or troponin + NSTEMI), intravascular imaging was performed in the proximal 6-10 cm of all 3 coronary arteries with a combination IVUS + NIRS catheter
- The study evaluated high risk plaque characterization such as: maxLCBI$_{4mm}$ ≥ 324.7, Plaque Burden ≥70% and Minimum Lumen Area < 4mm[1]
- After treatment of flow-limiting lesions in AMI with contemporary DES, MACE occurred in 14.4% of patients at median 3.7 year follow up
- The combination of lipid-rich plaque and large plaque burden, identified vulnerable plaques that placed patients at especially high risk for future MACE

THE PACMAN-AMI STUDY

300
Patients Enrolled

Principal Investigator:
Lorenz **Räber**

- The goal of this study was to understand the impact of statins and Alirocumab (PCSK9i) on coronary plaque
- PACMAN-AMI reveals that Alirocumab is able to achieve this MACE rate reduction by reducing the size of LRP as detected by NIRS
- Early intervention on LRP found by NIRS to reduce risk of MACE in ACS patients[2]
- PACMAN-AMI demonstrated the mechanism of MACE rate reduction from lowering LDL that starts with NIRS LRP

PACMAN-AMI POSITIVE IVUS AND NIRS ENDPOINTS[2]

Change Percent Atheroma Volume(PAV) by IVUS..... **-1.2% PAV**

Change Total Atheroma Volume (TAV) by IVUS..... **-11.3 mm^3**

Change maxLCBI$_{4mm}$ by NIRS..... **-41.2 maxLCBI$_{4mm}$**

THE LRP STUDY

1563
Patients Enrolled

Principal Investigator:
Ron **Waksman**

- Enrolled patients had coronary artery disease and were undergoing cardiac catheterization with possible ad hoc PCI for an index event, as well as imaging additional non-culprit territories.
- Patients with LRP maxLCBI$_{4mm}$ ≥ 250 and half of enrolled patients with LRP max$_{4mm}$LCBI < 250 were followed for 2 years.

VULNERABLE PATIENT LEVEL ENDPOINT - RESULTS

	HR (95%CI)	p Value	Conclusion
Primary Endpoint: maxLCBI$_{4mm}$ as a continuous variable	1.18 (1.05-1.32)	0.004	For each 100 unit increase of maxLCBI$_{4mm}$ the risk of NC-MACE increases by 18%
Secondary Endpoint: maxLCBI$_{4mm}$ >400	1.89 (1.26-2.83)	0.002	A patient with maxLCBI$_{4mm}$ greater than 400 is at 89% higher risk of NC-MACE

VULNERABLE PLAQUE LEVEL ENDPOINT - RESULTS

	HR (95%CI)	p Value	Conclusion
Primary Endpoint: maxLCBI$_{4mm}$ as a continuous variable	1.45 (1.30-1.60)	<0.0001	For each 100 unit increase of maxLCBI$_{4mm}$ the risk of NC-MACE increases by 45%
Secondary Endpoint: maxLCBI$_{4mm}$ >400	4.22 (2.39-7.45)	<0.0001	A coronary segment with maxLCBI$_{4mm}$ greater than 400 is at 322% higher risk of NC-MACE

Follow the links below to view the Studies in their entirety:

View The Lancet LRP Study
View The Lancet Prospect II Study
View the JAMA PACMAN-AMI Study

1. Erlinge D, Maehara A, Ben-Yehuda O, *et al.* Identification Of Vulnerable Plaques And Patients By Intracoronary Near-Infrared Spectroscopy And Ultrasound (PROSPECT II): A Prospective Natural History Study. *Lancet.* 2021;**397**(10278):985-995. doi: http://10.1016/S0140-6736(21)00249-X

2. Räber L, Ueki Y, Otsuka T, *et al.* Effect Of Alirocumab Added to High-Intensity Statin Therapy On Coronary Atherosclerosis In Patients With Acute Myocardial Infarction: The PACMAN-AMI Randomized Clinical Trial. *JAMA*. 2022;**327**(18):1771-1781. doi: http://10.1001/JAMA.2022.5218

3. Robinson JG, Farnier M, Krempf M, *et al.* Efficacy And Safety Of Alirocumab In Reducing Lipids And Cardiovascular Events. *N Engl J Med*. 2015;**372**(16):1489-1499. doi: http://10.1056/NEJMoa1501031

4. Mehta S, McCrary J, Frutkin A, *et al.* Intravascular Ultrasound Radio frequency Analysis Of Coronary Atherosclerosis: An Emerging Technology For The Assessment Of Vulnerable Plaque. *European Heart Journal*, Volume **28**, Issue 11, June 2007, Pages 1283–1288, https://doi.org/10.1093/eurheartj/ehm112

5. Waksman R, DiMario C, Torguson R, *et al.* Identification Of Patients And Plaques Vulnerable To Future Coronary Events With Near-Infrared Spectroscopy Intravascular Ultrasound Imaging: A Prospective, Cohort Study. *Lancet.* 2019;**394**(10209):1629-1637. doi: https://doi.org/10.1016/S0140-6736(19)31794-5

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