Role of Pitavastatin (Livalo®) in Asian Acute Myocardial Infarction Patients

: Insights from Livalo Acute Myocardial Infarction Study (LAMIS)

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4. Pitavastatin (Livalo) in NSTEMI
5. Pitavastatin (Livalo) in AMI with DM
6. Summary & Conclusion
### AMI with DES-Efficacy & Safety?

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1.</td>
<td>Still restenosis; DES failure</td>
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<tr>
<td>2.</td>
<td>Stent thrombosis; Clinically more risky</td>
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<tr>
<td>3.</td>
<td>DES-Spasm/Endothelial Dysfunction</td>
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<td>4.</td>
<td>DES aneurysm/ Late stent malapposition</td>
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<td>5.</td>
<td>Hypersensitivity reaction</td>
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<td>6.</td>
<td>Late catch up/ LTO (Late Total Occlusion)</td>
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<td>7.</td>
<td>Others...</td>
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</table>
Acute Ant Wall MI due to Acute Stent Thrombosis (1)

Pre PCI (Acute stent thrombosis at previously implanted DES)
Acute Ant Wall MI due to Acute Stent Thrombosis (2)

Post PCI
Post DES Spasm (1)

Ergonovine

NTG

Ach
Post DES Spasm (2)

Ach injection into RCA
Incomplete Stent Apposition (ISA) ; could Develop into Aneurysm
Definition of Coronary Neo-Aneurysm

• Focal or diffuse abnormal luminal dilatation 50% larger than that of reference segment beyond the implanted DES on the follow up angiography.
Neo Aneurysm Formation after DES Implantation

Cypher®

TAXUS®

JSIC 2008
For Prevention and Optimization of PCI in DES era..

1. Adequate device selection & technology
2. Optimal systemic medical therapy

*Role of Statins?*

; what are the rationale for using Statins in ACS, especially in AMI?
Pleiotropic Effects of Statin

1. Inhibition of VSMC growth
2. Restoration of Endothelial dysfunction
3. Atherosclerotic plaque stabilization/Regression
4. Reduced leukocyte adhesiveness
5. Reduced ischemia-reperfusion injury
6. Others....
Korean AMI Registry (KAMIR) & Livalo AMI Registry (LAMIS)

1. Korean prospective multicenter registry from 41 (currently more than 50) major PCI centers for AMI since 2005.11.
2. Korean prospective multicenter registry from 10 centers for evaluating role of Pitavastatin (Livalo) in AMI since 2007.5
3. DES penetration in KAMIR; over 92%, major DES & New DESs
   No regulation for the statins
Livalo AMI Study (LAMIS) “Updated issue with Pitavastatin”

Seung-Woon Rha1, Wang Lin1, Hyang Ran Yoon1, Byoung-Geol Choi1,, Young Joon Hong2, Tae Hoon Ahn3, Jang Ho Bae4, Seung Ho Hur5, In Ho Chae6, Jong Hyun Kim7, Kyeong Ho Yun8, Sang Wook Kim9, Kee Sik Kim10, Mi Hee Kim11, Ji Eun Oh 11, Myung Ho Jeong2*

(On behalf of LAMIS Investigators)

Korea University1, ChonNam University2, Gachon University3, KonYang University4, KeiMyung University5, Seoul National University6, Han Seo Hospital7, WonKwang University8, Chung Ang University9, Catholic University of Daegu10, Chung Wae Pharm11

* PI of LAMIS Investigators
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<td>Konyang University Hospital</td>
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<td>2007-06-26</td>
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<td>Korea University Guro Hospital</td>
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Background

1. There are very limited data regarding role of statin in managing acute myocardial infarction (AMI) patients, especially in drug-eluting stent (DES) era.

2. Statin therapy, specifically a lipophilic statin Pitavastatin (Livalo®) in AMI setting may play an important role by not only reducing LDL-cholesterol, but also through the pleiotrophic effects.

In the present study, we evaluated the efficacy and safety of routine administration of Pitavastatin in AMI pts as a substudy of Korea Acute Myocardial Infarction Registry (KAMIR).
The current data regarding CVD came from the subgroup analysis of Korea Acute Myocardial Infarction Registry (KAMIR study).

This study consisted of 1059 consecutive AMI patients (pts; male 73.9%; mean age, 61.5 yrs ± 12.7) presented in 10 major percutaneous coronary intervention (PCI) centers in Korea from April 2007 to March 13, 2010.

Initial dosage: 2mg/day
If it’s not enough to reduce LDL-C, increase up to 4mg/day.
Study Definition

- **CVD**: included ischemic and hemorrhagic cerebral events. TIA was not considered as CVD.

- **Revascularization**: both Re-PCI and CABG

- **All MACE**: included total death, revascularization, and myocardial re-infarction.
Study endpoints

1. The clinical outcomes up to 1 year
   1) Overall outcomes of LAMIS
   2) Outcome comparison with Historical Control group in KAMIR (No Statin group & All Statin group)

2. The changes of lipid profiles and noble biochemical markers at baseline, 1, 6 and 12 months

3. Adverse effects & Safety issues
LAMIS Enrollment Status 2010.3

Data extracted date: 2010.03.13

Enrolled Patients: N=1128

Analized Patients: N=1059

Exclusion: Protocol violations (69 patients)
- Did not administrated Pitavastatin (Livalo) at discharge (34)
- Death before discharge (11)
- Same patients (10)
- Transfer other hospital before discharge (4)
- Etc. (9)

Pts. Completed 1Month clinical follow up: N=1045 (98.7%)

Pts. Completed 6-Month clinical follow up: N=958 (90.5%)
## General background

### Demographic data

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<td>Mean±SD</td>
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## Risk Factors

### History of ischemic heart disease

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### History of hypertension

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<td>Previous PCI</td>
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<td>Previous AMI</td>
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<td>Untreated</td>
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## Risk Factors

### 5 History of diabetes mellitus

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<td>Insulin treated</td>
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<td>Oral + insulin</td>
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### 6 History of dyslipidemia

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<td>87.2</td>
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## Risk Factors

### 7 History of smoking

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<td>Current-smoking</td>
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<td>Ex-smoking</td>
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### 8 Family history of heart disease

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### Risk Factors

**Past regular medication**

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**History of statin**

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<td>Pitavastatin</td>
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<td>Rosuvastatin</td>
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<td>Pravastatin</td>
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<td>Atorvastatin</td>
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<td>Lovastatin</td>
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## AMI Management

### Initial therapeutic strategy

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### STEMI

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<td>Facilitated PCI</td>
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<td>Thrombolysis</td>
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<td>Conservative Management</td>
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### NSTEMI

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<td>Early invasive management</td>
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<td>Early conservative management</td>
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# AMI Management

## Treatment & Outcome

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<td>PCI</td>
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<td>CABG</td>
<td>4</td>
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<tr>
<td>Others</td>
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## Thrombolysis

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<td>Successful thrombolysis in clinical</td>
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<td>Successful thrombolysis on angiogram</td>
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<tr>
<td>Failed thrombolysis</td>
<td>4</td>
<td>7.8</td>
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<tr>
<td>No survival</td>
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<td>0</td>
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## AMI Management

### PCI

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<td>Successful PCI</td>
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<td>88.1</td>
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<tr>
<td>Sub-optimal PCI</td>
<td>106</td>
<td>11.1</td>
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<tr>
<td>Failed PCI</td>
<td>8</td>
<td>0.8</td>
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<tr>
<td>No survival</td>
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### PCI with stent

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### CABG

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<tr>
<td>Successful CABG</td>
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<td>100.0</td>
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<tr>
<td>Sub-optimal CABG</td>
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<tr>
<td>Failed CABG</td>
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<td>No survival</td>
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## Angiographic finding

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<td>One vessel</td>
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<td>Two vessel</td>
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<td>Three vessel</td>
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<td>Left main</td>
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<td>Myocardial bridge</td>
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<tr>
<td>Good thrombolytic state</td>
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<td>16</td>
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<td>Normal coronary artery</td>
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# AMI Management

## Post TIMI flow

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<td>TIMI 0</td>
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<td>1.8</td>
</tr>
<tr>
<td>TIMI I</td>
<td>7</td>
<td>0.7</td>
</tr>
<tr>
<td>TIMI II</td>
<td>76</td>
<td>7.7</td>
</tr>
<tr>
<td>TIMI III</td>
<td>893</td>
<td>89.8</td>
</tr>
</tbody>
</table>

## Stage of revascularization

<table>
<thead>
<tr>
<th>Revascularization Type</th>
<th>Frequency (n)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No revascularization of IRA</td>
<td>60</td>
<td>6.0</td>
</tr>
<tr>
<td>Revascularization of single IRA</td>
<td>519</td>
<td>52.2</td>
</tr>
<tr>
<td>Revascularization of only IRA in multi-vessel</td>
<td>155</td>
<td>15.6</td>
</tr>
<tr>
<td>Multi-vessel revascularization</td>
<td>121</td>
<td>12.2</td>
</tr>
<tr>
<td>Total revascularization</td>
<td>140</td>
<td>14.1</td>
</tr>
</tbody>
</table>
## Major Clinical Outcomes 2010.3

### Cumulative clinical outcomes up to 1 year

<table>
<thead>
<tr>
<th>Event</th>
<th>1M</th>
<th>3M</th>
<th>6M</th>
<th>%</th>
<th>9M</th>
<th>12M</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N</strong></td>
<td>1045</td>
<td>1006</td>
<td>958</td>
<td>%</td>
<td>906</td>
<td>870</td>
<td>%</td>
</tr>
<tr>
<td>Death</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>6</td>
<td>12</td>
<td>18</td>
<td>1.9</td>
<td>20</td>
<td>32</td>
<td>3.7</td>
</tr>
<tr>
<td>Cardiac death</td>
<td>5</td>
<td>10</td>
<td>12</td>
<td>1.3</td>
<td>14</td>
<td>20</td>
<td>2.3</td>
</tr>
<tr>
<td>Non-cardiac death</td>
<td>1</td>
<td>2</td>
<td>6</td>
<td>0.6</td>
<td>6</td>
<td>12</td>
<td>1.3</td>
</tr>
<tr>
<td>Repeat MI</td>
<td>2</td>
<td>9</td>
<td>11</td>
<td>1.1</td>
<td>11</td>
<td>14</td>
<td>1.6</td>
</tr>
<tr>
<td>STEMI</td>
<td>2</td>
<td>5</td>
<td>6</td>
<td>0.6</td>
<td>6</td>
<td>8</td>
<td>0.9</td>
</tr>
<tr>
<td>NSTEMI</td>
<td>1</td>
<td>4</td>
<td>5</td>
<td>0.5</td>
<td>5</td>
<td>6</td>
<td>0.7</td>
</tr>
<tr>
<td>Repeat Revascularization</td>
<td>2</td>
<td>8</td>
<td>31</td>
<td>3.2</td>
<td>69</td>
<td>93</td>
<td>10.7</td>
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<tr>
<td>CABG</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TVR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All MACE (TVR-MACE)</td>
<td>9</td>
<td>25</td>
<td>47</td>
<td>4.9</td>
<td>68</td>
<td>104</td>
<td>11.9</td>
</tr>
<tr>
<td>1) TLR-MACE</td>
<td>7</td>
<td>19</td>
<td>33</td>
<td>3.4</td>
<td>49</td>
<td>65</td>
<td>7.5</td>
</tr>
<tr>
<td>2) TVR-MACE</td>
<td>9</td>
<td>25</td>
<td>47</td>
<td>4.9</td>
<td>68</td>
<td>104</td>
<td>11.9</td>
</tr>
</tbody>
</table>
Discharge & follow up

Laboratory tests (result from every visit)

<table>
<thead>
<tr>
<th></th>
<th>Pre-discharge mean±SD (n)</th>
<th>1M mean±SD (n)</th>
<th>6M mean±SD (n)</th>
<th>12M mean±SD (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TC</td>
<td>190.7±42.4 1050</td>
<td>153.8±29.5 573</td>
<td>156.2±34.2 457</td>
<td>159.0±35.2 321</td>
</tr>
<tr>
<td>TG</td>
<td>124.7±90.7 1036</td>
<td>145.3±108.9 547</td>
<td>139.2±76.7 439</td>
<td>151.8±157.1 303</td>
</tr>
<tr>
<td>HDL-C</td>
<td>45.1±11.8 1034</td>
<td>44.4±10.6 541</td>
<td>44.4±11.2 435</td>
<td>43.7±9.6 300</td>
</tr>
<tr>
<td>LDL-C</td>
<td>122.0±37.2 1027</td>
<td>87.6±25.0 533</td>
<td>90.9±27.4 429</td>
<td>90.2±28.9 293</td>
</tr>
<tr>
<td>hs- CRP (Median)</td>
<td>19.2±262.9 922</td>
<td>2±9.5 0.5 538</td>
<td>2.1±9.5 0.3 397</td>
<td>2.5±13.6 0.2 255</td>
</tr>
<tr>
<td>Max. CK</td>
<td>1129.3±2132.9 969</td>
<td>105.4±95.9 505</td>
<td>120±97.7 378</td>
<td>117.6±79.5 220</td>
</tr>
<tr>
<td>GOT</td>
<td>90.6±138.9 1054</td>
<td>25±17.4 599</td>
<td>25.6±26.5 472</td>
<td>24.9±9.9 322</td>
</tr>
<tr>
<td>GPT</td>
<td>40.1±44 1054</td>
<td>27.8±26 600</td>
<td>26.8±29.4 467</td>
<td>26.3±16.1 322</td>
</tr>
</tbody>
</table>
Discharge & follow up

4 NCEP 치료목표 달성률

<table>
<thead>
<tr>
<th></th>
<th>1M (n)</th>
<th>6M (n)</th>
<th>12M (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LDL ≤ 100mg/dL 달성률</td>
<td>71.1%</td>
<td>67.6%</td>
<td>72.7%</td>
</tr>
<tr>
<td></td>
<td>(379/533)</td>
<td>(290/429)</td>
<td>(213/293)</td>
</tr>
<tr>
<td>LDL ≤ 70mg/dL 달성률</td>
<td>25.3%</td>
<td>24.0%</td>
<td>22.9%</td>
</tr>
<tr>
<td></td>
<td>(135/533)</td>
<td>(103/429)</td>
<td>(67/293)</td>
</tr>
<tr>
<td>DM 환자에서 LDL ≤ 70mg/dL 달성률</td>
<td>28.4%</td>
<td>29.9%</td>
<td>31.7%</td>
</tr>
<tr>
<td></td>
<td>(36/129)</td>
<td>(26/87)</td>
<td>(19/41)</td>
</tr>
</tbody>
</table>
## Adverse Drug Reaction

### Adverse Events

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Total AE</th>
<th>Total ADR</th>
<th>Serious case</th>
<th>Serious ADR</th>
<th>myalgia</th>
<th>CK↑</th>
<th>GOT/GPT↑</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gachon University Gil Medical Center</td>
<td>4</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0/1</td>
</tr>
<tr>
<td>Konyang University Hospital</td>
<td>18</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0/1</td>
</tr>
<tr>
<td>Keimyung University Dongsan Medical Center</td>
<td>79</td>
<td>1</td>
<td>8</td>
<td>0</td>
<td>1</td>
<td>5</td>
<td>8/6</td>
</tr>
<tr>
<td>Korea University Guro Hospital</td>
<td>41</td>
<td>3</td>
<td>7</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3/9</td>
</tr>
<tr>
<td>Daegu Catholic University Medical Center</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>5</td>
<td>0/1</td>
</tr>
<tr>
<td>Seoul National University Bundang Hospital</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3/3</td>
</tr>
<tr>
<td>Hanseo Hospital</td>
<td>6</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0/3</td>
</tr>
<tr>
<td>Wonkwang University Hospital</td>
<td>70</td>
<td>0</td>
<td>7</td>
<td>0</td>
<td>4</td>
<td>3</td>
<td>4/5</td>
</tr>
<tr>
<td>Chonnam National University Hospital</td>
<td>80</td>
<td>14</td>
<td>12</td>
<td>0</td>
<td>2</td>
<td>14</td>
<td>13/21</td>
</tr>
<tr>
<td>Chung-Ang University Hospital</td>
<td>14</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1/4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>316</strong></td>
<td><strong>21</strong></td>
<td><strong>43</strong></td>
<td><strong>0</strong></td>
<td><strong>8</strong></td>
<td><strong>30</strong></td>
<td><strong>32/5</strong></td>
</tr>
</tbody>
</table>

Number of cases
## Adverse Drug Reaction

### Adverse Events (n=1128)

<table>
<thead>
<tr>
<th></th>
<th>SAE</th>
<th>ADR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of cases (patients)</td>
<td>43(40)</td>
<td>21(15)</td>
</tr>
<tr>
<td>Rate of events</td>
<td>3.8%</td>
<td>1.9%</td>
</tr>
</tbody>
</table>

- **DEATH (11)**
- **LUNG EDEMA (3)**
- **CARDIAC DEATH (2)**
- **MI (2)**
- **CONGESTIVE HEART FAILURE (2)**
- **CEREBRAL HAEMORRHAGE (2)**
- **GASTRITIS (2)**
- **GASTRIC ULCER HAEMORRHAGIC (2)**
- **CHEST DISCOMFORT (1)**
- **THYROID NEOPLASM MALIGNANT (1)**
- **PULMONARY TUBERCULOSIS REACTIVE (1)**
- **CEREBELLAR INFARCTION (1)**
- **ENDOPHTHALMITIS (1)**
- **BLADDER CARCINOMA (1)**
- **ARRHYTHMIA NODAL (1)**
- **INTERSTITIAL LUNG DISEASE (1)**
- **HEART THROBBING (1)**
- **CARDIAC FAILURE (1)**
- **BILE DUCT CARCINOMA (1)**
- **INFLAMMATORY SWELLING (1)**
- **ASTHMA (1)**
- **DERMATITIS (1)**
- **ABDOMINAL PAIN (1)**

- **Elevated GOT (4)**
- **Elevated GPT (4)**
- **MYALGIA (3)**
- **Elevated CK (1)**
- **CONVULSIONS, legs (1)**
- **VOMITING (1)**
- **COUGHING (1)**
- **CONSTIPATION (1)**
- **ABDOMINAL PAIN (1)**
- **DIARRHEA (1)**
- **DIZZINESS (1)**
- **PAIN NECK/SHOULDER (1)**
- **RASH (1)**
- **GASTRIC ULCER HAEMORRHAGIC (2)**
- **CHEST DISCOMFORT (1)**
- **THYROID NEOPLASM MALIGNANT (1)**
- **PULMONARY TUBERCULOSIS REACTIVE (1)**
- **CEREBELLAR INFARCTION (1)**
- **ENDOPHTHALMITIS (1)**
- **BLADDER CARCINOMA (1)**
- **ARRHYTHMIA NODAL (1)**
- **INTERSTITIAL LUNG DISEASE (1)**
- **HEART THROBBING (1)**
- **CARDIAC FAILURE (1)**
- **BILE DUCT CARCINOMA (1)**
- **INFLAMMATORY SWELLING (1)**
- **ASTHMA (1)**
- **DERMATITIS (1)**
- **ABDOMINAL PAIN (1)**
LAMIS Summary

1. Major clinical outcomes in AMI pts who received routine Pitavastatin (LIVALO) were excellent up to 12 months.

2. Long-term administration of Pitavastatin in pts with AMI was safe and effective in reducing future cardiovascular events.
Routine administration of 2mg Pitavastatin daily in pts with AMI showed excellent biochemical and clinical outcomes without significant adverse effects.
New Cath Lab (Oct 2007)
Pitavastatin (Livalo®) versus No Statin in Patients with Acute Myocardial Infarction Undergoing Percutaneous Coronary Intervention: 12-month Clinical Outcomes from Livalo Acute Myocardial Infarction Study (LAMIS)

Seung-Woon Rha, Lin Wang, Ji Young Park, Kanhaiya L. Poddar, Sureshkumar Ramasamy, Byoung Geol Choi, Ji Bak Kim, Seung Yong Shin, Un-Jung Choi, Cheol Ung Choi, Hong Euy Lim, Jin Won Kim, Eung Ju Kim, Chang Gyu Park, Hong Seog Seo, Dong Joo Oh, Young Keun Ahn*, Myung Ho Jeong* and Other KAMIR Investigators

Cardiovascular Center,
Korea University Guro Hospital, Seoul, Korea
* Chonnam National University Hospital, Gwangju, Korea

KSC 2009 Meeting
Background

1. Current guidelines recommend that the goal of lipid-lowering therapy in patients (pts) with coronary artery disease is LDL-C level < 100mg/dl.

2. Pitavastatin (Livalo) is a potent lipophilic statin and may play an important role in acute myocardial infarction (AMI) setting but there have been limited data regarding role of pitavastatin in managing AMI patients (pts), especially in the drug-eluting stent era.
Purpose

This study was to evaluate whether the routine administration of Pitavastatin daily in AMI pts can positively impact on clinical outcomes compared with those of AMI pts without statin therapy up to 12 months.
Methods

1. Source Data

1) Pitavastatin Data were originated from the Livalo AMI study *(LAMIS; 2007.2-2009.7)*

2) AMI pts without statin usage were drawn as a ‘historical comparison group’ from the subgroup analysis of Korea Acute Myocardial Infarction Registry *(KAMIR study; 2005.11-2009.2)*

2. Study population

1) The study population consisted of 1,069 consecutive AMI pts enrolled for the interim analysis.

2) Pitavastatin group; exclusively used Pitavastatin (2mg/day as sole statin therapy from the presentation time
3. Study Groups

All the pts were divided into 2 groups according to their use of statins:

- Pitavastatin group  N=1070 pts
- No Statin group    N=3011 pts
Methods

4. Antithrombotic therapy

1) Enoxaparin (Clexane®); 60mg bid before PCI and after PCI during the hospital stay (within 7 days).
2) Unfractionated Heparin; a bolus of 50 U/kg prior to PCI for 1st one hour
3) GP IIbIIIa blocker (Reopro®); depend on physician’s discretion
Methods

5. Percutaneous Coronary Intervention (PCI) Procedure

1) A variety of atheroablative devices were not utilized and mostly simple predilation or was performed to get an adequate luminal diameter which was necessary to accommodate the unexpanded DES or BMS and their delivery system.

2) Thrombus aspiration was done using Thrombuster II catheter or Export catheter if there were significant angiographic visible thrombi in the target lesion before stenting.

6. Study Endpoints

; We compared the major clinical outcomes of both groups at 12-month.
Statistics (1)

1. All statistical analyses were performed using SPSS 17.0.
2. Continuous variables were expressed as means ± standard deviation and were compared using Student’s t-test.
3. Categorical data were expressed as percentages and were compared using chi-square statistics or Fisher’s exact test.
4. A $P$-value of 0.05 was considered statistically significant.
5. To rule out the confounding effects from the baseline biases, multivariate Cox regression analysis were performed.

6. Confounding factors included age, gender, body mass index, conventional cardiovascular risk factors (hypertension, diabetes mellitus, hyperlipidemia, smoking and family history of coronary heart disease), past history (prior myocardial infarction, prior heart failure, peripheral artery disease, cerebrovascular disease), diagnosis of AMI, and major treatments (PCI or thrombolysis, aspirin, clopidogrel, cilostazol, heparins, glycoprotein IIb/IIIa receptor blockers, beta-blockers, angiotensin converting enzyme inhibitors, angiotensin II receptor blockers, calcium channel blockers).
## Baseline Characteristics

<table>
<thead>
<tr>
<th>Variable, n (%)</th>
<th>No statin (N=3011 pts)</th>
<th>Pitavastatin (N=1070 pts)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>63.6 ± 13.0</td>
<td>61.4 ± 12.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Gender (Male)</td>
<td>2190 (71.2)</td>
<td>793 (74.1)</td>
<td>0.065</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STEMI</td>
<td>1696 (55.5)</td>
<td>676 (63.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>NSTEMI</td>
<td>1362 (44.5)</td>
<td>390 (36.6)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1465 (48.2)</td>
<td>495 (46.6)</td>
<td>0.375</td>
</tr>
<tr>
<td>Untreatment</td>
<td>187 (6.2)</td>
<td>73 (6.9)</td>
<td>0.405</td>
</tr>
<tr>
<td>treatment</td>
<td>1260 (41.4)</td>
<td>403 (37.9)</td>
<td>0.046</td>
</tr>
<tr>
<td>DM</td>
<td>896 (29.6)</td>
<td>261 (24.5)</td>
<td>0.002</td>
</tr>
<tr>
<td>Untreatment</td>
<td>105 (3.5)</td>
<td>31 (2.9)</td>
<td>0.387</td>
</tr>
<tr>
<td>Oral</td>
<td>691 (22.8)</td>
<td>206 (19.4)</td>
<td>0.019</td>
</tr>
<tr>
<td>insulin</td>
<td>96 (3.2)</td>
<td>15 (1.4)</td>
<td>0.002</td>
</tr>
</tbody>
</table>
## Baseline Characteristics (2)

<table>
<thead>
<tr>
<th>Variable, n (%)</th>
<th>No statin (N=3011 pts)</th>
<th>Pitavastatin (N=1070 pts)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dyslipidemia</td>
<td>203 (7.7)</td>
<td>104 (10.1)</td>
<td>0.018</td>
</tr>
<tr>
<td>Untreatment</td>
<td>71 (2.7)</td>
<td>57 (5.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>treatment</td>
<td>132 (5.0)</td>
<td>47 (4.5)</td>
<td>0.577</td>
</tr>
<tr>
<td>Smoking</td>
<td>1739 (57.1)</td>
<td>666 (62.5)</td>
<td>0.002</td>
</tr>
<tr>
<td>Current</td>
<td>1286 (42.2)</td>
<td>509 (47.8)</td>
<td>0.002</td>
</tr>
<tr>
<td>Quit</td>
<td>453 (14.9)</td>
<td>157 (14.8)</td>
<td>0.924</td>
</tr>
<tr>
<td>IHD (Ischemic Heart Disease)</td>
<td>503 (16.4)</td>
<td>123 (11.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Previous angina</td>
<td>175 (5.6)</td>
<td>51 (4.8)</td>
<td>0.290</td>
</tr>
<tr>
<td>Previous PCI</td>
<td>289 (9.3)</td>
<td>53 (5.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Previous AMI</td>
<td>105 (3.4)</td>
<td>20 (1.9)</td>
<td>0.013</td>
</tr>
<tr>
<td>Previous CABG</td>
<td>30 (1.0)</td>
<td>3 (0.3)</td>
<td>0.030</td>
</tr>
<tr>
<td>Family Hx of IHD</td>
<td>173 (5.7)</td>
<td>55 (5.2)</td>
<td>0.522</td>
</tr>
<tr>
<td>Multi Vessle disease</td>
<td>1489 (58.1)</td>
<td>544 (50.8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>LM lesion</td>
<td>113 (4.4)</td>
<td>12 (1.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Variable, n (%)</td>
<td>No statin (N=3011 pts)</td>
<td>Pitavastatin (N=1070 pts)</td>
<td>p-value</td>
</tr>
<tr>
<td>-------------------------</td>
<td>------------------------</td>
<td>---------------------------</td>
<td>---------</td>
</tr>
<tr>
<td><strong>Killip Class</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class 1</td>
<td>2108 (71.7)</td>
<td>842 (80.0)</td>
<td>-</td>
</tr>
<tr>
<td>Class 2</td>
<td>406 (13.8)</td>
<td>157 (14.9)</td>
<td>-</td>
</tr>
<tr>
<td>Class 3</td>
<td>293 (10.0)</td>
<td>37 (3.5)</td>
<td>-</td>
</tr>
<tr>
<td>Class 4</td>
<td>135 (4.6)</td>
<td>16 (1.5)</td>
<td>-</td>
</tr>
<tr>
<td><strong>Post LVEF</strong></td>
<td>50.9 ±12.7</td>
<td>52.7 ±11.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>Total Cholesterol</strong></td>
<td>174.1 ±43.6</td>
<td>190.5 ±42.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>Triglyceride</strong></td>
<td>123.3 ±91.9</td>
<td>126.3 ±92.0</td>
<td>0.376</td>
</tr>
<tr>
<td><strong>HDL-C</strong></td>
<td>44.8 ±13.9</td>
<td>45.2 ±11.8</td>
<td>0.378</td>
</tr>
<tr>
<td><strong>LDL-C</strong></td>
<td>108.3 ±42.3</td>
<td>121.8 ±36.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>hs-CRP</strong></td>
<td>8.8 ±35.4</td>
<td>9.9 ±30.2</td>
<td>0.394</td>
</tr>
<tr>
<td><strong>CK</strong></td>
<td>1393.9 ±2078.6</td>
<td>1106.2 ±2111.8</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
## In-hospital Treatment Strategies

<table>
<thead>
<tr>
<th>Variable, n (%)</th>
<th>No statin (N=3011 pts)</th>
<th>Pitavastatin (N=1070 pts)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medication</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Past Medication</td>
<td>1108 (35.6)</td>
<td>459 (43.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Single</td>
<td>116 (3.9)</td>
<td>25 (2.4)</td>
<td>0.030</td>
</tr>
<tr>
<td>Dual</td>
<td>2111 (71.1)</td>
<td>607 (59.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Triple</td>
<td>744 (25.0)</td>
<td>389 (38.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>STEMI</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary PCI</td>
<td>1240/1676 (74.0)</td>
<td>544/665 (81.8)</td>
<td>-</td>
</tr>
<tr>
<td>Facilitated PCI</td>
<td>53/1676 (3.2)</td>
<td>46/665 (6.9)</td>
<td>-</td>
</tr>
<tr>
<td>Thrombolysis</td>
<td>133/1676 (7.9)</td>
<td>39/665 (5.9)</td>
<td>-</td>
</tr>
<tr>
<td>Conservative</td>
<td>250/1676 (14.9)</td>
<td>36/665 (5.4)</td>
<td>-</td>
</tr>
<tr>
<td><strong>NSTEMI</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Early invasive therapy</td>
<td>612/1306 (46.9)</td>
<td>255/383 (66.6)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Early conservative therapy</td>
<td>694/1306 (53.1)</td>
<td>128/383 (33.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Thrombolysis</td>
<td>204 (6.7)</td>
<td>54 (5.0)</td>
<td>0.057</td>
</tr>
<tr>
<td>PCI</td>
<td>2332 (76.0)</td>
<td>987 (92.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Variable, n (%)</td>
<td>No statin (N=2574 pts)</td>
<td>Pitavastatin (N=1025 pts)</td>
<td>p-value</td>
</tr>
<tr>
<td>-----------------------</td>
<td>------------------------</td>
<td>---------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Total Death</td>
<td>137 (5.3)</td>
<td>22 (2.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>86 (3.3)</td>
<td>11 (1.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Non Cardiac Death</td>
<td>51 (2.0)</td>
<td>12 (1.2)</td>
<td>0.094</td>
</tr>
<tr>
<td>Recurrent MI</td>
<td>23 (0.9)</td>
<td>11 (1.1)</td>
<td>0.543</td>
</tr>
<tr>
<td>QMI</td>
<td>11 (0.4)</td>
<td>5 (0.5)</td>
<td>0.806</td>
</tr>
<tr>
<td>NQMI</td>
<td>12 (0.5)</td>
<td>5 (0.5)</td>
<td>0.932</td>
</tr>
<tr>
<td>Repeat PCI</td>
<td>107 (4.2)</td>
<td>34 (3.3)</td>
<td>0.241</td>
</tr>
<tr>
<td>TLR</td>
<td>47 (1.8)</td>
<td>22 (2.1)</td>
<td>0.527</td>
</tr>
<tr>
<td>TVR</td>
<td>54 (2.1)</td>
<td>27 (2.6)</td>
<td>0.328</td>
</tr>
<tr>
<td>Non TVR</td>
<td>50 (1.9)</td>
<td>8 (0.8)</td>
<td>0.012</td>
</tr>
<tr>
<td>CABG</td>
<td>24 (0.9)</td>
<td>0 (0.0)</td>
<td>0.002</td>
</tr>
<tr>
<td>Total MACE</td>
<td>264 (10.3)</td>
<td>57 (5.6)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>TLR MACE</td>
<td>133 (5.2)</td>
<td>33 (3.2)</td>
<td>0.012</td>
</tr>
<tr>
<td>TVR MACE</td>
<td>189 (7.3)</td>
<td>49 (4.8)</td>
<td>0.005</td>
</tr>
</tbody>
</table>
## Clinical outcomes at 6 months.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Unadjusted OR (95% CI)</th>
<th>p-value</th>
<th>Adjusted OR* (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Death</td>
<td>2.559 (1.622-4.038)</td>
<td>&lt;0.001</td>
<td>1.762 (0.995-3.122)</td>
<td>0.052</td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>3.186 (1.694-5.994)</td>
<td>&lt;0.001</td>
<td>2.193 (1.018-4.726)</td>
<td>0.045</td>
</tr>
<tr>
<td>Non Cardiac Death</td>
<td>1.706 (0.906-3.214)</td>
<td>0.094</td>
<td>1.172 (0.509-2.699)</td>
<td>0.709</td>
</tr>
<tr>
<td>Recurrent MI</td>
<td>0.800 (0.388-1.647)</td>
<td>0.543</td>
<td>0.588 (0.196-1.760)</td>
<td>0.324</td>
</tr>
<tr>
<td>QMI</td>
<td>0.876 (0.303-2.526)</td>
<td>0.806</td>
<td>0.658 (0.141-3.073)</td>
<td>0.594</td>
</tr>
<tr>
<td>NQMI</td>
<td>0.956 (0.336-2.719)</td>
<td>0.932</td>
<td>0.634 (0.103-3.891)</td>
<td>0.623</td>
</tr>
<tr>
<td>Repeat PCI</td>
<td>1.264 (0.853-1.872)</td>
<td>0.241</td>
<td>1.445 (0.868-2.405)</td>
<td>0.157</td>
</tr>
<tr>
<td>TLR</td>
<td>0.848 (0.508-1.414)</td>
<td>0.527</td>
<td>0.939 (0.489-1.802)</td>
<td>0.850</td>
</tr>
<tr>
<td>TVR</td>
<td>0.792 (0.496-1.264)</td>
<td>0.328</td>
<td>0.963 (0.516-1.798)</td>
<td>0.906</td>
</tr>
<tr>
<td>Non TVR</td>
<td>2.518 (1.190-5.331)</td>
<td>0.012</td>
<td>2.195 (0.911-5.289)</td>
<td>0.080</td>
</tr>
<tr>
<td>CABG</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total MACE</td>
<td>1.941 (1.444-2.609)</td>
<td>&lt;0.001</td>
<td>1.851 (1.266-2.705)</td>
<td>0.001</td>
</tr>
<tr>
<td>TLR MACE</td>
<td>1.638 (1.111-2.415)</td>
<td>0.012</td>
<td>1.406 (0.863-2.293)</td>
<td>0.172</td>
</tr>
<tr>
<td>TVR MACE</td>
<td>1.578 (1.143-2.180)</td>
<td>0.005</td>
<td>1.364 (0.894-2.081)</td>
<td>0.150</td>
</tr>
</tbody>
</table>
## Clinical outcomes at 12 month.

<table>
<thead>
<tr>
<th>Variable, n (%)</th>
<th>No statin (N=2067 pts)</th>
<th>Pitavastatin (N=930 pts)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Death</strong></td>
<td>158 (7.6)</td>
<td>28 (3.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>96 (4.6)</td>
<td>15 (1.6)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Non Cardiac Death</td>
<td>64 (3.1)</td>
<td>13 (1.4)</td>
<td>0.007</td>
</tr>
<tr>
<td><strong>Recurrent MI</strong></td>
<td>30 (1.5)</td>
<td>13 (1.4)</td>
<td>0.903</td>
</tr>
<tr>
<td>QMI</td>
<td>16 (0.8)</td>
<td>6 (0.6)</td>
<td>0.702</td>
</tr>
<tr>
<td>NQMI</td>
<td>14 (0.7)</td>
<td>6 (0.6)</td>
<td>0.920</td>
</tr>
<tr>
<td><strong>Repeat PCI</strong></td>
<td>146 (7.1)</td>
<td>66 (7.1)</td>
<td>0.974</td>
</tr>
<tr>
<td>TLR</td>
<td>70 (3.4)</td>
<td>42 (4.5)</td>
<td>0.131</td>
</tr>
<tr>
<td>TVR</td>
<td>82 (4.0)</td>
<td>55 (5.9)</td>
<td>0.018</td>
</tr>
<tr>
<td>Non TVR</td>
<td>65 (3.1)</td>
<td>13 (1.4)</td>
<td>0.005</td>
</tr>
<tr>
<td>CABG</td>
<td>24 (1.2)</td>
<td>1 (0.1)</td>
<td>0.003</td>
</tr>
<tr>
<td><strong>Total MACE</strong></td>
<td>328 (15.9)</td>
<td>97 (10.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>TLR MACE</td>
<td>164 (7.9)</td>
<td>57 (6.1)</td>
<td>0.080</td>
</tr>
<tr>
<td>TVRMACE</td>
<td>240 (11.6)</td>
<td>82 (8.8)</td>
<td>0.022</td>
</tr>
</tbody>
</table>
### Clinical outcomes at 12month.

<table>
<thead>
<tr>
<th></th>
<th>Unadjusted OR (95% CI)</th>
<th>p-value</th>
<th>Adjusted OR* (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Death</td>
<td>2.650 (1.759-3.991)</td>
<td>&lt;0.001</td>
<td>1.119 (1.119-3.261)</td>
<td>0.018</td>
</tr>
<tr>
<td>Cardic Death</td>
<td>2.971 (1.715-5.149)</td>
<td>&lt;0.001</td>
<td>2.146 (1.056-4.360)</td>
<td>0.035</td>
</tr>
<tr>
<td>Non Cardic Death</td>
<td>2.254 (1.235-4.112)</td>
<td>0.007</td>
<td>1.575 (0.715-3.470)</td>
<td>0.259</td>
</tr>
<tr>
<td>Recurrent MI</td>
<td>0.960 (0.499-1.849)</td>
<td>0.903</td>
<td>0.734 (0.266-2.025)</td>
<td>0.550</td>
</tr>
<tr>
<td>QMI</td>
<td>1.201 (0.469-3.080)</td>
<td>0.702</td>
<td>0.899 (0.236-3.425)</td>
<td>0.876</td>
</tr>
<tr>
<td>NQMI</td>
<td>1.050 (0.402-2.741)</td>
<td>0.920</td>
<td>0.536 (0.104-2.664)</td>
<td>0.438</td>
</tr>
<tr>
<td>Repeat PCI</td>
<td>0.995 (0.736-1.345)</td>
<td>0.974</td>
<td>1.038 (0.700-1.540)</td>
<td>0.852</td>
</tr>
<tr>
<td>TLR</td>
<td>0.741 (0.501-1.095)</td>
<td>0.131</td>
<td>0.780 (0.477-1.277)</td>
<td>0.323</td>
</tr>
<tr>
<td>TVR</td>
<td>0.657 (0.463-0.933)</td>
<td>0.018</td>
<td>0.725 (0.465-1.151)</td>
<td>0.173</td>
</tr>
<tr>
<td>Non TVR</td>
<td>2.290 (1.256-4.175)</td>
<td>0.005</td>
<td>2.100 (1.016-4.340)</td>
<td>0.045</td>
</tr>
<tr>
<td>CABG</td>
<td>10.913 (1.474-80.791)</td>
<td>0.003</td>
<td>11.726 (1.511-90.972)</td>
<td>0.019</td>
</tr>
<tr>
<td>Total MACE</td>
<td>1.620 (1.273-2061)</td>
<td>&lt;0.001</td>
<td>1.441 (1.053-1.972)</td>
<td>0.022</td>
</tr>
<tr>
<td>TLR MACE</td>
<td>1.320 (0.966-1.803)</td>
<td>0.080</td>
<td>1.132 (0.760-1.686)</td>
<td>0.541</td>
</tr>
<tr>
<td>TVRMACE</td>
<td>1.358 (1.044-1.768)</td>
<td>0.022</td>
<td>1.125 (0.794-1.594)</td>
<td>0.507</td>
</tr>
</tbody>
</table>
Results

1. The baseline characteristics were similar between the two groups except that pts in Livalo group were younger (61.2±12.0 vs 63.0±12, p<0.05) and showed higher total cholesterol level (194.9±41.3 vs 174.5±42.2, mg/dl, p<0.01) than no statin group.

2. Although the incidence of recurrent AMI was similar between the groups, the incidence of mortality, repeat PCI and MACE were significantly lower in the Pitavastatin group.
**Results**

3. Pitavastatin administration was associated with less incidence of MACE at 12 months (OR unadjusted: 0.560, 95% CI: 0.360-0.873, \( P = 0.010 \), OR adjusted by propensity score: 0.200, 95% CI: 0.065-0.613, \( P = 0.005 \)).
Conclusions

Routine administration of 2mg Pitavastatin daily in AMI pts showed better clinical outcomes compared with those of AMI pts without statin therapy up to 12 months.
Propensity Score Analysis of 12-month Clinical Outcomes following Pitavastatin (Livalo®) Administration in Patients with Acute Myocardial Infarction: Results from Livalo Acute Myocardial Infarction Study (LAMIS)

Seung-Woon Rha, Lin Wang, Ji Young Park, Kanhaiya L. Poddar, Sureshkumar Ramasamy, Byoung Geol Choi, Ji Bak Kim, Seung Yong Shin, Un-Jung Choi, Cheol Ung Choi, Hong Euy Lim, Jin Won Kim, Eung Ju Kim, Chang Gyu Park, Hong Seog Seo, Dong Joo Oh, Young Keun Ahn*, Myung Ho Jeong* and Other KAMIR Investigators

Cardiovascular Center,
Korea University Guro Hospital, Seoul, Korea
* Chonnam National University Hospital, Gwangju, Korea

KSC 2009
Methods

1. Source Data
   1) Pitavastatin Data were originated from the Livalo AMI study (LAMIS)
   2) AMI pts without statin usage were drawn as a ‘historical comparison group’ from the subgroup analysis of Korea Acute Myocardial Infarction Registry (KAMIR study).

2. Study population
   1) The study population consisted of 2,530 consecutive AMI pts enrolled for the interim analysis.
   2) Pitavastatin group; exclusively used Pitavastatin (2mg/day as sole statin therapy from the presentation time
Methods

3. Study Groups

All the pts were divided into 3 groups according to their use of statins:

- Pitavastatin in LAMIS group  N=601 pts
- Statin in KAMIR group  N=1461 pts
- No Statin in KAMIR group  N=468 pts
Figure. Twelve-Month Cumulative Clinical Events: Total MACEs

Clinical Follow Up upto 12 Months, DAYS.
Results

1. Patients in Livalo group were younger and successful PCI rate and ejection fraction (EF) was higher than those of no statin group (p<0.05).

2. Pitavastatin (ORunadjusted: 0.560, 95% CI: 0.360-0.873, P=0.010, ORadjusted by propensity score: 0.200, 95% CI: 0.065-0.613, P= 0.005) was associated with less incidence of MACE at 12 months compared with the AMI pts without any statin therapy.

3. Overall statin administration (OR: 0.812, 95% CI: 0.550-1.199, P=0.295) was associated with less incidence of MACE at 12 months compared with the AMI pts without any statin therapy (Figure).
Research Family 2007-8
Efficacy and Safety of Pitavastatin (Livalo®) in Acute ST-Segment Elevation Myocardial Infarction Patients: 12-month follow up data from Livalo Acute Myocardial Infarction Study (LAMIS) and Korea Acute Myocardial Infarction Registry (KAMIR)

Seung-Woon Rha, Lin Wang, Ji Young Park, Kanhaiya L. Poddar, Sureshkumar Ramasamy, Byoung Geol Choi, Ji Bak Kim, Seung Yong Shin, Un-Jung Choi, Cheol Ung Choi, Hong Euy Lim, Jin Won Kim, Eung Ju Kim, Chang Gyu Park, Hong Seog Seo, Dong Joo Oh, Young Keun Ahn*, Myung Ho Jeong* and Other LAMIS Investigators

Cardiovascular Center,
Korea University Guro Hospital, Seoul, Korea
* Chonnam National University Hospital, Gwangju, Korea

CCT 2010 Meeting
Purpose

This study was to evaluate whether the routine administration of Pitavastatin daily in STEMI pts can positively impact on clinical outcomes compared with those of AMI pts without statin therapy up to 12 months.
Methods

1. Source Data
   1) Pitavastatin Data were originated from the Livalo AMI study (LAMIS)
   2) AMI pts without statin usage were drawn as a ‘historical comparison group’ from the subgroup analysis of Korea Acute Myocardial Infarction Registry (KAMIR study).

2. Study population
   1) The study population consisted of 675 consecutive STEMI pts enrolled for the interim analysis.
   2) Pitavastatin group; exclusively used Pitavastatin (2mg/day as sole statin therapy from the presentation time)
Methods

3. Study Groups

All the pts were divided into 2 groups according to their use of statins:

- Pitavastatin group  N=675 pts
- No Statin group     N=1696 pts
# Clinical outcomes at 6 month.

<table>
<thead>
<tr>
<th>Variable, n (%)</th>
<th>No statin (N=1420 pts)</th>
<th>Pitavastatin (645 pts)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Death</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>38 (2.7)</td>
<td>6 (0.9)</td>
<td>0.011</td>
</tr>
<tr>
<td>Non Cardiac Death</td>
<td>26 (1.8)</td>
<td>7 (1.1)</td>
<td>0.210</td>
</tr>
<tr>
<td><strong>Recurrent MI</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>QMI</td>
<td>7 (0.5)</td>
<td>4 (0.6)</td>
<td>0.713</td>
</tr>
<tr>
<td>NQMI</td>
<td>3 (0.2)</td>
<td>1 (0.2)</td>
<td>0.788</td>
</tr>
<tr>
<td><strong>Repeat PCI</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TLR</td>
<td>32 (2.3)</td>
<td>13 (2.0)</td>
<td>0.731</td>
</tr>
<tr>
<td>TVR</td>
<td>37 (2.6)</td>
<td>18 (2.8)</td>
<td>0.809</td>
</tr>
<tr>
<td>Non TVR</td>
<td>28 (2.0)</td>
<td>5 (0.8)</td>
<td>0.044</td>
</tr>
<tr>
<td>CABG</td>
<td>10 (0.7)</td>
<td>0 (0.0)</td>
<td>0.035</td>
</tr>
<tr>
<td><strong>Total MACE</strong></td>
<td>136 (9.6)</td>
<td>33 (5.1)</td>
<td>0.001</td>
</tr>
<tr>
<td>TLR MACE</td>
<td>70 (4.9)</td>
<td>19 (2.9)</td>
<td>0.040</td>
</tr>
<tr>
<td>TVRMACE</td>
<td>96 (6.8)</td>
<td>28 (4.3)</td>
<td>0.032</td>
</tr>
</tbody>
</table>
Clinical outcomes at 6 month.

<table>
<thead>
<tr>
<th>Event</th>
<th>Unadjusted OR (95% CI)</th>
<th>p-value</th>
<th>Adjusted OR* (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Death</td>
<td>2.291 (1.253-2.291)</td>
<td>0.007</td>
<td>1.049 (1.018-1.082)</td>
<td>0.002</td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>2.2928 (1.232-6.963)</td>
<td>0.015</td>
<td>0.593 (2.778-1.265)</td>
<td>0.176</td>
</tr>
<tr>
<td>Non Cardiac Death</td>
<td>1.700 (0.734-3.937)</td>
<td>0.216</td>
<td>0.487 (0.174-1.363)</td>
<td>0.171</td>
</tr>
<tr>
<td>Recurrent MI</td>
<td>0.733 (0.265-2.025)</td>
<td>0.549</td>
<td>2.631 (0.574-12064)</td>
<td>0.213</td>
</tr>
<tr>
<td>QMI</td>
<td>0.794 (0.232-2.722)</td>
<td>0.713</td>
<td>2.241 (0.387-12.975)</td>
<td>0.368</td>
</tr>
<tr>
<td>NQMI</td>
<td>1.363 (0.141-13.133)</td>
<td>0.789</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Repeat PCI</td>
<td>1.446 (0.887-2.359)</td>
<td>0.139</td>
<td>0.558 (0.229-1.038)</td>
<td>0.066</td>
</tr>
<tr>
<td>TLR</td>
<td>1.121 (0.584-2.150)</td>
<td>0.731</td>
<td>0.754 (0.341-1.667)</td>
<td>0.486</td>
</tr>
<tr>
<td>TVR</td>
<td>0.932 (0.526-1.650)</td>
<td>0.809</td>
<td>0.747 (0.355-1.576)</td>
<td>0.444</td>
</tr>
<tr>
<td>Non TVR</td>
<td>2.575 (0.990-6.699)</td>
<td>0.045</td>
<td>0.490 (0.172-1.397)</td>
<td>0.182</td>
</tr>
<tr>
<td>CABG</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total MACE</td>
<td>1.964 (1.327-2.908)</td>
<td>0.001</td>
<td>0.486 (0.295-0.800)</td>
<td>0.005</td>
</tr>
<tr>
<td>TLR MACE</td>
<td>1.708 (1.020-2.861)</td>
<td>0.042</td>
<td>0.649 (0.347-1.217)</td>
<td>0.178</td>
</tr>
<tr>
<td>TVRMACE</td>
<td>1.598 (1.038-2.460)</td>
<td>0.033</td>
<td>0.617 (0.353-1.080)</td>
<td>0.091</td>
</tr>
</tbody>
</table>
**Clinical outcomes at 12 month.**

<table>
<thead>
<tr>
<th>Variable, n (%)</th>
<th>No statin (N=1148 pts)</th>
<th>Pitavastatin (N=583 pts)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Death</strong></td>
<td>72 (6.2)</td>
<td>15 (2.6)</td>
<td>0.001</td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>43 (3.7)</td>
<td>8 (1.4)</td>
<td>0.006</td>
</tr>
<tr>
<td>Non Cardiac Death</td>
<td>30 (2.6)</td>
<td>6 (1.0)</td>
<td>0.029</td>
</tr>
<tr>
<td><strong>Recurrent MI</strong></td>
<td>12 (1.0)</td>
<td>7 (1.2)</td>
<td>0.664</td>
</tr>
<tr>
<td>QMI</td>
<td>9 (0.8)</td>
<td>5 (0.9)</td>
<td>0.872</td>
</tr>
<tr>
<td>NQMI</td>
<td>3 (0.3)</td>
<td>1 (0.2)</td>
<td>0.713</td>
</tr>
<tr>
<td><strong>Repeat PCI</strong></td>
<td>91 (7.9)</td>
<td>41 (7.0)</td>
<td>0.508</td>
</tr>
<tr>
<td>TLR</td>
<td>44 (3.8)</td>
<td>25 (4.3)</td>
<td>0.647</td>
</tr>
<tr>
<td>TVR</td>
<td>52 (4.5)</td>
<td>36 (6.2)</td>
<td>0.141</td>
</tr>
<tr>
<td>Non TVR</td>
<td>39 (3.4)</td>
<td>7 (1.2)</td>
<td>0.007</td>
</tr>
<tr>
<td>CABG</td>
<td>10 (0.9)</td>
<td>0 (0.0)</td>
<td>0.024</td>
</tr>
<tr>
<td><strong>Total MACE</strong></td>
<td>169 (14.7)</td>
<td>54 (9.3)</td>
<td>0.001</td>
</tr>
<tr>
<td>TLR MACE</td>
<td>86 (7.5)</td>
<td>33 (5.7)</td>
<td>0.155</td>
</tr>
<tr>
<td>TVR MACE</td>
<td>119 (10.4)</td>
<td>46 (7.9)</td>
<td>0.097</td>
</tr>
</tbody>
</table>
## Clinical outcomes at 12month.

<table>
<thead>
<tr>
<th>Event</th>
<th>Unadjusted OR (95% CI)</th>
<th>p-value</th>
<th>Adjusted OR* (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Death</td>
<td>2.520 (1.431-4.436)</td>
<td>0.001</td>
<td>0.542 (0.262-1.120)</td>
<td>0.098</td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>2.797 (1.306-5.989)</td>
<td>0.008</td>
<td>0.507 (0.196-1.311)</td>
<td>0.161</td>
</tr>
<tr>
<td>Non Cardiac Death</td>
<td>2.581 (1.068-6.235)</td>
<td>0.035</td>
<td>0.466 (0.144-1.510)</td>
<td>0.203</td>
</tr>
<tr>
<td>Recurrent MI</td>
<td>0.813 (0.318-2.075)</td>
<td>0.665</td>
<td>1.990 (0.476-8.328)</td>
<td>0.346</td>
</tr>
<tr>
<td>QMI</td>
<td>0.872 (0.305-2.738)</td>
<td>0.872</td>
<td>1.651 (0.359-7.598)</td>
<td>0.520</td>
</tr>
<tr>
<td>NQMI</td>
<td>1.525 (0.158-14.692)</td>
<td>0.715</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Repeat PCI</td>
<td>1.138 (0.776-1.669)</td>
<td>0.508</td>
<td>0.766 (0.477-1,229)</td>
<td>0.269</td>
</tr>
<tr>
<td>TLR</td>
<td>0.890 (0.539-1.469)</td>
<td>0.647</td>
<td>0.973 (0.533-1.776)</td>
<td>0.928</td>
</tr>
<tr>
<td>TVR</td>
<td>0.721 (0.466-1.116)</td>
<td>0.142</td>
<td>1.112 (0.645-1.919)</td>
<td>0.702</td>
</tr>
<tr>
<td>Non TVR</td>
<td>2.894 (1.286-6.510)</td>
<td>0.010</td>
<td>0.409 (0.168-0.996)</td>
<td>0.049</td>
</tr>
<tr>
<td>CABG</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total MACE</td>
<td>1.691 (1.223-2.338)</td>
<td>0.001</td>
<td>0.615 (0.410-0.922)</td>
<td>0.019</td>
</tr>
<tr>
<td>TLR MACE</td>
<td>1.350 (0.892-2.043)</td>
<td>0.159</td>
<td>0.806 (0.486-1.337)</td>
<td>0.403</td>
</tr>
</tbody>
</table>
Results

1. The baseline characteristics were similar between the two groups, except that pts in Patavastatin group were younger than no statin group (59.9±12.6 vs 62.2±12.6, p<0.05) whereas past medication was unfavorable in Pitavastatin group (P<0.05).

2. Although the incidence of target lesion & vessel revascularization (TLR & TVR) and recurrent AMI were similar between the two groups, the all cause mortality, repeat PCI (primarily by reduced non-TVR) and total MACE were significantly lower in the Pitavastatin group (Table).
Results

3. Pitavastatin administration was associated with less incidence of MACE at 12 months (OR: 0.463, 95% CI: 0.276-0.776, P=0.003).
Conclusions

Routine administration of 2mg Pitavastatin daily in *STEMI* pts showed better clinical outcomes compared with those of STEMI pts without statin therapy up to 12 months.
International Research Fellow
2006

Dr. Wani from India
International Research Fellow 2007

* KUMC Guro Hospital Research Fellows 2007
Zhe Jin. Tianjin Medical University Nankai Hospital
Kang-yin Chen. Tianjin Medical University Second Hospital
Yoshiyasu Minami. Kamakura General Hospital
Research Fellow 2008

Yong-Jian Li, Kang-Yin Chen, Yoshiyasu Minami, Kanhaiya L Poddar & Dr Rha
Research Fellow 2009

Kanhaiya L Poddar (India), Lin Wang (China) & SW Rha (Korea)
Research Fellow 2009-2010

Dr Ramasamy, Dr Poddar from India

RN, Seo Young Park
Korean Research Fellow, Ji Young Park
Dr Wang from Tianjin, China
Efficacy and Safety of Pitavastatin (Livalo®) in Acute Non ST-Segment Elevation Myocardial Infarction Patients

: 12-month follow up data from Livalo Acute Myocardial Infarction Study (LAMIS)

Seung-Woon Rha, Lin Wang, Ji Young Park, Kanhaiya L. Poddar, Sureshkumar Ramasamy, Byoung Geol Choi, Ji Bak Kim, Seung Yong Shin, Un-Jung Choi, Cheol Ung Choi, Hong Euy Lim, Jin Won Kim, Eung Ju Kim, Chang Gyu Park, Hong Seog Seo, Dong Joo Oh, Young Keun Ahn*, Myung Ho Jeong* and Other LAMIS Investigators

Cardiovascular Center,

Korea University Guro Hospital, Seoul, Korea
* Chonnam National University Hospital, Gwangju, Korea

AP TCT 2010 Meeting
Purpose

This study was to evaluate whether the routine administration of Pitavastatin daily in NSTEMI pts can positively impact on clinical outcomes compared with those of AMI pts without statin therapy up to 12 months.
Methods

1. Source Data
   1) Pitavastatin Data were originated from the Livalo AMI study (LAMIS)
   2) AMI pts without statin usage were drawn as a ‘historical comparison group’ from the subgroup analysis of Korea Acute Myocardial Infarction Registry (KAMIR study).

2. Study population
   1) The study population consisted of 377 consecutive NSTEMI pts enrolled for the interim analysis.
   2) Pitavastatin group; exclusively used Pitavastatin (2mg/day as sole statin therapy from the presentation time
Methods

3. Study Groups

All the pts were divided into 2 groups according to their use of statins:

- Pitavastatin group  N=377 pts
- No Statin group    N=1117 pts
Clinical outcomes at 6month.

<table>
<thead>
<tr>
<th>Variable, n (%)</th>
<th>No statin (N=1117 pts)</th>
<th>Pitavastatin (N=377 pts)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Death</td>
<td>72 (6.4)</td>
<td>9 (2.4)</td>
<td>0.003</td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>48 (4.3)</td>
<td>5 (1.3)</td>
<td>0.007</td>
</tr>
<tr>
<td>Non Cardiac Death</td>
<td>24 (2.1)</td>
<td>5 (1.3)</td>
<td>0.317</td>
</tr>
<tr>
<td>Recurrent MI</td>
<td>13 (1.2)</td>
<td>5 (1.3)</td>
<td>0.730</td>
</tr>
<tr>
<td>QMI</td>
<td>4 (0.4)</td>
<td>1 (0.3)</td>
<td>0.787</td>
</tr>
<tr>
<td>NQMI</td>
<td>9 (0.8)</td>
<td>4 (1.1)</td>
<td>0.644</td>
</tr>
<tr>
<td>Repeat PCI</td>
<td>36 (3.2)</td>
<td>12 (3.2)</td>
<td>0.970</td>
</tr>
<tr>
<td>TLR</td>
<td>14 (1.3)</td>
<td>9 (2.4)</td>
<td>0.122</td>
</tr>
<tr>
<td>TVR</td>
<td>16 (1.4)</td>
<td>9 (2.4)</td>
<td>0.211</td>
</tr>
<tr>
<td>Non TVR</td>
<td>21 (1.9)</td>
<td>3 (0.8)</td>
<td>0.148</td>
</tr>
<tr>
<td>CABG</td>
<td>14 (1.2)</td>
<td>0 (0.0)</td>
<td>0.033</td>
</tr>
<tr>
<td>Total MACE</td>
<td>126 (11.3)</td>
<td>24 (6.4)</td>
<td>0.006</td>
</tr>
<tr>
<td>TLR MACE</td>
<td>62 (5.6)</td>
<td>14 (3.7)</td>
<td>0.160</td>
</tr>
<tr>
<td>TVR MACE</td>
<td>91 (8.1)</td>
<td>21 (5.6)</td>
<td>0.100</td>
</tr>
</tbody>
</table>
## Clinical outcomes at 6 month.

<table>
<thead>
<tr>
<th>Event</th>
<th>Unadjusted OR (95% CI)</th>
<th>p-value</th>
<th>Adjusted OR* (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Death</strong></td>
<td>0.356 (0.176-0.718)</td>
<td>0.004</td>
<td>0.606 (0.253-1.450)</td>
<td>0.261</td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>0.299 (0.118-0.795)</td>
<td>0.022</td>
<td>0.550 (0.171-1.761)</td>
<td>0.314</td>
</tr>
<tr>
<td>Non Cardiac Death</td>
<td>0.612 (0.232-1.616)</td>
<td>0.322</td>
<td>0.904 (0.263-3.116)</td>
<td>0.974</td>
</tr>
<tr>
<td><strong>Recurrent MI</strong></td>
<td>1.200 (0.425-3.389)</td>
<td>0.730</td>
<td>1.159 (0.241-5.573)</td>
<td>0.854</td>
</tr>
<tr>
<td>QMI</td>
<td>0.740 (0.082-6.642)</td>
<td>0.788</td>
<td>0.543 (0.017-16.992)</td>
<td>0.728</td>
</tr>
<tr>
<td>NQMI</td>
<td>1.320 (0.404-4.312)</td>
<td>0.646</td>
<td>1.121 (0.160=7.867)</td>
<td>0.908</td>
</tr>
<tr>
<td><strong>Repeat PCI</strong></td>
<td>0.987 (0.508-1.918)</td>
<td>0.970</td>
<td>0.809 (0.349-1.876)</td>
<td>0.621</td>
</tr>
<tr>
<td>TLR</td>
<td>1.927 (0.827-4.489)</td>
<td>0.126</td>
<td>1.404 (0.478-4.123)</td>
<td>0.537</td>
</tr>
<tr>
<td>TVR</td>
<td>1.683 (0.737-3.841)</td>
<td>1.683</td>
<td>1.404 (0.478-4.123)</td>
<td>0.537</td>
</tr>
<tr>
<td>Non TVR</td>
<td>0.419 (0.124-1/412)</td>
<td>0.160</td>
<td>0.325 (0.067-1.574)</td>
<td>0.163</td>
</tr>
<tr>
<td>CABG</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Total MACE</strong></td>
<td>0.535 (0.340-0.841)</td>
<td>0.007</td>
<td>0.598 (0.338-1.058)</td>
<td>0.077</td>
</tr>
<tr>
<td>TLR MACE</td>
<td>0.656 (0.363-1.186)</td>
<td>0.163</td>
<td>0.861 (0.401-1.849)</td>
<td>0.702</td>
</tr>
<tr>
<td>TVRMACE</td>
<td>0.665 (0.408-1.085)</td>
<td>0.103</td>
<td>0.937 (0.496-1.770)</td>
<td>0.842</td>
</tr>
</tbody>
</table>
## Clinical outcomes at 12month.

<table>
<thead>
<tr>
<th>Variable, n (%)</th>
<th>No statin (N=905 pts)</th>
<th>Pitavastatin (N=345 pts)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Death</strong></td>
<td>85 (9.4)</td>
<td>13 (3.8)</td>
<td>0.001</td>
</tr>
<tr>
<td><strong>Cardic Death</strong></td>
<td>53 (5.9)</td>
<td>7 (2.0)</td>
<td>0.005</td>
</tr>
<tr>
<td><strong>Non Cardic Death</strong></td>
<td>33 (3.6)</td>
<td>7 (2.0)</td>
<td>0.146</td>
</tr>
<tr>
<td><strong>Recurrent MI</strong></td>
<td>18 (2.0)</td>
<td>6 (1.7)</td>
<td>0.926</td>
</tr>
<tr>
<td><strong>QMI</strong></td>
<td>7 (0.8)</td>
<td>1 (0.3)</td>
<td>0.338</td>
</tr>
<tr>
<td><strong>NQMI</strong></td>
<td>11 (1.2)</td>
<td>5 (1.4)</td>
<td>0.742</td>
</tr>
<tr>
<td><strong>Repeat PCI</strong></td>
<td>52 (5.7)</td>
<td>25 (7.2)</td>
<td>0.324</td>
</tr>
<tr>
<td><strong>TLR</strong></td>
<td>24 (2.7)</td>
<td>17 (4.9)</td>
<td>0.043</td>
</tr>
<tr>
<td><strong>TVR</strong></td>
<td>28 (3.1)</td>
<td>19 (5.5)</td>
<td>0.045</td>
</tr>
<tr>
<td><strong>Non TVR</strong></td>
<td>25 (2.8)</td>
<td>6 (1.7)</td>
<td>0.298</td>
</tr>
<tr>
<td><strong>CABG</strong></td>
<td>14 (1.5)</td>
<td>1 (0.3)</td>
<td>0.068</td>
</tr>
<tr>
<td><strong>Total MACE</strong></td>
<td>156 (17.2)</td>
<td>43 (12.5)</td>
<td>0.039</td>
</tr>
<tr>
<td><strong>TLR MACE</strong></td>
<td>76 (8.4)</td>
<td>24 (7.0)</td>
<td>0.401</td>
</tr>
<tr>
<td><strong>TVRMACE</strong></td>
<td>118 (13.0)</td>
<td>36 (10.4)</td>
<td>0.211</td>
</tr>
</tbody>
</table>
## Clinical outcomes at 12month.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Unadjusted OR (95% CI)</th>
<th>p-value</th>
<th>Adjusted OR* (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Death</strong></td>
<td>0.381 (0.209-0.692)</td>
<td>0.002</td>
<td>0.515 (0.233-1.138)</td>
<td>0.101</td>
</tr>
<tr>
<td><strong>Cardiac Death</strong></td>
<td>0.333 (0.150-0.740)</td>
<td>0.007</td>
<td>0.519 (0.179-1.508)</td>
<td>0.228</td>
</tr>
<tr>
<td><strong>Non Cardiac Death</strong></td>
<td>0.547 (0.240-1.249)</td>
<td>0.152</td>
<td>0.675 (0.233-1.955)</td>
<td>0.469</td>
</tr>
<tr>
<td><strong>Recurrent MI</strong></td>
<td>0.957 (0.377-2.430)</td>
<td>0.926</td>
<td>1.103 (0.278-4.385)</td>
<td>0.889</td>
</tr>
<tr>
<td><strong>QMI</strong></td>
<td>0.373 (0.046-3.042)</td>
<td>0.357</td>
<td>0.255 (0.014-4.501)</td>
<td>0.351</td>
</tr>
<tr>
<td><strong>NQMI</strong></td>
<td>1.195 (0.412-3.465)</td>
<td>0.743</td>
<td>1.508 (0.279-8.157)</td>
<td>0.633</td>
</tr>
<tr>
<td><strong>Repeat PCI</strong></td>
<td>1.282 (0.782-2.100)</td>
<td>0.325</td>
<td>1.220 (0.629-2.365)</td>
<td>0.557</td>
</tr>
<tr>
<td><strong>TLR</strong></td>
<td>1.903 (1.009-3.587)</td>
<td>0.047</td>
<td>1.690 (0.757-3.775)</td>
<td>0.200</td>
</tr>
<tr>
<td><strong>TVR</strong></td>
<td>1.825 (1.006-3.314)</td>
<td>0.048</td>
<td>1.690 (0.757-3.775)</td>
<td>0.200</td>
</tr>
<tr>
<td><strong>Non TVR</strong></td>
<td>0.623 (0.253-1.532)</td>
<td>0.303</td>
<td>0.536 (0.160-1.790)</td>
<td>0.310</td>
</tr>
<tr>
<td><strong>CABG</strong></td>
<td>0.185 (0.024-1.412)</td>
<td>0.104</td>
<td>0.143 (0.018-1.171)</td>
<td>0.070</td>
</tr>
<tr>
<td><strong>Total MACE</strong></td>
<td>0.484 (0.475-0.983)</td>
<td>0.040</td>
<td>0.757 (0.468-1.2230)</td>
<td>0.255</td>
</tr>
<tr>
<td><strong>TLR MACE</strong></td>
<td>0.816 (0.506-1.314)</td>
<td>0.402</td>
<td>0.996 (0.534-1.855)</td>
<td>0.989</td>
</tr>
<tr>
<td><strong>TVRMACE</strong></td>
<td>0.777 (0.523-1.154)</td>
<td>0.211</td>
<td>0.975 (0.562-1.664)</td>
<td>0.927</td>
</tr>
</tbody>
</table>
Results

1. The baseline characteristics were similar between the two groups, except that pts in Pitavastatin group were younger (59.9±12.6 vs 62.2±12.6, p<0.05) whereas past medication was unfavorable (P<0.05) than no statin group.

2. At 12 months, the Pitavastatin group showed no definite evidence in reducing major clinical outcomes except lower trend of CABG than those of no statin group (Table).
Results

3. Pitavastatin administration was associated with less incidence of MACE at 12 months (OR: 0.503, 95% CI: 0.265-0.954, P=0.035).
Routine administration of 2mg Pitavastatin daily in NSTEMI pts failed to show better major clinical outcomes compared with those of NSTEMI pts without statin therapy up to 12 months, but needs more detailed data with larger study population.
Efficacy and Safety of Pitavastatin (Livalo®) in Acute Myocardial Infarction Patients with Diabetes Mellitus: 12-month follow up data from Livalo Acute Myocardial Infarction Study (LAMIS) and Korea Acute Myocardial Infarction Registry (KAMIR)

Seung-Woon Rha, Lin Wang, Ji Young Park, Kanhaiya L. Poddar, Sureshkumar Ramasamy, Byoung Geol Choi, Ji Bak Kim, Seung Yong Shin, Un-Jung Choi, Cheol Ung Choi, Hong Euy Lim, Jin Won Kim, Eung Ju Kim, Chang Gyu Park, Hong Seog Seo, Dong Joo Oh, Young Keun Ahn*, Myung Ho Jeong* and Other LAMIS Investigators

Cardiovascular Center,
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* Chonnam National University Hospital, Gwangju, Korea

AP TCT 2010 Meeting
Background

1. Pitavastatin (Livalo) is a potent lipophilic statin and may play an important role in acute myocardial infarction (AMI) setting.

2. There have been limited data regarding role of pitavastatin in managing AMI patients (pts) with diabetes mellitus, especially in the drug-eluting stent era.

3. Pitavastatin may play an important role by not only reducing LDL-cholesterol, but also through the pleiotrophic effects, especially in diabetic pts.
This study was to evaluate whether the routine administration of Pitavastatin daily in diabetic AMI pts can positively impact on clinical outcomes compared with those of AMI pts without statin therapy up to 12 months.
Methods

1. Source Data

   1) Pitavastatin Data were originated from the Livalo AMI study (LAMIS)

   2) AMI pts without statin usage were drawn as a ‘historical comparison group’ from the subgroup analysis of Korea Acute Myocardial Infarction Registry (KAMIR study).

2. Study population

   1) The study population consisted of 181 consecutive diabetic AMI pts (from LAMIS) and 212 diabetic AMI pts without statin (from KAMIR) enrolled for the interim analysis.

   2) Pitavastatin group; exclusively used Pitavastatin (2mg/day as sole statin therapy from the presentation time
Methods

3. Study Groups

All the pts were divided into 2 groups according to their use of statins:

- Pitavastatin group N=181 pts
- No Statin group N=212 pts
# Clinical Outcomes at 12 months

<table>
<thead>
<tr>
<th>Variables</th>
<th>No Statin (N=212 pts)</th>
<th>Pitavastatin (N=181 pts)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac Death</td>
<td>4 (1.9)</td>
<td>1 (0.6)</td>
<td>0.239</td>
</tr>
<tr>
<td>Repeat PCI</td>
<td>19 (9.0)</td>
<td>6 (3.3)</td>
<td>0.022</td>
</tr>
<tr>
<td>TLR</td>
<td>9 (4.2)</td>
<td>5 (2.8)</td>
<td>0.429</td>
</tr>
<tr>
<td>TVR</td>
<td>10 (4.7)</td>
<td>5 (2.8)</td>
<td>0.313</td>
</tr>
<tr>
<td>Non-TVR</td>
<td>9 (4.2)</td>
<td>1 (0.6)</td>
<td>0.020</td>
</tr>
<tr>
<td>Recurrent AMI</td>
<td>3 (1.4)</td>
<td>1 (0.6)</td>
<td>0.396</td>
</tr>
<tr>
<td>CABG</td>
<td>4 (1.9)</td>
<td>0 (0)</td>
<td>0.063</td>
</tr>
<tr>
<td>Total MACE</td>
<td>31 (14.6)#</td>
<td>11(6.1)*</td>
<td>0.006</td>
</tr>
</tbody>
</table>
Results

1. Baseline characteristics were similar between the groups, except past medications were unfavorable in Livalo group (p<0.05).

2. At 12 months, although the cardiac mortality was not different, the incidence of repeat PCI (primarily due to less incidence of non-target vessel revascularization), coronary artery bypass graft (CABG) and major adverse cardiac events (MACE) were lower in the Pitavastatin group (Table).
Results

3. Pitavastatin administration was associated with less incidence of MACE at 12 months (OR\textsubscript{unadjusted} : 0.394, 95% CI: 0.198-0.784, P=0.008, OR\textsubscript{adjusted by propensity score} : 0.215, 95% CI: 0.075-0.620, P= 0.004).
Conclusions

Routine administration of 2mg Pitavastatin daily in diabetic AMI pts showed better clinical outcomes compared with those of AMI pts without statin therapy up to 12 months.
Summary & Conclusion

1. Introduction; ACS in DES Era & LAMIS
2. Pitavastatin (Livalo) in AMI
   ; insights from LAMIS (Livalo AMI Study) & KAMIR (Korea AMI Registry)
3. Pitavastatin (Livalo) in STEMI
4. Pitavastatin (Livalo) in NSTEMI
5. Pitavastatin (Livalo) in Diabetic AMI

** Pitavastatin is crucial, essential and absolutely needed in pts with AMI in DES era!! **
Research Family Members
International Research Fellow

대한민국 Research Fellow도 대환영!!
(자격)
1. English Proficiency
2. Paperwork & Research가 최우선
3. Cardiovascular Intervention
4. Clinical Fellow 1년 이상 수료자
5. Highly motivated!!
Thank You for Your Attention!!

Korea University Guro Hospital