

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

**: Insights from Livalo Acute Myocardial Infarction  
Study (LAMIS)**

*Seung-Woon Rha, MD, PhD*  
*FACC, FAHA, FESC, FSCAI, FAPSIC*

**Cardiovascular Center,  
Korea University Guro Hospital, Seoul, Korea**

April 16, 2010

KSC 2010 Spring Meeting, Busan

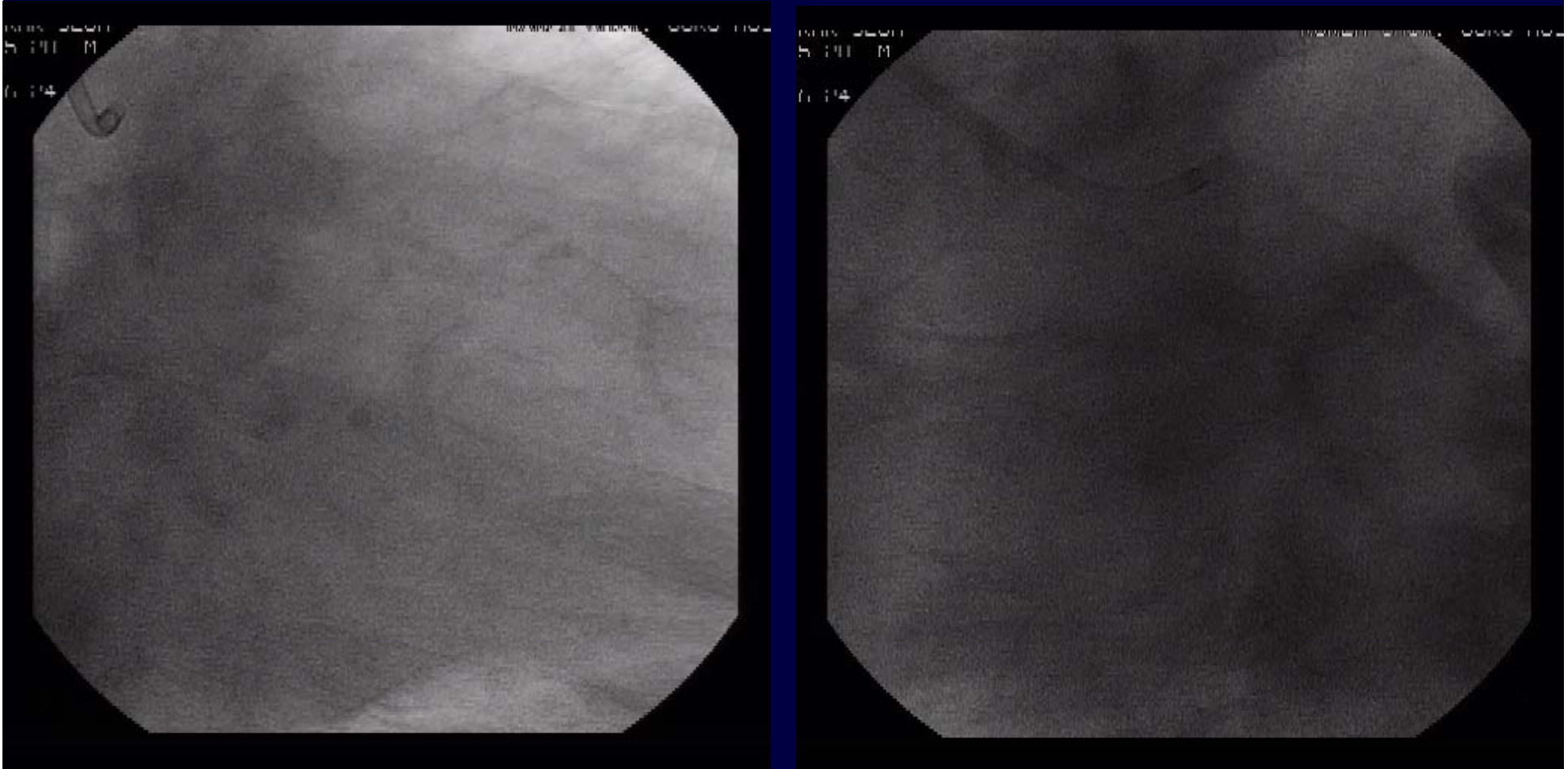
# Contents

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 AMI with DM
6. Summary & Conclusion

# AMI with DES-Efficacy & Safety?

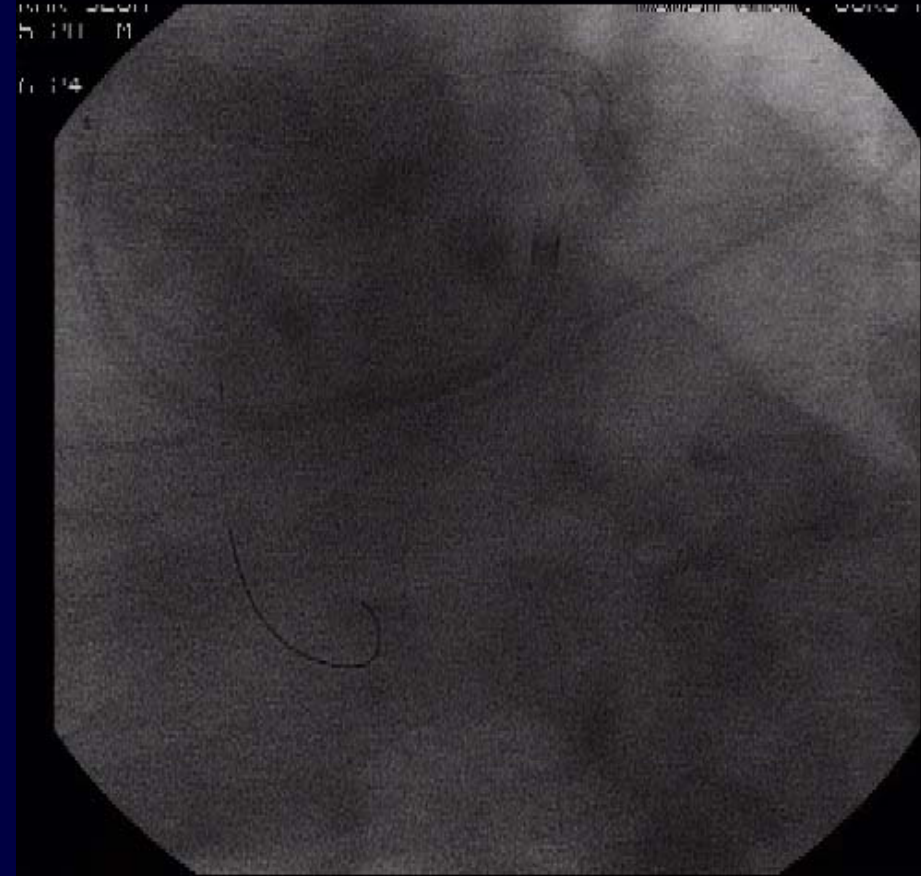
1. Still restenosis; DES failure
2. Stent thrombosis; Clinically more risky
3. DES-Spasm/Endothelial Dysfunction
4. DES aneurysm/ Late stent malapposition
5. Hypersensitivity reaction
6. Late catch up/ LTO (Late Total Occlusion)
7. Others...

# Acute Ant Wall MI due to Acute Stent Thrombosis (1)



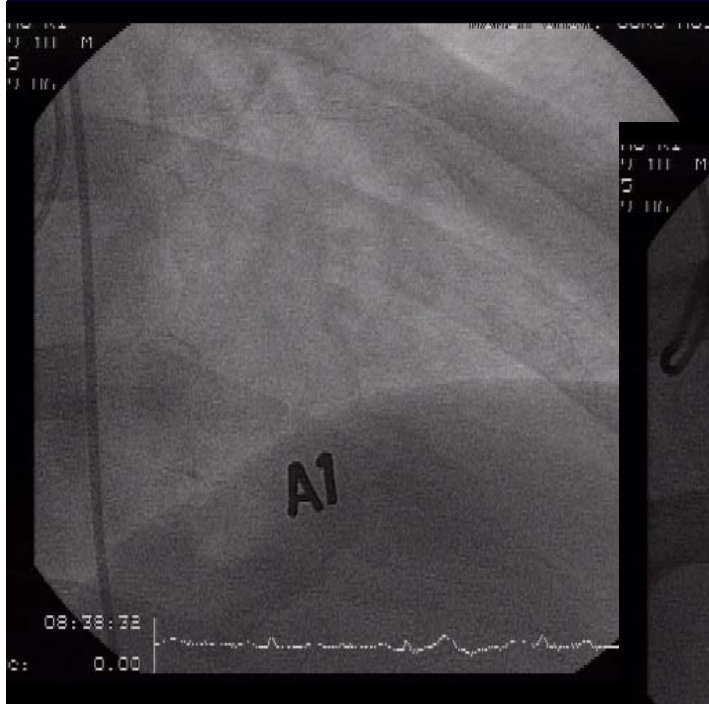
Pre PCI (Acute stent thrombosis at previously implanted DES)

# Acute Ant Wall MI due to Acute Stent Thrombosis (2)



Post PCI

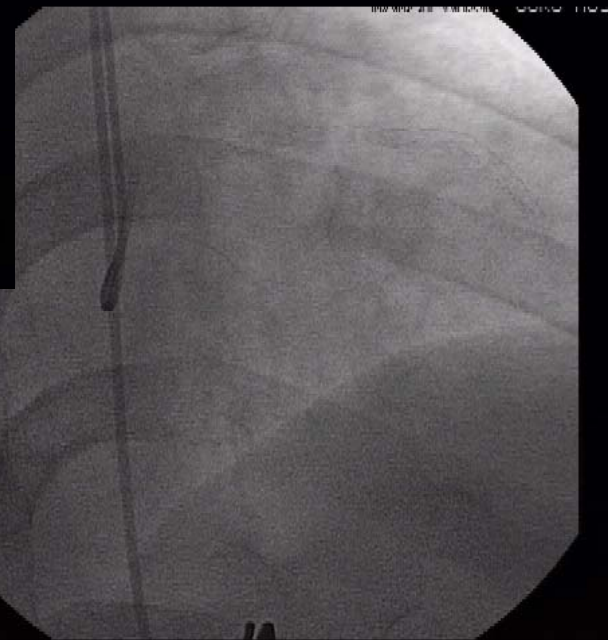
# Post DES Spasm (1)



Ergonovine

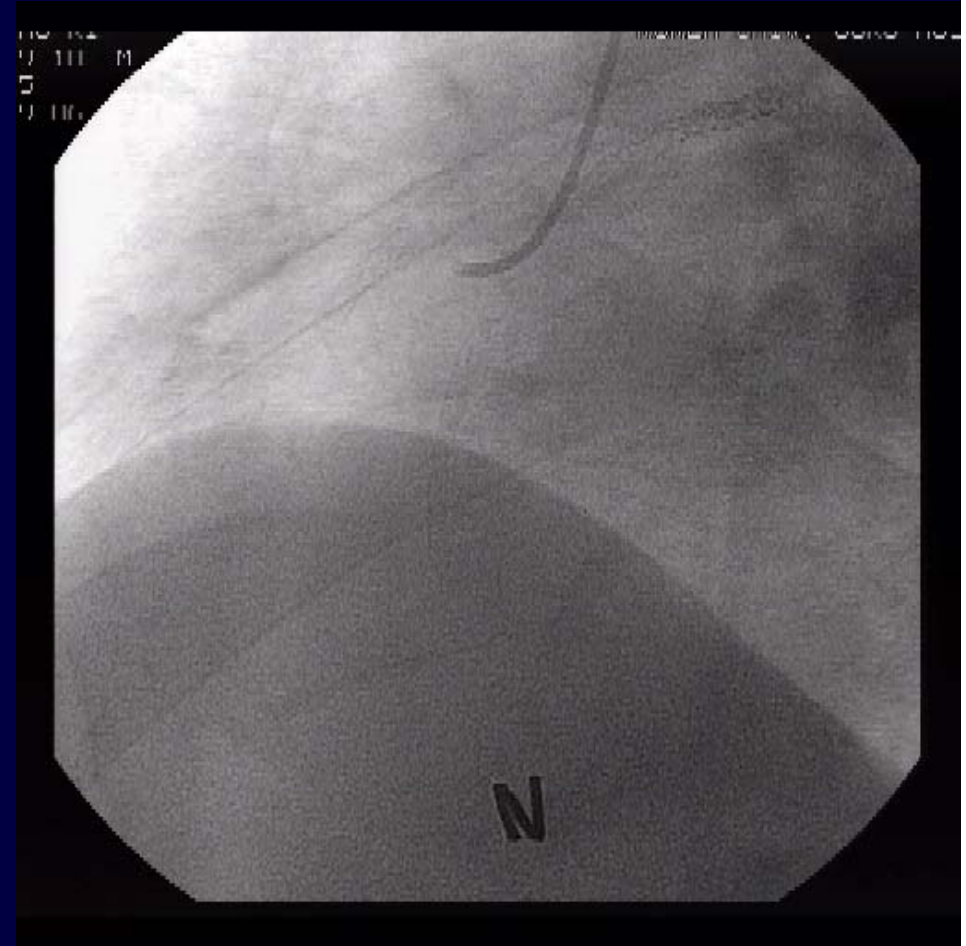
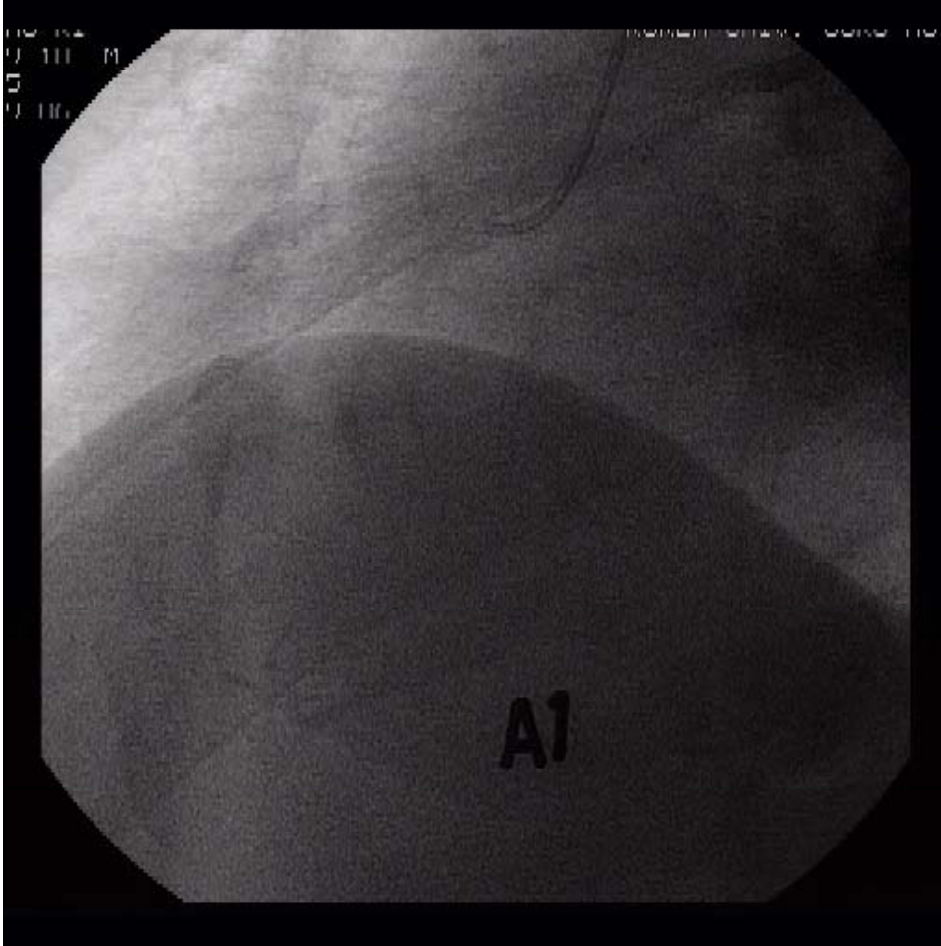


Ach



NTG

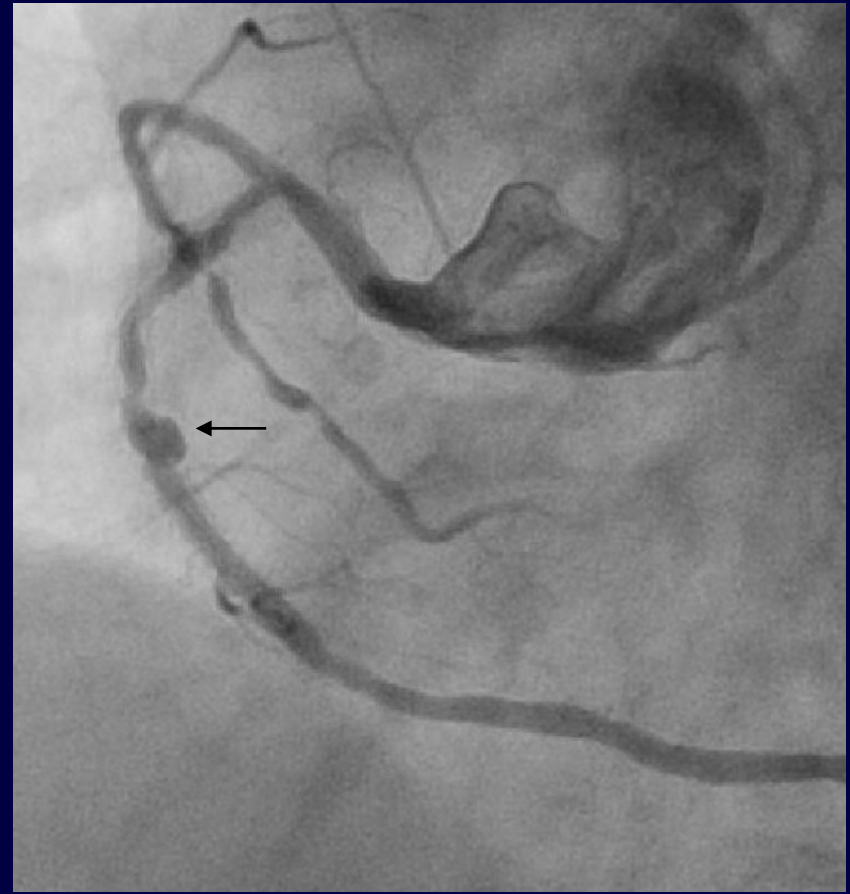
# Post DES Spasm (2)



Ach injection into RCA

# Incomplete Stent Apposition (ISA)

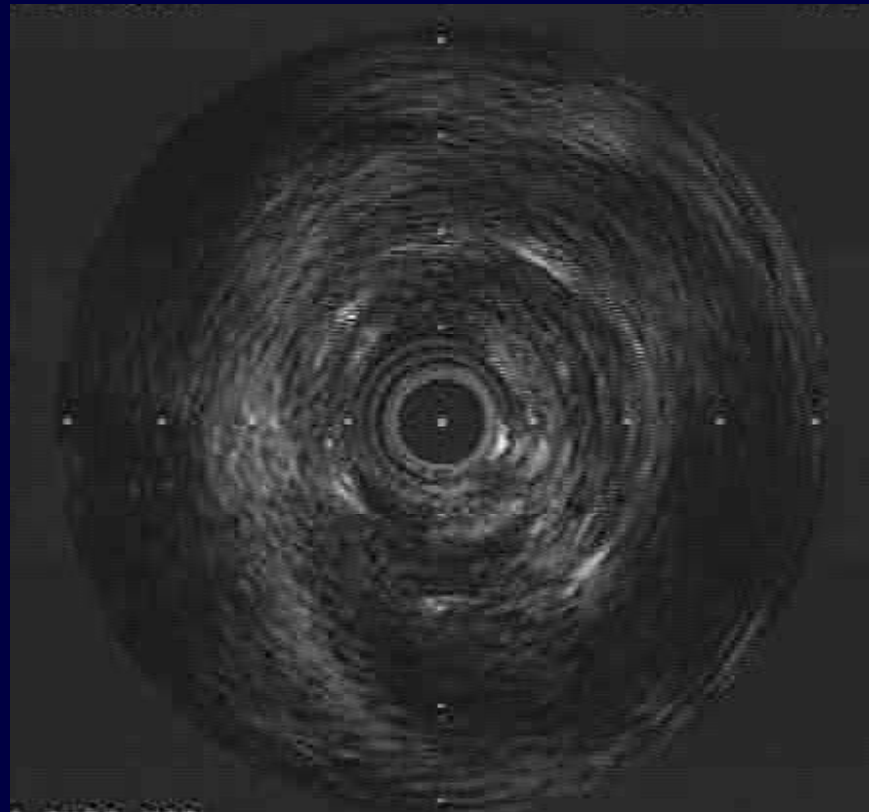
; could Develop into Aneurysm





# 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



# 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 Rha<sup>1</sup>, Wang Lin<sup>1</sup>, Hyang Ran Yoon<sup>1</sup>, Byoung-Geol Choi<sup>1</sup>,  
Young Joon Hong<sup>2</sup>, Tae Hoon Ahn<sup>3</sup>, Jang Ho Bae<sup>4</sup>, Seung Ho Hur<sup>5</sup>,  
In Ho Chae<sup>6</sup>, Jong Hyun Kim<sup>7</sup>, Kyeong Ho Yun<sup>8</sup>, Sang Wook Kim<sup>9</sup>,  
Kee Sik Kim<sup>10</sup>, Mi Hee Kim<sup>11</sup>, Ji Eun Oh<sup>11</sup>, Myung Ho Jeong<sup>2\*</sup>

(On behalf of LAMIS Investigators)

**Korea University<sup>1</sup>, ChonNam University<sup>2</sup>, Gachon University<sup>3</sup>, KonYang  
University<sup>4</sup>, KeiMyung University<sup>5</sup>, Seoul National University<sup>6</sup>, Han Seo  
Hospital<sup>7</sup>, WonKwang University<sup>8</sup>, Chung Ang University<sup>9</sup>, Catholic University  
of Daegu<sup>10</sup>, Chung Wae Pharm<sup>11</sup>**

**\* PI of LAMIS Investigators**

# LAMIS-Major Enrolling Hospitals

Data extracted date : 2010. 03. 13

Center	PI	First enroll date	Enroll No.
Gachon University Gil Medical Center	Tae Hoon Ahn	2007-12-10	33
Konyang University Hospital	Jang Ho Bae	2007-06-26	120
Keimyung University Dongsan Medical Center	Seung Ho Hur	2007-06-26	121
<u>Korea University Guro Hospital</u>	<u>Seung Woon Rha</u>	2007-04-23	131
Daegu Catholic University Medical Center	Kee Sik Kim	2007-06-26	124
Seoul National University Bundang Hospital	In Ho Chae	2007-10-31	51
Hanseong Hospital	Jong Hyun Kim	2007-05-21	132
Wonkwang University Hospital	Kyeong Ho Yun	2007-04-30	131
<u>Chonnam National University Hospital</u>	<u>Myung Ho Jeong</u>	2007-07-18	165
Chung-Ang University Hospital	Sang Wook Kim	2007-06-20	120
<b>Total</b>			<b>1128</b>

# 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).**



# Method

## Source Data

The current data regarding CVD came from the subgroup analysis of Korea Acute Myocardial Infarction Registry (*KAMIR study*).

## Study population

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

## Administraion

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)

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

- 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 6-Month  
clinical follow up :  
N=958 (90.5%)

# General background

## Demographic data

Data extracted date : 2010. 03. 13

variables		frequency(n)	percentage (%)	
Gender	n=1059	Male	783	73.9
		Female	276	26.1
Age	n=1059	Mean±SD	61.5± 12.7	
		Under 40	53	5.0
		41~70	728	68.7
		Over 70	278	26.3
Height(cm)	n=1052	Mean±SD	164.3±8.8	
Weight(kg)	n=1059	Mean±SD	65.4 ±11.3	
BMI(Kg/m <sup>2</sup> )	n=1052	Mean±SD	24.2±3.2	
		Under 25	683	64.5
		25 ~ 29.9	322	30.4
		Over 30	54	5.1

# Risk Factors

## ③ History of ischemic heart disease

	frequency(n)	percentage(%)
Yes	118	11.2
No	938	88.8



	frequency(n)	percentage(%)
Previous angina	49	0.4
Previous PCI	53	0.4
Previous AMI	19	0.2
Previous CABG	2	0.0

## ④ History of hypertension

	frequency(n)	percentage(%)
Yes	491	46.4
No	561	53.1
Unknown	5	0.5



	frequency(n)	percentage(%)
Treated	397	84.1
Untreated	75	15.9

# Risk Factors

## ⑤ History of diabetes mellitus

	frequency(n)	percentage(%)
Yes	255	24.1
No	799	75.6
Unknown	3	0.3

	frequency(n)	percentage(%)
Oral treated	199	80.6
Insulin treated	16	6.5
Oral + insulin	0	0
Untreated	32	13.0

## ⑥ History of dyslipidemia

	frequency(n)	percentage(%)
Yes	102	9.6
No	923	87.2
Unknown	33	3.1

	frequency(n)	percentage(%)
Treated	40	43.0
Untreated	53	57.0

# Risk Factors

## ⑦ History of smoking

	frequency(n)	percentage(%)
Current-smoking	506	48.1
Ex-smoking	155	14.7
No	392	37.2

## ⑧ Family history of heart disease

	frequency(n)	percentage(%)
Yes	54	5.1
No	903	85.5
Unknown	99	9.4



# Risk Factors

## ⑨ Past regular medication

	frequency(n)	percentage(%)
Yes	447	42.8
No	598	57.2

## ⑩ History of statin

	frequency(n)	percentage(%)
Yes	50	4.8
No	999	95.2



	frequency(n)	percentage(%)
Pitavastatin	14	29.2
Rosuvastatin	8	16.7
Pravastatin	0	0.0
Fluvastatin	1	2.1
Atorvastatin	11	22.9
Simvastatin	13	27.1
Lovastatin	1	2.1

# AMI Management

## ① Initial therapeutic strategy

	frequency(n)	percentage(%)
STEMI	674	63.9
NSTEMI	381	36.1



## STEMI

	frequency(n)	percentage(%)
Primary PCI	540	81.5
Facilitated PCI	45	6.8
Thrombolysis	38	5.7
Conservative Management	40	6.0

## NSTEMI

	frequency(n)	percentage(%)
Early invasive management	245	65.7
Early conservative management	128	34.3

# AMI Management

## ② Treatment & outcome

	frequency(n)	percentage(%)
Thrombolysis	51	4.67
PCI	971	88.8
CABG	4	0.4
Others	67	6.1



## Thrombolysis

	frequency(n)	percentage(%)
Successful thrombolysis in clinical	33	64.7
Successful thrombolysis on angiogram	14	27.5
Failed thrombolysis	4	7.8
No survival	0	0

# AMI Management



## PCI

	frequency(n)	percentage(%)
Successful PCI	844	88.1
Sub-optimal PCI	106	11.1
Failed PCI	8	0.8
No survival	0	0

## PCI with stent

	frequency(n)	percentage(%)
Yes	935	97.3
No	26	2.7

## CABG

	frequency(n)	percentage(%)
Successful CABG	4	100.0
Sub-optimal CABG	0	0.0
Failed CABG	0	0.0
No survival	0	0.0

# AMI Management

## ③ Angiographic finding

	frequency(n)	percentage(%)
One vessel	465	44.8
Two vessel	344	33.2
Three vessel	190	18.3
Left main	12	1.2
No significant stenosis	26	2.5



	frequency(n)	percentage(%)
Spasm	10	40
Myocardial bridge	1	4
Good thrombolytic state	4	16
Normal coronary artery	8	32
others	2	8

# AMI Management

## ④ Post TIMI flow

	frequency(n)	percentage(%)
TIMI 0	18	1.8
TIMI I	7	0.7
TIMI II	76	7.7
TIMI III	893	89.8

## ⑤ Stage of revascularization

	frequency(n)	percentage(%)
No revascularization of IRA	60	6.0
Revascularization of single IRA	519	52.2
Revascularization of only IRA in multi-vessel	155	15.6
Multi-vessel revascularization	121	12.2
Total revascularization	140	14.1

# Major Clinical Outcomes 2010.3

## ① Cumulative clinical outcomes up to 1 year

	1M	3M	6M		9M	12M	
<b>N</b>	<b>1045</b>	<b>1006</b>	<b>958</b>	<b>%</b>	<b>906</b>	<b>870</b>	<b>%</b>
<b>Death</b>	<b>6</b>	<b>12</b>	<b>18</b>	<b>1.9</b>	<b>20</b>	<b>32</b>	<b>3.7</b>
cardiac death	5	10	12	1.3	14	20	2.3
non-cardiac death	1	2	6	0.6	6	12	1.3
<b>Repeat MI</b>	<b>2</b>	<b>9</b>	<b>11</b>	<b>1.1</b>	<b>11</b>	<b>14</b>	<b>1.6</b>
STEMI	2	5	6	0.6	6	8	0.9
NSTEMI	1	4	5	0.5	5	6	0.7
<b>Repeat Revascularization</b>	<b>2</b>	<b>8</b>	<b>31</b>	<b>3.2</b>	<b>69</b>	<b>93</b>	<b>10.7</b>
CABG	0	0	0	0.0	14	22	2.5
TLR	1	7	19	2.0	33	41	4.7
TVR	1	7	23	2.0	43	53	6.1
non-TVR	1	1	8	0.8	12	18	2.1
<b>All MACE (TVR-MACE)</b>	<b>9</b>	<b>25</b>	<b>47</b>	<b>4.9</b>	<b>68</b>	<b>104</b>	<b>11.9</b>
1) TLR-MACE	7	19	33	3.4	49	65	7.5
2) TVR-MACE	9	25	47	4.9	68	104	11.9

# Discharge & follow up

## ② Laboratory tests (result from every visit)

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



# Discharge & follow up

## ④ NCEP 치료목표 달성률

	1M	6M	12M
	% (n)	% (n)	% (n)
LDL $\leq$ 100mg/dL 달성률	71.1 (379/533)	67.6 (290/429)	72.7 (213/293)
LDL $\leq$ 70mg/dL 달성률	25.3 (135/533)	24.0 (103/429)	22.9 (67/293)
DM 환자에서 LDL $\leq$ 70mg/dL 달성률	28.4 (36/129)	29.9 (26/87)	31.7 (19/41)

# Adverse Drug Reaction

## ④ Adverse Events

Number of cases

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

# Adverse Drug Reaction

## ④ Adverse Events(n=1128)

	SAE	ADR
Number of cases(patients)	43(40)	21(15)
Rate of events	3.8%	1.9%

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)

# 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.

# LAMIS-Conclusion

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)



# Cath Lab Family



# Korea University Guro Hospital





**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**

# Background

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

# Methods

## 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<sup>®</sup>); 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 1<sup>st</sup> one hour
- 3) GP IIbIIIa blocker (Reopro<sup>®</sup>); 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  $\pm$  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.



## Statistics (2)

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(1)

Variable, n (%)	No statin (N=3011 pts)	Pitavastatin (N=1070 pts)	p-value
Age, years	63.6 ±13.0	61.4 ±12.6	<0.001
Gender(Male)	2190 (71.2)	793 (74.1)	0.065
<b>Diagnosis</b>			
STEMI	1696 (55.5)	676 (63.4)	<0.001
NSTEMI	1362 (44.5)	390 (36.6)	<0.001
<b>Hypertension</b>			
Untreatment	187 (6.2)	73 (6.9)	0.405
treatment	1260 (41.4)	403 (37.9)	0.046
<b>DM</b>			
Untreatment	105 (3.5)	31 (2.9)	0.387
Oral	691 (22.8)	206 (19.4)	0.019
insulin	96 (3.2)	15 (1.4)	0.002

# Baseline Characteristics(2)

Variable, n (%)	No statin (N=3011 pts)	Pitavastatin (N=1070 pts)	p-value
<b>Dyslipidemia</b>	203 (7.7)	104 (10.1)	0.018
Untreatment	71 (2.7)	57 (5.5)	<0.001
treatment	132 (5.0)	47 (4.5)	0.577
<b>Smoking</b>	1739 (57.1)	666 (62.5)	0.002
Current	1286 (42.2)	509 (47.8)	0.002
Quit	453 (14.9)	157 (14.8)	0.924
<b>IHD</b> (Ischemic Heart Disease)	503 (16.4)	123 (11.5)	<0.001
Previous angina	175 (5.6)	51 (4.8)	0.290
Previous PCI	289 (9.3)	53 (5.0)	<0.001
Previous AMI	105 (3.4)	20 (1.9)	0.013
Previous CABG	30 (1.0)	3 (0.3)	0.030
<b>Family Hx of IHD</b>	173 (5.7)	55 (5.2)	0.522
<b>Multi Vessel disease</b>	1489 (58.1)	544 (50.8)	<0.001
<b>LM lesion</b>	113 (4.4)	12 (1.1)	<0.001

# Baseline Characteristics(3)

Variable, n (%)	No statin (N=3011 pts)	Pitavastatin (N=1070 pts)	p-value
<b>KillipClass</b>			
Class1	2108 (71.7)	842 (80.0)	-
Class2	406 (13.8)	157 (14.9)	-
Class3	293 (10.0)	37 (3.5)	-
Class4	135 (4.6)	16 (1.5)	-
<b>Post LVEF</b>	50.9 ±12.7	52.7 ±11.4	<0.001
<b>Total Cholesterol</b>	174.1 ±43.6	190.5 ±42.2	<0.001
<b>Triglyceraide</b>	123.3 ±91.9	126.3 ±92.0	0.376
<b>HDL-C</b>	44.8 ±13.9	45.2 ±11.8	0.378
<b>LDL-C</b>	108.3 ±42.3	121.8 ±36.8	<0.001
<b>hs-CRP</b>	8.8 ±35.4	9.9 ±30.2	0.394
<b>CK</b>	1393.9 ±2078.6	1106.2 ±2111.8	<0.001

# In-hospital Treatment Strategies

Variable, n (%)	No statin (N=3011 pts)	Pitavastatin (N=1070 pts)	p-value
<b>Medication</b>			
Past Medication	1108 (35.6)	459 (43.4)	<0.001
Single	116 (3.9)	25 (2.4)	0.030
Dual	2111 (71.1)	607 (59.5)	<0.001
Triple	744 (25.0)	389 (38.1)	<0.001
<b>STEMI</b>			
Primary PCI	1240/1676 (74.0)	544/665 (81.8)	-
Facilitated PCI	53/1676 (3.2)	46/665 (6.9)	-
Thrombolysis	133/1676 (7.9)	39/665 (5.9)	-
Conservative	250/1676 (14.9)	36/665 (5.4)	-
<b>NSTEMI</b>			
Early invasive therapy	612/1306 (46.9)	255/383 (66.6)	<0.001
Early conservative therapy	694/1306 (53.1)	128/383 (33.4)	<0.001
Thrombolysis	204 (6.7)	54 (5.0)	0.057
PCI	2332 (76.0)	987 (92.2)	<0.001

# Clinical outcomes at 6month.

Variable, n (%)	No statin (N=2574 pts)	Pitavastatin (N=1025 pts)	p-value
<b>Total Death</b>	137 (5.3)	22 (2.1)	<0.001
Cardic Death	86 (3.3)	11 (1.1)	<0.001
Non Cardic Death	51 (2.0)	12 (1.2)	0.094
<b>Recurrent MI</b>	23 (0.9)	11 (1.1)	0.543
QMI	11 (0.4)	5 (0.5)	0.806
NQMI	12 (0.5)	5 (0.5)	0.932
<b>Repeat PCI</b>	107 (4.2)	34 (3.3)	0.241
TLR	47 (1.8)	22 (2.1)	0.527
TVR	54 (2.1)	27 (2.6)	0.328
Non TVR	50 (1.9)	8 (0.8)	0.012
CABG	24 (0.9)	0 (0.0)	0.002
<b>Total MACE</b>	264 (10.3)	57 (5.6)	<0.001
TLR MACE	133 (5.2)	33 (3.2)	0.012
TVR MACE	189 (7.3)	49 (4.8)	0.005

# Clinical outcomes at 6month.

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

# Clinical outcomes at 12month.

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



# Clinical outcomes at 12month.

	Unadjusted OR (95% CI)	p-value	Adjusted OR* (95% CI)	p-value
<b>Total Death</b>	2.650 (1.759-3.991)	<0.001	<b>1.119 (1.119-3.261)</b>	<b>0.018</b>
<b>Cardic Death</b>	2.971 (1.715-5.149)	<0.001	<b>2.146 (1.056-4.360)</b>	<b>0.035</b>
Non Cardic Death	2.254 (1.235-4.112)	<b>0.007</b>	1.575 (0.715-3.470)	0.259
Recurrent MI	0.960 (0.499-1.849)	0.903	0.734 (0.266-2.025)	0.550
QMI	1.201 (0.469-3.080)	0.702	0.899 (0.236-3.425)	0.876
NQMI	1.050 (0.402-2.741)	0.920	0.536 (0.104-2.664)	0.438
Repeat PCI	0.995 (0.736-1.345)	0.974	1.038 (0,700-1.540)	0.852
TLR	0.741 (0.501-1.095)	0.131	0.780 (0.477-1.277)	0.323
TVR	0.657 (0.463-0.933)	<b>0.018</b>	0.725 (0.465-1.151)	0.173
<b>Non TVR</b>	2.290 (1.256-4.175)	<b>0.005</b>	<b>2.100 (1.016-4.340)</b>	<b>0.045</b>
<b>CABG</b>	10.913 (1.474-80.791)	<b>0.003</b>	<b>11.726 (1.511-90.972)</b>	<b>0.019</b>
<b>Total MACE</b>	1.620 (1.273-2061)	<0.001	<b>1.441 (1.053-1.972)</b>	<b>0.022</b>
TLR MACE	1.320 (0.966-1.803)	0.080	1.132 (0.760-1.686)	0.541
TVRMACE	1.358 (1.044-1.768)	<b>0.022</b>	1.125 (0.794-1,594)	0.507

# Results

1. The baseline characteristics were similar between the two groups except that pts in Livalo group were younger ( $61.2 \pm 12.0$  vs  $63.0 \pm 12$ ,  $p < 0.05$ ) and showed higher total cholesterol level ( $194.9 \pm 41.3$  vs  $174.5 \pm 42.2$ , 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<sub>unadjusted</sub>: 0.560, 95% CI: 0.360-0.873, P=0.010, OR<sub>adjusted</sub> 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

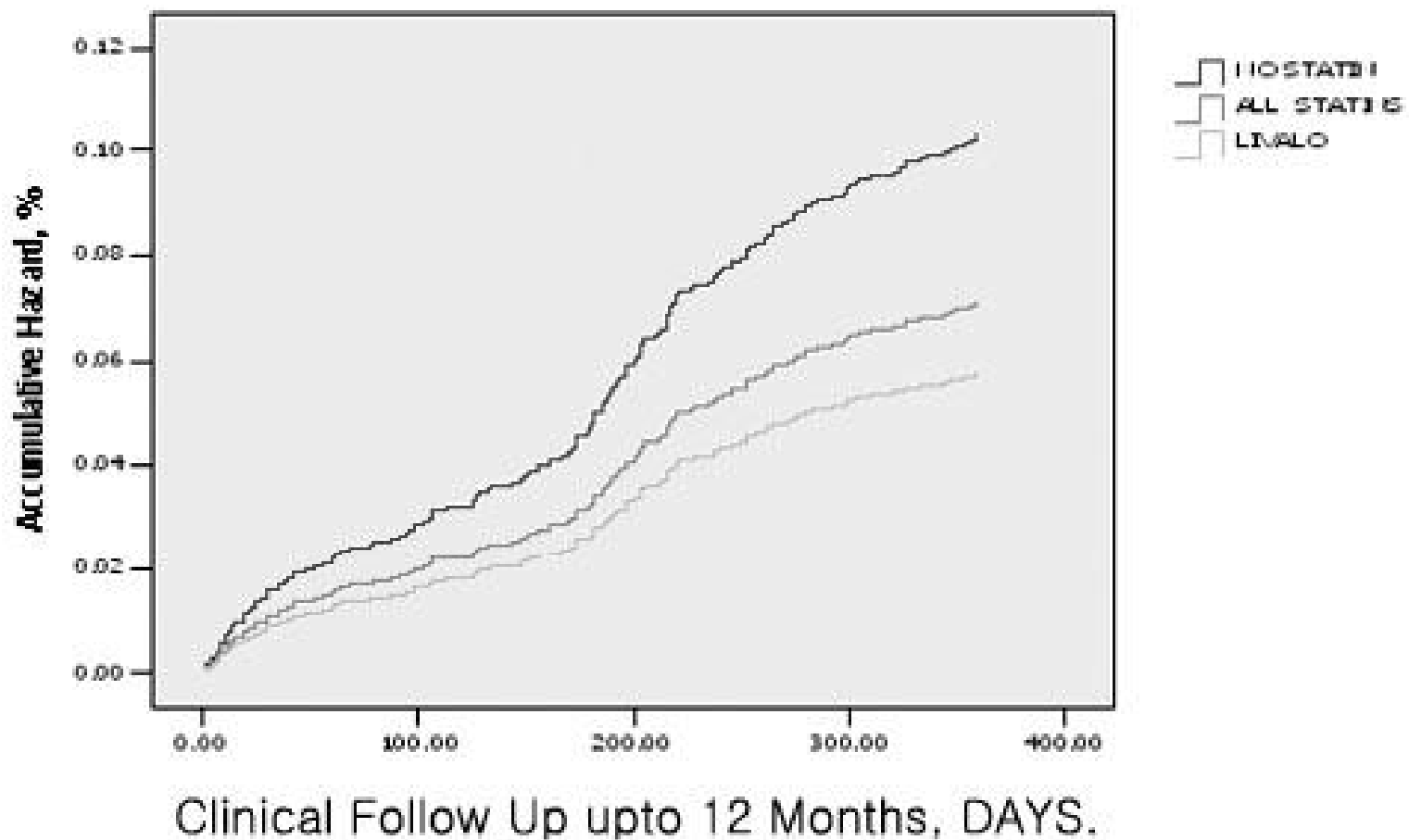
# Methods

## 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





# 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



# Research Family 2008-2010



# Cath Lab Family 2008-9



**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**

# 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 6month.

Variable, n (%)	No statin (N=1420 pts)	Pitavastatin (645 pts)	p-value
<b>Total Death</b>	64 (4.5)	13 (2.0)	<b>0.006</b>
Cardic Death	38 (2.7)	6 (0.9)	<b>0.011</b>
Non Cardic Death	26 (1.8)	7 (1.1)	0.210
<b>Recurrent MI</b>	10 (0.7)	6 (0.9)	0.548
QMI	7 (0.5)	4 (0.6)	0.713
NQMI	3 (0.2)	1 (0.2)	0.788
<b>Repeat PCI</b>	69 (4.9)	22 (3.4)	0.137
TLR	32 (2.3)	13 (2.0)	0.731
TVR	37 (2.6)	18 (2.8)	0.809
Non TVR	28 (2.0)	5 (0.8)	<b>0.044</b>
CABG	10 (0.7)	0 (0.0)	<b>0.035</b>
<b>Total MACE</b>	136 (9.6)	33 (5.1)	<b>0.001</b>
TLR MACE	70 (4.9)	19 (2.9)	<b>0.040</b>
TVRMACE	96 (6.8)	28 (4.3)	<b>0.032</b>

# Clinical outcomes at 6month.

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

# Clinical outcomes at 12month.

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

# Clinical outcomes at 12month.

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

# Results

1. The baseline characteristics were similar between the two groups, except that pts in Pitavastatin group were younger than no statin group ( $59.9 \pm 12.6$  vs  $62.2 \pm 12.6$ ,  $p < 0.05$ ) 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**

# 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.

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

# Clinical outcomes at 6month.

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

# Clinical outcomes at 12month.

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

# Clinical outcomes at 12month.

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

# Results

1. The baseline characteristics were similar between the two groups, except that pts in Pitavastatin group were younger ( $59.9 \pm 12.6$  vs  $62.2 \pm 12.6$ ,  $p < 0.05$ ) 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).

# Conclusions

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,**

**Korea University Guro Hospital, Seoul, Korea**

**\* Chonnam National University Hospital, Gwangju, Korea**



# 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.

# Purpose

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

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

# 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<sub>unadjusted</sub>: 0.394, 95% CI: 0.198-0.784, P=0.008, OR<sub>adjusted by propensity score</sub>: 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.

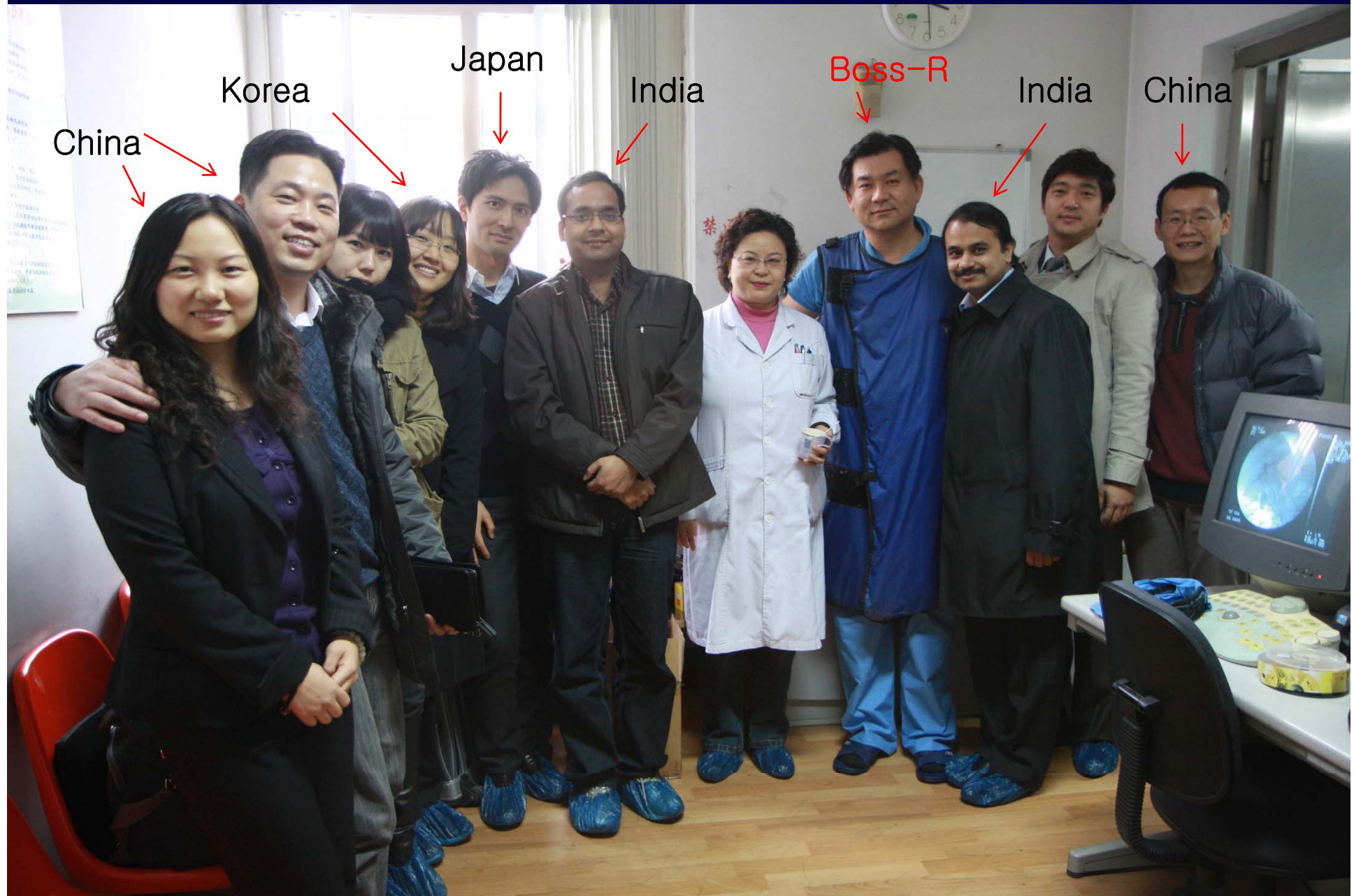


# Summary & Conclusion

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!!**

# R Family at Tianjin 2009



# 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

