PROSPECT II: A Prospective Natural History Study Using NIRS-IVUS Imaging in Patients with Acute Myocardial Infarction

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PROSPECT II Natural History Study

PROSPECT ABSORB RCT

902 pts with troponin + ACS after successful PCI enrolled at 16 centers
3 vessel IVUS + NIRS (blinded)

898 pts: ≥1 non-flow limiting lesion with ≥65% plaque burden?

Yes (N=182)

ABSORB BVS + GDMT (N=93)
Routine angio/3V IVUS-NIRS FU at 25 months

No (n=716)

GDMT (N=89)

Clinical FU in PROSPECT II:
Median 3.7 years

ClinicalTrials.gov
NCT02171065
Representative case
An adverse event attributed to an untreated NCL

Index (day 0)
Non-culprit lesion 1
Non-culprit lesion 2
Culprit stent

Event (day 1116)

B
NCL 1
NCL 2
Culprit Lesion +
5 mm Reference

maxLCBI_{4mm} = 687

C
MLA = 3.8 mm²
Plaque burden = 80.1%

C'

Proximal
Distal
MACE Through 4-year Follow-up

Number at risk:

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
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</thead>
<tbody>
<tr>
<td>Non-culprit</td>
<td>898</td>
<td>869</td>
<td>848</td>
<td>623</td>
<td>331</td>
</tr>
<tr>
<td>Culprit</td>
<td>898</td>
<td>869</td>
<td>855</td>
<td>646</td>
<td>351</td>
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<tr>
<td>BVS</td>
<td>93</td>
<td>90</td>
<td>90</td>
<td>78</td>
<td>45</td>
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<tr>
<td>Indeterminate</td>
<td>898</td>
<td>882</td>
<td>877</td>
<td>653</td>
<td>357</td>
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<tr>
<td>Total</td>
<td>898</td>
<td>837</td>
<td>810</td>
<td>593</td>
<td>317</td>
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</tbody>
</table>

MACE (%)

- Total MACE: 13.2%
- Non-culprit lesion related MACE: 8.0%
- Culprit lesion related MACE: 4.2%
- BVS randomized lesion related MACE: 4.3%
- Indeterminate MACE: 2.5%

Median follow-up 3.7 yrs
NCL-related MACE According to the Presence of HR Plaque Defined by Upper Quartile MaxLCBI_{4mm}

**Patient-level events**

- MaxLCBI_{4mm} ≥324.7
- MaxLCBI_{4mm} <324.7

OR 2.08 [95% CI, 1.18-3.69]

**Lesion-level events**

- MaxLCBI_{4mm} ≥324.7
- MaxLCBI_{4mm} <324.7

OR 7.47 [95% CI, 3.94-14.20]

**Number at risk:**

- ≥324.7: 520, 503, 490, 359, 202
- <324.7: 364, 352, 345, 255, 127
NCL-related MACE According to the Presence of HR Plaque Defined by Plaque Burden ≥70%

Patient-level events

- PB ≥70%
- PB <70%

OR 3.09 [95% CI, 1.65-5.76]

Lesion-level events

- PB ≥70%
- PB <70%

OR 11.37 [95% CI, 5.60-23.11]

Number at risk:

<table>
<thead>
<tr>
<th>Group</th>
<th>PB ≥70%</th>
<th>PB &lt;70%</th>
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</thead>
<tbody>
<tr>
<td>Number</td>
<td>530</td>
<td>368</td>
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<tr>
<td>Time (Years)</td>
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<tr>
<td>0</td>
<td>787</td>
<td>2,842</td>
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<tr>
<td>1</td>
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<td>2,816</td>
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<td>2</td>
<td>764</td>
<td>2,804</td>
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<td>3</td>
<td>576</td>
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<tr>
<td>4</td>
<td>338</td>
<td>1,162</td>
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</table>
Lesion-level NCL-MACE According to the Presence of HR Plaque Defined by MaxLCBI\textsubscript{4mm} ≥ 324.7 and PB ≥ 70%

**Lesion-level NCL-MACE (%)**

![Graph showing event rates over time](image)

**OR 11.33 [95% CI, 6.10-21.03]**
PB ≥ 70% and maxLCBI\textsubscript{4mm} ≥ 324.7 vs. others

**OR 36.73 [95% CI, 13.59-99.28]**
PB ≥ 70% and maxLCBI\textsubscript{4mm} ≥ 324.7 vs. PB < 70% and maxLCBI\textsubscript{4mm} < 324.7

**Number at risk:**
- PB ≥ 70% and maxLCBI\textsubscript{4mm} ≥ 324.7: 374, 368, 362, 271, 162
- PB ≥ 70% and maxLCBI\textsubscript{4mm} < 324.7: 391, 383, 381, 293, 168
- PB < 70% and maxLCBI\textsubscript{4mm} ≥ 324.7: 477, 469, 468, 350, 197
- PB < 70% and maxLCBI\textsubscript{4mm} < 324.7: 2,258, 2,240, 2,229, 1,683, 924
Conclusions

• Following treatment of flow-limiting lesions in AMI with contemporary DES, MACE occurred in 14.4% of pts at median 3.7-year FU
  - 8.0% were caused by unanticipated events arising from untreated non-flow-limiting plaques vs. 4.6% from recurrent events at treated culprit lesions

• 3-vessel intracoronary imaging with NIRS-IVUS was safe

• NIRS identified lipid-rich angiographically mild non-flow-limiting plaques that were responsible for future coronary events

• The combination of lipid-rich plaque and large plaque burden identified vulnerable plaques that placed patients at especially high risk for future MACE

• Whether prophylactic treatment of these high-risk plaques is safe and effective was investigated in the integrated PROSPECT ABSORB trial