Controversies in Acute Myocardial Infarction
- Is Early Statin Therapy is Beneficial in all Patients?-
: Insights from Korea Acute Myocardial Infarction Registry (KAMIR)

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

Cardiovascular Center,
Korea University Guro Hospital, Seoul, Korea

Contents

1. Introduction; ACS in DES Era
2. Statin in AMI & NSTEMI
   ; insights from KAMIR (Korea AMI Registry)
3. Statin in AMI with Low LDL-C
5. Pitavastatin (Livalo) in AMI: LAMIS data
6. Summary & Conclusion

AMI with DES-Efficacy & Safety?

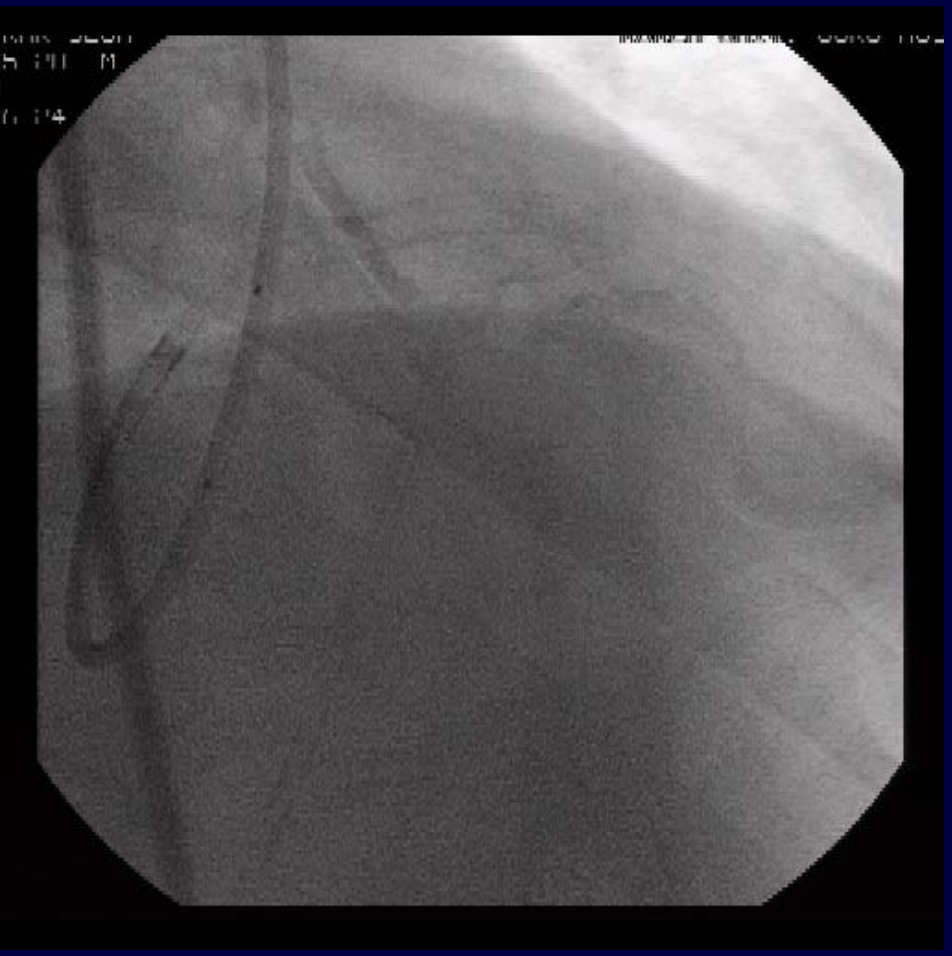
1. Still restenosis; DES failure
2. Stent thrombosis; Clinically more risky
3. DES-Spasm/Endothelial Dysfunction
4. DES aneurysm/ Late stent malapposition
5. Hypersensitivity reaction
6. Late catch up/ LTO (Late Total Occlusion)
7. Others…

DES Penetration in AMI in Korea; 92–93%

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)



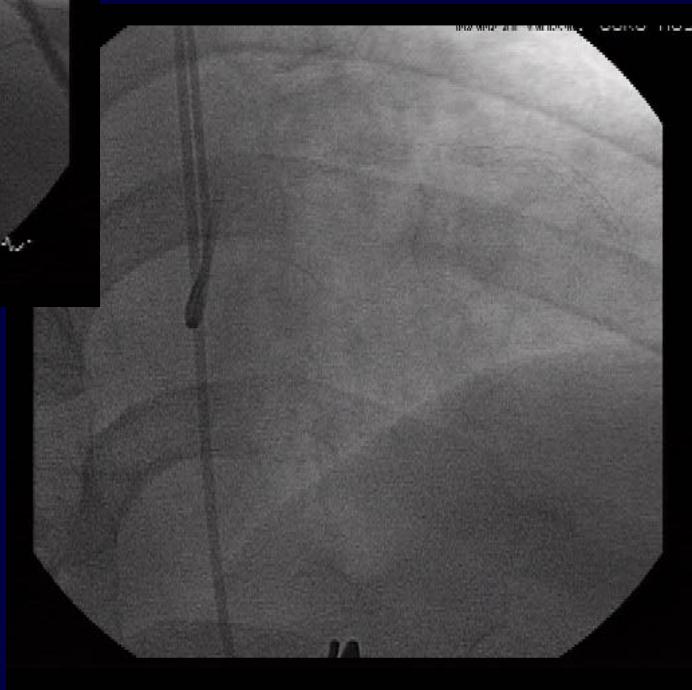
Post PCI

Post DES Spasm (1)

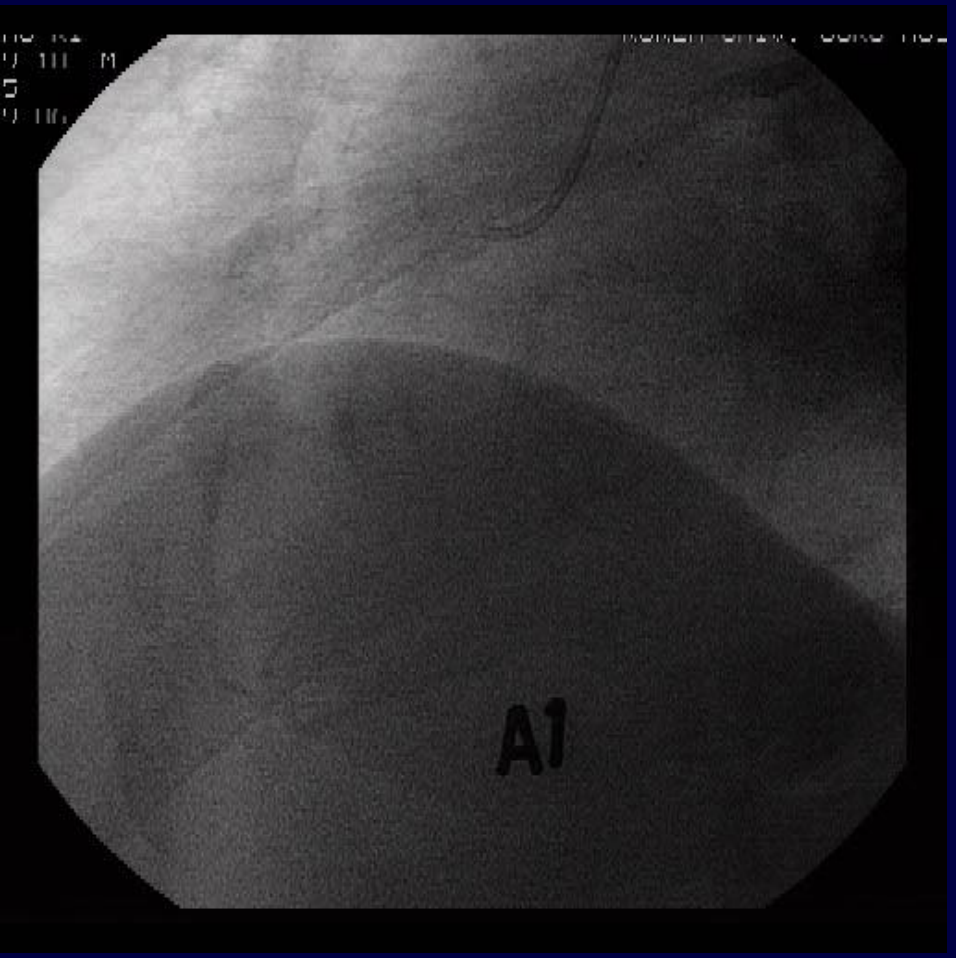
Ergonovine

Ach

NTG



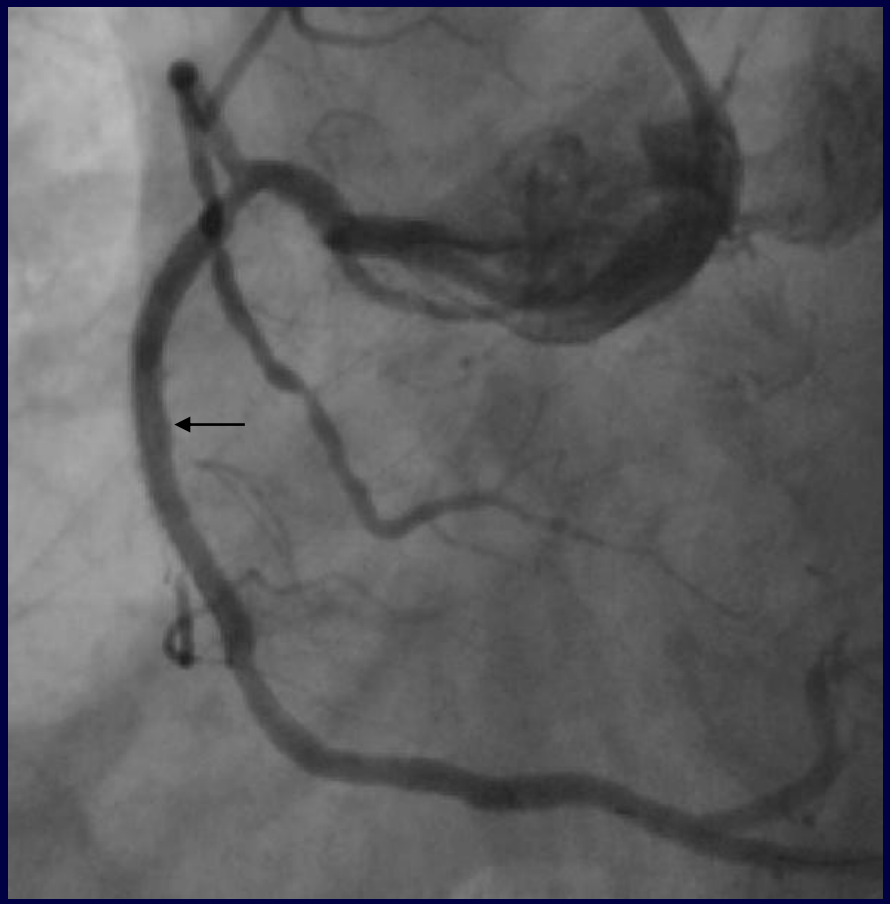
Post DES Spasm (2)

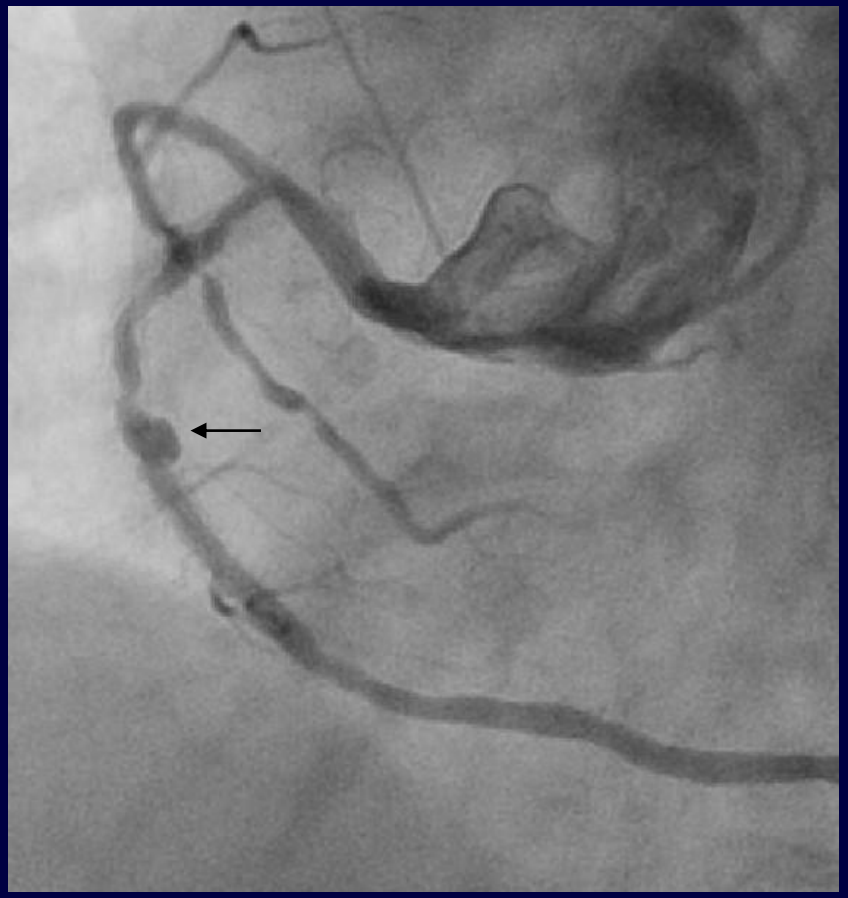


Ach injection into RCA

Incomplete Stent Apposition (ISA)

; could Develop into Aneurysm

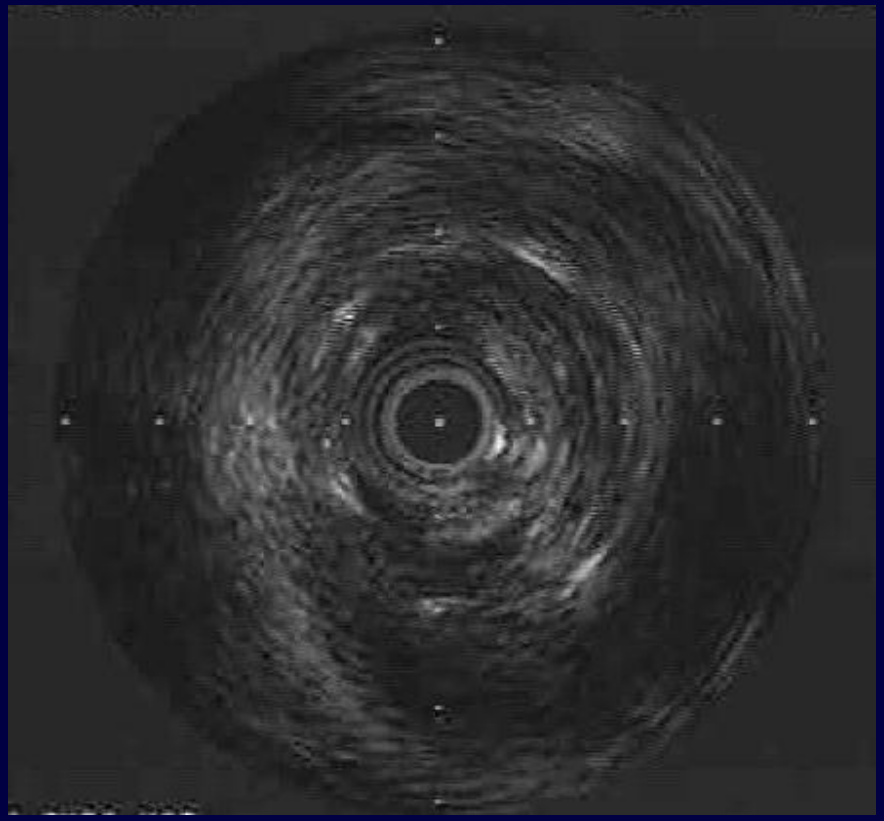




JSIC 2008

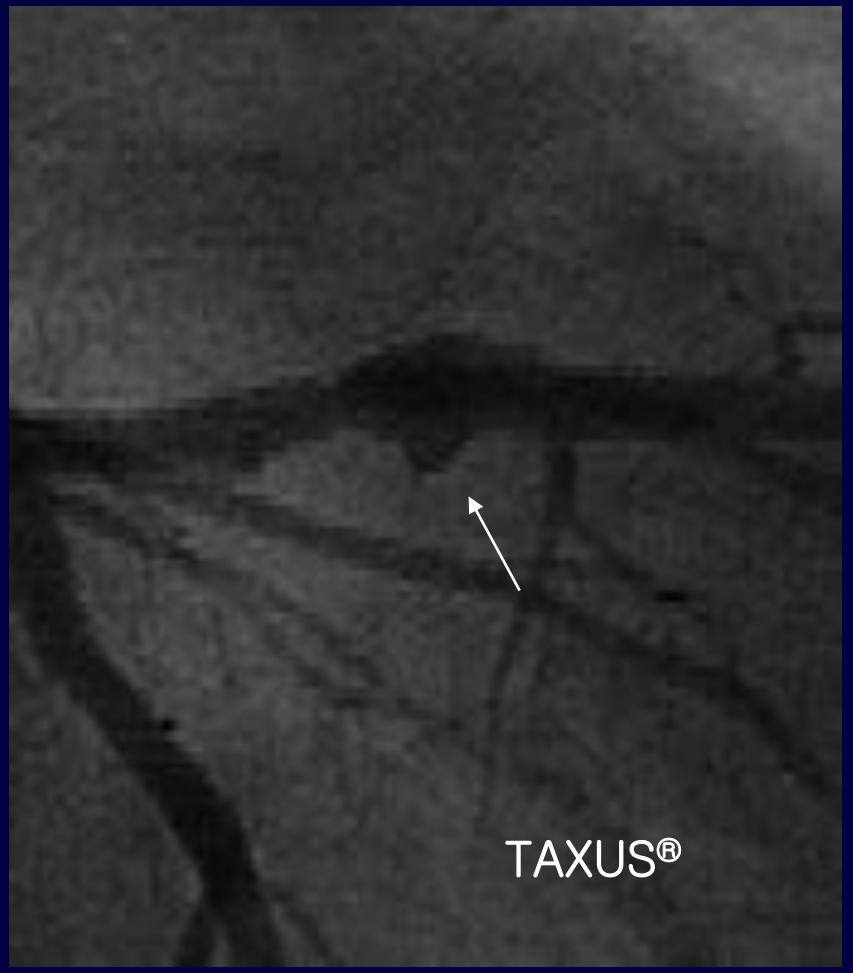
Definition of Coronary Neo-Aneurysm

- Focal or diffuse abnormal luminal dilatation 50% larger than that of reference segment beyond the implanted DES on the follow up angiography.



JSIC 2008

Neo Aneurysm Formation after DES Implantation



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….

Impact of Statins on 12- month Clinical Outcomes in Patients with Acute Myocardial Infarction

Seung-Woon Rha*, Lin Wang, Ji Young Park, Kanhaiya L. Poddar, 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**

Internal Review for Submission

Background (1)

1. Statin improve vascular function exerting the so-called ***'pleiotropic effects'***, which include improvement of endothelial function, inhibition of platelet function, and smooth muscle cell proliferation, enhancing stability of arteriosclerotic plaque and attenuating vascular inflammation.
2. In AMI situation, *statin suppress reactive oxygen* species production and inhibition of myocardial injury, and statin significantly limit myocardial infarction size.

Sakamoto T et al. Circ J. 2007;71:1348–53

Background (2)

3. Statin may *influence on myocardial energy generation*, particularly under pathological condition.
4. So statin may have direct cardioprotective effect and may play an important role in AMI *not only by reducing LDL-cholesterol, but also through the pleiotropic effects.*

Background (3)

5. Now statin is widely administrated to AMI patients but the direct impact of statin therapy on the long term clinical outcomes following stent implantation is still limited.
6. There are very limited data regarding role of ***early statins*** in managing AMI, especially in drug-eluting stent (DES) era.

Purpose

The present study was aimed to evaluate the efficacy of statins therapy in patients with AMI in *Korean Acute Myocardial Infarction Registry* (KAMIR) study.

Methods

1. Source Data

The current data regarding *statin therapy* in patients with *AMI* came from the subgroup analysis of *Korea Acute Myocardial Infarction Registry* (*KAMIR study*).

2. Study population

A total of 6729 AMI pts treated with or without STATIN were enrolled for the study.

Methods

3. Study Groups

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

1) No Statin Group	(n=1569 pts)
2) Statin Group	(n=5160 pts)

Methods

4. Study Definition

1) No statin group: patients never received statins during this study.

2) Statin group: patients received statins on and after admission.

5. Study Endpoints

The clinical outcomes at 12 months between the 2 groups.

Statistics (1)

1. All statistical analyses were performed using SPSS 13.0.

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.

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).

Results

KAMIR

(Korea Acute Myocardial Infarction Registry)

http://www.kamir.or.kr

Baseline Clinical Characteristics (1)

Variable, n (%)	No Statin Group (n=1569)	Statin Group (n=5160)	P VALUE
Age, years	63.75 ± 12.15	61.95± 12.36	<0.001
Male	1,179 (75.1)	3,819(74.0)	0.375
Body mass index, Kg/m^2	23.75± 3.14	24.16± 3.14	<0.001
Hypertension	736 (46.9)	2,376 (46.0)	0.549
Diabetes mellitus	438 (27.9)	1,369(26.5)	0.278
Dyslipidemia	1,569(2.3)	5160(9.0)	<0.001
Current smoking	491(44.0)	2,462 (47.7)	0.038
Family history of CAD	75 (4.8)	376 (7.3)	<0.001
Chronic heart failure	29 (1.8)	54 (1.0)	0.012

Baseline Clinical Characteristics (2)

Variable, n (%)	No Statin Group (n=1569)	Statin Group (n=5160)	P VALUE
Peripheral arterial disease	24 (1.5)	58 (1.1)	0.200
Prior cerebrovascular disease	87 (5.5)	307(5.9)	0.550
Chronic renal disease	42 (2.7)	79 (1.5)	0.003
Diagnosis			
ST elevation MI	949 (60.5)	3,355 (65.0)	0.001
Non-ST elevation MI	620 (39.5)	1,805 (35)	0.001
Killip class III-IV	216(13.8)	464(9.0)	<0.001

In-hospital Treatment Strategies

Variable, n (%)	No Statin Group (n=1569)	Statin Group (n=5160)	P VALUE
PCI procedure	1,395(88.9)	4,775 (92.5)	<0.001
Successful PCI	1291 (92.5)	4503 (94.3)	0.016
Thrombolysis	160 (10.2)	342 (6.6)	<0.001
Conservative treatment	14 (0.9)	43 (0.8)	0.823

Medical Therapy

Variable, n (%)	No Statin Group (n=1569)	Statin Group (n=5160)	P VALUE
Aspirin	1,486 (94.7)	5,119 (99.2)	<0.001
Clopidogrel	1,422 (90.6)	4,974(96.4)	<0.001
Cilostazol	234(14.9)	1,486 (28.8)	<0.001
Glycoprotein IIb/IIIa	126 (8.0)	526 (10.2)	0.011
Unfractionated heparin	519 (33.1)	2,611 (50.6)	<0.001
LMWH	584 (37.2)	1,460 (28.3)	<0.001
ACEIs	880 (56.1)	3,844 (74.5)	<0.001
ARBs	234 (14.7)	784 (15.2)	0.648
Beta-blockers	825(52.6)	3916 (75.9)	<0.001
CCB	283 (15.2)	893 (17.3)	0.047

Clinical Outcomes up to 12 months

Variable, n (%)	No Statin Group (n=1569)	Statin Group (n=5160)	P Value
At 12 months			
Total Mortality	64(4.1)	104(2.0)	**<0.001**
Cardiac Death	43(2.7)	67(1.3)	**<0.001**
Re-PCI	136(8.57)	255(4.9)	**<0.001**
TLR	44(2.8)	102(2.0)	**0.049**
TVR	59(3.8)	148(2.9)	**0.073**
Non-TVR	77(4.9)	107(2.1)	**<0.001**
Re-AMI	24(1.5)	37(0.7)	**0.003**
Total Mace	228(14.5)	406(7.9)	**<0.001**

Cumulative Clinical Outcomes of Patients with or without Statins (Multivariate Cox Regression Analysis)

Variables	OR	95% CI	*P* value
Unadjusted	0.526	0.448-0.619	**<0.001**
Adjusted by ps*	0.627	0.516-762	**<0.001**
Adjusted by other variables#	0.555	0.469-0.658	**<0.001**
Adjusted by other variables and ps	0.636	0.522-0.775	**<0.001**

***ps: propensity score**
#Other variables including age, gender, past history, smoking,medications, Killip's classes, strategies et al.

Summary

1. Data from this observational study suggest that Asian AMI pts who had been on the Statin therapy after the AMI attack showed worse baseline clinical profiles compared with those without statin treatment (No Statin group).

2. Routine statin administration might get extra benefit in major clinical endpoints from statin therapy up to 12 months as compared with pts in No Statin group.

Conclusions

1. The administration of Statin in AMI patients showed *lower total MACEs* compared with the patients without statin *(No Statin group)* up to 12 months by the Univariate analysis.
2. When we analyze by Multivariate analysis with other variables and/or propensity score, the *statin administration in AMI setting* was still clearly associated with *better clinical outcomes up to 12 months.*

Impact of Statins on 12- month Clinical Outcomes in Patients with Non-ST Elevation Myocardial Infarction

Seung-Woon Rha*, Lin Wang, Ji Young Park, Kanhaiya L. Poddar, 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**

Clinical Outcomes up to 12 months

Variable, n (%)	No Statin Group (n=620 pts)	Statin Group (n=1805 pts)	P Value
Total Death	32 (5.2)	39 (2.2)	0.001
Cardiac Death	21 (3.4)	24 (1.3)	0.001
Repeat PCI	53 (8.5)	83 (4.6)	<0.001
TLR	18 (2.9)	38 (2.1)	0.254
TVR	25 (4.0)	49 (2.7)	0.100
Non-TVR	28 (4.5)	34 (1.9)	<0.001
Recurrent AMI	12 (1.9)	17 (0.9)	0.050
Total MACE	100 (16.1)	145 (8.0)	<0.001

Conclusions

Routine administration of Statins in acute NSTEMI pts regardless of the revascularization strategy showed better 12-month clinical outcomes compared with those of NSTEMI pts without Statin therapy.

Benefit of Early Statin Therapy in Patients With Acute Myocardial Infarction Who Have Extremely Low Low-Density Lipoprotein Cholesterol

Ki Hong Lee, MD,* Myung Ho Jeong, MD, PhD,* Ha Mi Kim, RN,* Youngkeun Ahn, MD, PhD,* Jong Hyun Kim, MD,† Shung Chull Chae, MD, PhD,‡ Young Jo Kim, MD, PhD,§ Seung Ho Hur, MD, PhD,‖ In Whan Seong, MD, PhD,¶ Taek Jong Hong, MD, PhD,# Dong Hoon Choi, MD, PhD,** Myeong Chan Cho, MD, PhD,†† Chong Jin Kim, MD, PhD,‡‡ Ki Bae Seung, MD, PhD,§§ Wook Sung Chung, MD, PhD,§§ Yang Soo Jang, MD, PhD,‖‖ Seung Woon Rha, MD, PhD,¶¶ Jang Ho Bae, MD, PhD,## Jeong Gwan Cho, MD, PhD,* Seung Jung Park, MD, PhD,*** for the KAMIR (Korea Acute Myocardial Infarction Registry) Investigators

Gwangju, Busan, Daegu, Daejeon, Busan, Cheongju, Seoul, and Ulsan, South Korea

Objectives We investigated whether statin therapy could be beneficial in patients with acute myocardial infarction (AMI) who have baseline low-density lipoprotein cholesterol (LDL-C) levels below 70 mg/dl.

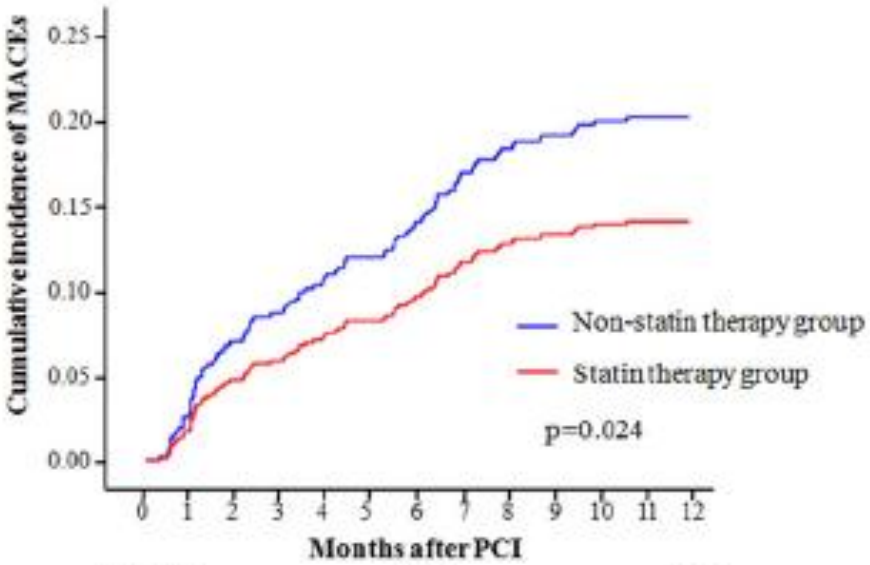
Background Intensive lipid-lowering therapy with a target LDL-C value <70 mg/dl is recommended in patients with very high cardiovascular risk. However, whether to use statin therapy in patients with baseline LDL-C levels below 70 mg/dl is controversial.

Methods We analyzed 1,054 patients with AMI who had baseline LDL-C levels below 70 mg/dl and survived at discharge from the Korean Acute MI Registry between November 2005 and December 2007. They were divided into 2 groups according to the prescribing of statins at discharge (statin group n = 607; nonstatin group n = 447). The primary endpoint was the composite of 1-year major adverse cardiac events, including death, recurrent MI, target vessel revascularization, and coronary artery bypass grafting.

Results Statin therapy significantly reduced the risk of the composite primary endpoint (adjusted hazard ratio [HR]: 0.56; 95% confidence interval [CI]: 0.34 to 0.89; p = 0.015). Statin therapy reduced the risk of cardiac death (HR: 0.47; 95% CI: 0.23 to 0.93; p = 0.031) and coronary revascularization (HR: 0.45, 95% CI: 0.24 to 0.85; p = 0.013). However, there were no differences in the risk of the composite of all-cause death, recurrent MI, and repeated percutaneous coronary intervention rate.

Conclusions Statin therapy in patients with AMI with LDL-C levels below 70 mg/dl was associated with improved clinical outcome. (J Am Coll Cardiol 2011;58:1664–71)

Benefit of Early Statin Therapy



No.at risk	1,054	894	780	680
Statin therapy group	607	529	457	400
Non-statin therapy group	447	365	323	280

Figure 1 **Estimates of the Rate of the Primary Endpoint Events**

The primary endpoint was the composite of death, recurrent myocardial infarction, and coronary revascularization. MACE = major adverse cardiac event(s); PCI = percutaneous coronary intervention.

Lee KH, Jeong MH et al. JACC 2011;58:1664-71

Benefit of Early Statin Therapy

Table 3 Clinical Outcomes at 6 and 12 Months According to Statin Medication

	Statin Group (n = 607)	Nonstatin Group (n = 447)	p Value
6-month outcomes			
Cardiac death	14 (3.1)	19 (5.9)	0.031
Total death	19 (4.2)	22 (6.8)	0.071
MI	9 (2.0)	2 (0.6)	0.386
Repeated PCI	14 (3.1)	13 (4.0)	0.336
TVR	5 (1.1)	8 (2.5)	0.081
CABG	8 (1.8)	9 (2.8)	0.012
MACE	50 (10.9)	45 (13.9)	0.048
12-month outcomes			
Cardiac death	16 (4.0)	21 (7.5)	0.048
Total death	23 (5.8)	26 (9.3)	0.101
MI	9 (2.3)	5 (1.8)	0.644
Repeated PCI	19 (4.8)	17 (6.1)	0.232
TVR	8 (2.0)	10 (3.6)	0.209
CABG	8 (2.0)	11 (3.9)	0.003
MACE	58 (14.5)	57 (20.4)	0.014

Values are n (%). All comparisons were made using the chi-square test.
MACE = major adverse cardiac event(s); TVR = target vessel revascularization; other abbreviations as in Table 1.

Table 4 Cumulative Secondary Endpoints at 12 Months According to Statin Medication

	Unadjusted HR (95% CI)	p Value	Adjusted HR (95% CI)	p Value
Death	0.62 (0.35–1.09)	0.092	0.56 (0.26–1.20)	0.133
Cardiac death	0.54 (0.28–0.90)	0.036	0.47 (0.23–0.93)	0.031
Noncardiac death	0.98 (0.31–3.07)	0.966	0.89 (0.20–4.09)	0.885
MI	1.27 (0.43–3.78)	0.671	1.38 (0.45–4.19)	0.570
Coronary revascularization	0.57 (0.33–0.98)	0.044	0.45 (0.24–0.85)	0.013
Repeated PCI	0.77 (0.40–1.48)	0.435	0.63 (0.29–1.35)	0.232
TVR	0.55 (0.22–1.40)	0.202	0.51 (0.19–1.40)	0.191
CABG	0.25 (0.08–0.79)	0.018	0.15 (0.04–0.55)	0.004
MACE	0.66 (0.45–0.95)	0.026	0.56 (0.34–0.89)	0.015

Lee KH, Jeong MH et al. JACC 2011;58:1664–71

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**

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
Korea University Guro Hospital	*Seung Woon Rha*	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
Hanseo Hospital	Jong Hyun Kim	2007-05-21	132
Wonkwang University Hospital	Kyeong Ho Yun	2007-04-30	131
Chonnam National University Hospital	*Myung Ho Jeong*	2007-07-18	165
Chung-Ang University Hospital	Sang Wook Kim	2007-06-20	120
Total			1128

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

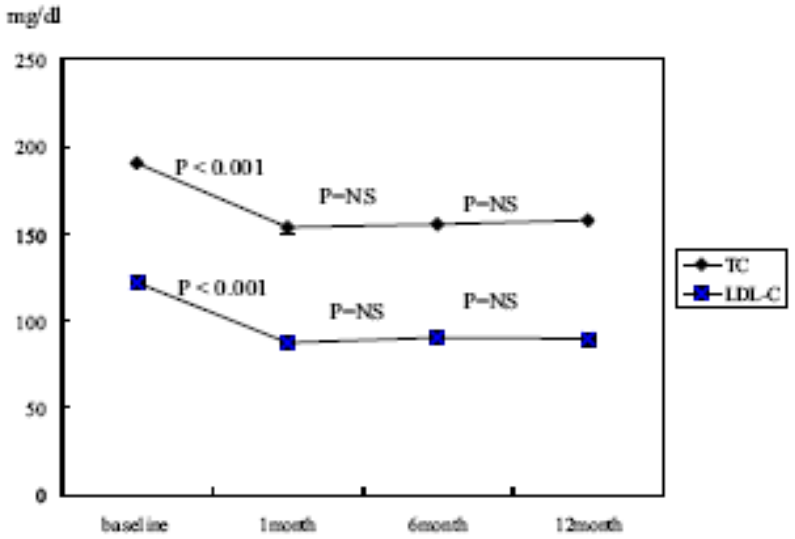
3. Adverse effects & Safety issues

Long-Term Safety and Efficacy of *Pitavastatin* in Patients With Acute Myocardial Infarction (from the Livalo Acute Myocardial Infarction Study [LAMIS])

Soon Yong Suh, MD[a], Seung-Woon Rha, MD[b,*], Tae Hoon Ahn, MD[a], Eak Kyun Shin, MD[a], Cheol Ung Choi, MD[b], Dong Joo Oh, MD[b], Jang-Ho Bae, MD[c], Seung-Ho Hur, MD[d], Kyung Ho Yoon, MD[e], Seok-Kyu Oh, MD[e], Jong Hyun Kim, MD[f], Sang Wook Kim, MD[g], In Ho Chae, MD[h], Kee-Sik Kim, MD[i], Young Joon Hong, MD[j], and Myung Ho Jeong, MD[j], for the LAMIS Investigators

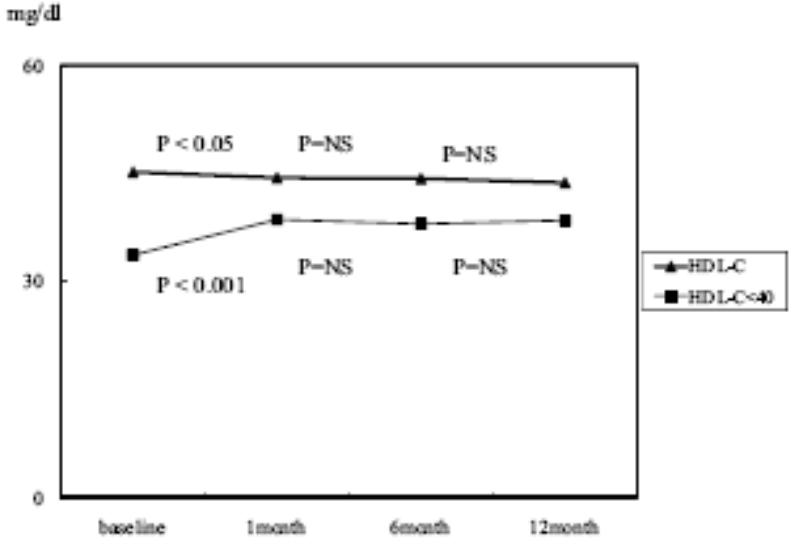
Pitavastatin is a potent lipophilic statin and may play an important role in acute myocardial infarction (AMI) but there have been limited data on the safety and efficacy of pitavastatin in AMI. This study consisted of 1,039 consecutive patients with AMI (74.0% men, mean age 61.4 ± 12.6 years) who presented in 10 major percutaneous coronary intervention centers in Korea from February 2007 through September 2009. Pitavastatin 2 mg/day was routinely administered in patients with AMI from time of presentation. We investigated changes of lipid profiles, biochemical markers, adverse events, and clinical outcomes up to 12 months. During the study 318 events overall occurred in 220 patients (21.2%) who reported ≥1 treatment emergent adverse event, although 20 events in 14 patients (1.4%) were treatment-related adverse events. Low-density lipoprotein (LDL) cholesterol percent change was −25.6% and LDL cholesterol target attainment was 70.5% at 12-month follow-up. Levels of creatinine phosphokinase, serum glutamic oxaloacetic transaminase, glutamic pyruvic transaminase, and high-sensitivity C-reactive protein decreased significantly during the first 1 month of pitavastatin treatment and were sustained to 12-month follow-up. Major adverse cardiac events occurred in 66 patients (7.3%). All-cause deaths occurred in 32 patients (3.5%) including 19 (2.1%) cardiac deaths and recurrent MIs occurred in 14 (1.6%) and target lesion revascularizations in 42 (4.7%). In conclusion, administration of pitavastatin 2 mg/day in patients with AMI showed 70.5% LDL cholesterol target attainment with good tolerance and was associated with favorable clinical outcomes up to 12 months. (Am J Cardiol 2011;xx:xxx)

Suh SY, Rha SW et al. AJC 2011, In Press



Changes in TC & LDL-C

A



Changes in HDL-C

B

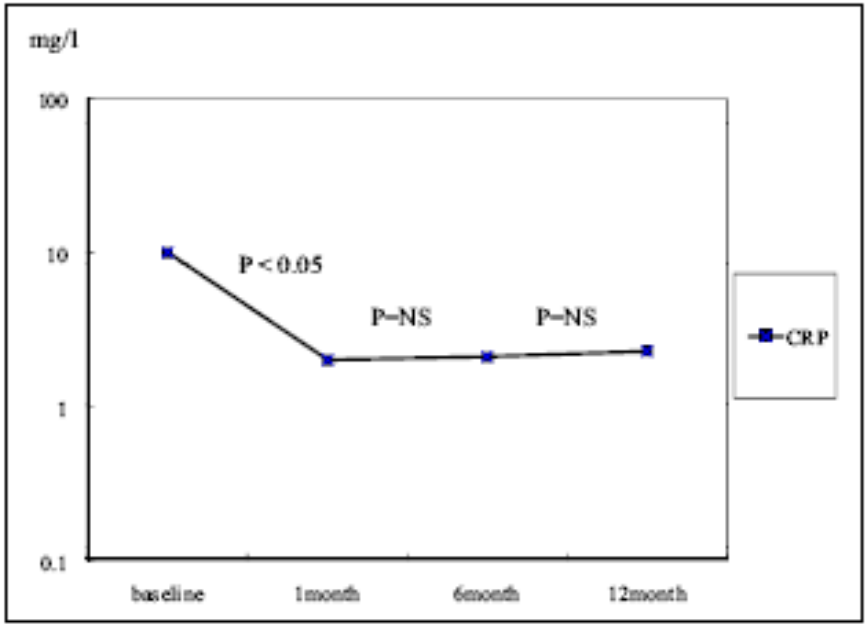


Figure 3. Serial changes in high-sensitive C-reactive protein in LAMIS.

Table 4
Overall summary of treatment emergent adverse events

Category	Number of Patients (%)	Number of Events (%)
With any treatment emergent adverse event	220 (21.2%)	318 (30.6%)
With any serious treatment emergent adverse event		42
Death or life-threatening		17
Need admission		24
Other		1
With any treatment-related adverse event	14 (1.4%)	20 (1.92%)

Suh SY, Rha SW et al. AJC 2011, In Press

Clinical Outcomes at 12 months

Cumulative clinical outcomes up to 12 months

Variables	1 Month (n = 1,039)	6 Months (n = 963)	12 Months (n = 901)
Total deaths	8 (0.8%)	20 (2.1%)	32 (3.6%)
Cardiac deaths	6 (0.6%)	13 (1.4%)	19 (2.1%)
Noncardiac deaths	2 (0.2%)	7 (0.7%)	13 (1.4%)
Recurrent myocardial infarction			
ST-segment elevation myocardial infarction	1 (0.1%)	5 (0.5%)	8 (0.9%)
Non–ST-segment elevation myocardial infarction	1 (0.1%)	5 (0.5%)	6 (0.7%)
Repeat percutaneous coronary intervention			
Target lesion revascularization	1 (0.1%)	18 (1.8%)	42 (4.7%)
Target vessel revascularization	2 (0.1%)	26 (2.7%)	59 (6.5%)
Coronary bypass grafting	0	0	2 (0.2%)
Total major adverse cardiac event	8 (0.8%)	34 (3.5%)	66 (7.3%)

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**

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 accordin g to their use of statins:

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

Clinical outcomes at 6month.

Variable, n (%)	No statin (N=2574 pts)	Pitavastatin (N=1025 pts)	p-value
Total Death	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
Recurrent MI	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
Repeat PCI	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
Total MACE	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
Total Death	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
Recurrent MI	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
Repeat PCI	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	-	-	-	-
Total MACE	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
Total Death	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
Recurrent MI	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
Repeat PCI	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
Total MACE	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
Total Death	2.650 (1.759-3.991)	<0.001	1.119 (1.119-3.261)	0.018
Cardic Death	2.971 (1.715-5.149)	<0.001	2.146 (1.056-4.360)	0.035
Non Cardic Death	2.254 (1.235-4.112)	0.007	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)	0.018	0.725 (0.465-1.151)	0.173
Non TVR	2.290 (1.256-4.175)	0.005	2.100 (1.016-4.340)	0.045
CABG	10.913 (1.474-80.791)	0.003	11.726 (1.511-90.972)	0.019
Total MACE	1.620 (1.273-2061)	<0.001	1.441 (1.053-1.972)	0.022
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)	0.022	1.125 (0.794-1,594)	0.507

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

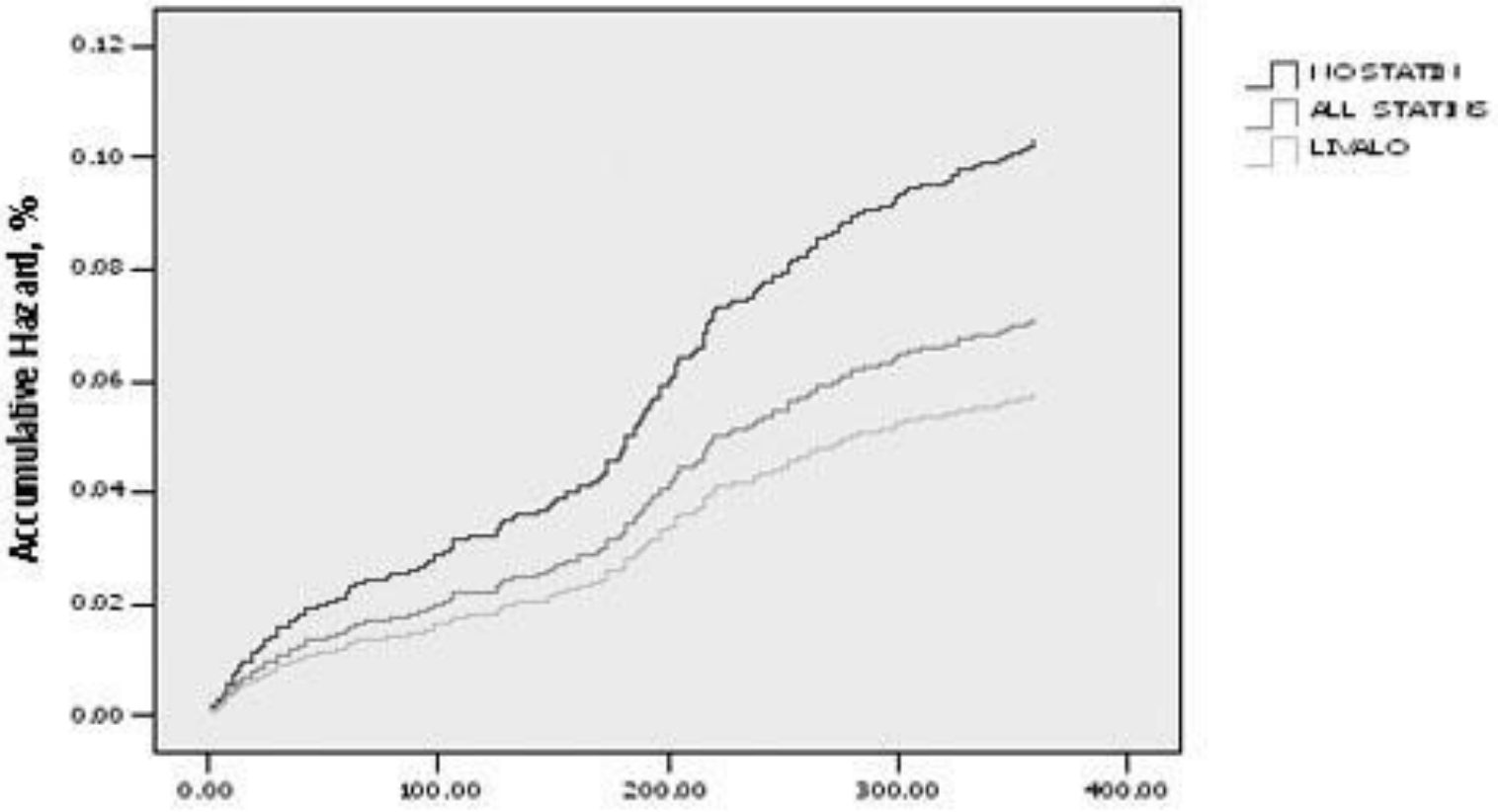
Methods

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).

Summary & Conclusion

1. Introduction; ACS in DES Era
2. Statin in AMI & NSTEMI
   ; insights from KAMIR (Korea AMI Registry)
3. Statin in AMI with Low LDL-C
5. Pitavastatin (Livalo) in AMI: LAMIS data
6. Summary & Conclusion

Early Statin give great benefit AMI patients regardless of revascularization strategy or lipid profile…

Thank You for Your Attention!!