Unprotected left main coronary stenting with a second generation drug-eluting stent. One-year clinical follow-up of the LeMaX pilot study.

Potential conflicts of interest

Speaker’s name: Dr Nicolas BOUDOU

☐ I have the following potential conflicts of interest to report:

☐ Research contracts
☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

X I do not have any potential conflict of interest
Background

- CABG is still the gold standard for treatment of left main stenosis.
- PCI: an alternative therapeutic option.
- Results with first-generation DES for LM stenosis are promising.
- Second-generation DES in other settings: efficacy and safety profiles at least equivalent to first-generation DES.
- Data regarding use of second-generation DES for unprotected LM stenosis are lacking.
The LeMaX Pilot Study

- 4 French centers
- Prospective observational study, December 07 to May 09
- Efficacy and safety of Xience V everolimus-eluting stent for unprotected de novo LM stenosis
- Primary end point: MACCE at 1 year
- e-CRF
- Angiographic analysis and adjudication of events by independent committee
- Clinical follow-up at 1 month, 1, 2 & 3 years
Inclusion Criteria

• De novo unprotected left main stenosis > 50% by visual estimate, amenable for PCI

• Written informed consent

• No contraindication to dual antiplatelet therapy for ≥ 6 months
Exclusion criteria

- Cardiogenic shock
- STEMI
- Previous CABG with one or more functioning grafts to left coronary artery
Recommended Treatment Strategy

- Dual antiplatelet therapy > 12h before PCI, and for at least 6 months
- MB stenting with provisional side branch stenting strategy
- Final kissing balloon
- Ostial coverage in all cases
# Patient Characteristics (n=173)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years (mean, range)</td>
<td>69 (38-89)</td>
</tr>
<tr>
<td>Male (%)</td>
<td>75</td>
</tr>
<tr>
<td>Dyslipidaemia (%)</td>
<td>68</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>59</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>27</td>
</tr>
<tr>
<td>Current / past smoker (%)</td>
<td>51</td>
</tr>
<tr>
<td>Renal failure (estimated Creat Cl&lt; 50 mL/min) (%)</td>
<td>23</td>
</tr>
<tr>
<td>Previous MI (%)</td>
<td>13</td>
</tr>
<tr>
<td>Peripheral vascular disease (%)</td>
<td>18</td>
</tr>
<tr>
<td>Previous PCI (%)</td>
<td>29</td>
</tr>
<tr>
<td>Previous CABG (%)</td>
<td>1</td>
</tr>
</tbody>
</table>
Baseline Characteristics

• Indication for the procedure

- 23% silent ischaemia
- 41% NSTEACS
- 15% stable angina
- 20% other

• Euroscore : 4.6 ± 3.8 / 5.8 ± 8.0%
• LVEF : 59 ± 10 %
SYNTAX Score
tercile distribution

Mean Syntax score : 25.2 ± 9.5 (range 10.5-65)
Left Main Lesion Location

19% Non-distal
81% Distal

Medina for distal location

<table>
<thead>
<tr>
<th>Code</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,1,1</td>
<td>15%</td>
</tr>
<tr>
<td>1,1,0</td>
<td>34%</td>
</tr>
<tr>
<td>1,0,0</td>
<td>31%</td>
</tr>
<tr>
<td>1,0,1</td>
<td>15%</td>
</tr>
<tr>
<td>0,1,1</td>
<td>1%</td>
</tr>
<tr>
<td>0,1,0</td>
<td>4%</td>
</tr>
</tbody>
</table>
## Procedural Characteristics

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Radial approach (%)</td>
<td>63</td>
</tr>
<tr>
<td>Number of stents/patient</td>
<td>2.3 ± 0.5</td>
</tr>
<tr>
<td>Number of stents in left main / patient</td>
<td>1.2 ± 0.4</td>
</tr>
<tr>
<td>Left main stent diameter (mm)</td>
<td>3.63 ± 0.33</td>
</tr>
<tr>
<td>Left main stent length (mm)</td>
<td>18.3 ± 5.1</td>
</tr>
<tr>
<td>Final Kissing Ballon for distal lesions (%)</td>
<td>95</td>
</tr>
<tr>
<td>Angiographic success rate (%)</td>
<td>100</td>
</tr>
</tbody>
</table>
In-hospital outcome (n = 173)

MACCE = 2.9%

hierarchical ranking
MACCE at 1 year

n = 172/173 patients

Any Revascul. 9.3

MACCE = 13.3%
hierarchical ranking

Total MACCE 13.3

Death 2.9
MI 1.7
Stroke 2.3

Pôle Cardiovasculaire et Métabolique
MACCE Predictive factors at 1 year
Multivariate analysis

<table>
<thead>
<tr>
<th>Factor</th>
<th>Hazard Ratio</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>1.011 (0.973-1.049)</td>
<td>0.6</td>
</tr>
<tr>
<td>Sexe</td>
<td>0.937 (0.370-2.377)</td>
<td>0.9</td>
</tr>
<tr>
<td>Diabetes</td>
<td>2.262 (0.991-5.159)</td>
<td>0.05</td>
</tr>
<tr>
<td>Logistic Euroscore</td>
<td>1.024 (0.988-1.062)</td>
<td>0.2</td>
</tr>
<tr>
<td>Cretinine Clearance</td>
<td>1.008 (0.991-1.024)</td>
<td>0.4</td>
</tr>
<tr>
<td>LVEF &lt;50%</td>
<td>2.365 (0.961-5.821)</td>
<td>0.06</td>
</tr>
<tr>
<td>Distal Left Main</td>
<td>1.099 (0.405-2.979)</td>
<td>0.8</td>
</tr>
<tr>
<td>Syntax Score &gt; 32</td>
<td>1.035 (0.997-1.075)</td>
<td>0.07</td>
</tr>
</tbody>
</table>
Safety at 1 year

• **Cause of death**: 5 patients : 2.9%
  - 1 mesenteric infarction at 4 month
  - 1 post CABG at 3 month
  - 1 MI : definite LM stent thrombosis in hospital
  - 1 haemorragic stroke at 4 month
  - 1 septic complication after leg amputation at 8 months

• **Stent thrombosis**: 1.1%
  - Definite : 2 patients : 1 LM in Hos., 1 BMS in RCA!
  - Probable : 0
  - Possible : 0
Repeat revascularisation at 1 year (n= 172)

• TLR of left main (2.3%)
  – 2 cases in-hospital
    • 1 subacute LM stent thrombosis, death
    • 1 LAD secondary to distal dissection
  – 2 cases during follow-up : 2 distal LM
    • 1 CABG at 3 month, death
    • 1 PTCA at 1 year

• Repeat revascularisation of other lesions (6.9%)
Stenting Technique in Bifurcation Lesions (n = 139)

80% single stent for distal lesions

- Single stent: 128
- T-stenting: 112
- Culotte: 24
- SKS: 1
- Crush: 1
### French Multi-center Left Main studies with DES

<table>
<thead>
<tr>
<th></th>
<th>Pilot Taxus* 2004</th>
<th>FRIEND** 2006</th>
<th>LEMAX 2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nb patients</td>
<td>291</td>
<td>151</td>
<td>174</td>
</tr>
<tr>
<td>% distal lesion</td>
<td>78</td>
<td>69</td>
<td>81</td>
</tr>
<tr>
<td>% 2 stents</td>
<td>42</td>
<td>26</td>
<td>19</td>
</tr>
<tr>
<td>Mean LM stent diameter (mm)</td>
<td>3.44±0.39</td>
<td>3.59±0.49</td>
<td>3.63±0.33</td>
</tr>
<tr>
<td>12 month TLR</td>
<td>5.9%</td>
<td>2.7%</td>
<td>2.3%</td>
</tr>
</tbody>
</table>

*B. Vaquerizo *et al.* Circulation 2009;119:2349-5

**D.Carrié *et al.,* Eurointerv 2009;4:449-56
Conclusion

- Unprotected left main PCI using everolimus eluting stent provided excellent immediate results and very good in-hospital outcomes.
- At one year follow up, results are promising:
  - Total death 2.9%, cardiac death 1.1%
  - TLR 2.3%
  - No late stent thrombosis!
- There is an increase of MACCE in patients with high Syntax Score (≥ 33)
- Diabetes is the strongest predictor of MACCE
- Longer follow-up is needed to confirm these results