Safety and Efficacy of Pitavastatin (Livalo®) in Patients with Acute Myocardial Infarction

: Insights from Livalo Acute Myocardial Infarction Study (LAMIS)

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Introduction

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

2. Should consider higher DES penetration rate in AMI in Korea (>92%) and increasing DES usage in all around the world.

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…

For Prevention of DES related Complications and Optimization of PCI results 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….

Role of Pitavastatin in AMI?

1. Pitavastatin (Livalo®), a 'lipophilic' potent inhibitor of HMG-CoA reductase, was launched 2003.
2. Lipophilic statin may influence on myocardial energy generation, particularly under pathological condition.
3. Lipophilic pitavastatin may have direct cardioprotective effect and play an important role in AMI not only reducing LDL-cholesterol, but also through pleiotropic effects.

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"

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*** PI of LAMIS Investigators**

LAMIS-Major Enrolling Hospitals

시험기관	N=1,039	
	명	%
1. 가천의과대학교 길병원	32	3.08
2. 건양대학교 병원	74	7.12
3. 계명대학교 동산의료원	114	10.97
4. 고려대학교 의과대학 부속 구로병원	123	11.84
5. 대구가톨릭대학교병원	114	10.97
6. 분당서울대학교병원	50	4.81
7. 수영한서병원	129	12.42
8. 광대학교의과대학병원	130	12.51
9. 전남대학교병원	165	15.88
10. 중앙대학교병원	108	10.39

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 1039 consecutive AMI patients (pts; male 74.0 %; mean age, 61.4 ± 12.6 years) presented in 10 major percutaneous coronary intervention (PCI) centers in Korea from Feb 2007 to Sep, 2009.

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

Final LAMIS Enrollment Status

	명
등록	1,128
안전성 평가 대상례	**1,039**
유효성 평가 대상례	**1,039**
제외된 피험자의 사유[a)]	89
동의철회	1
리바로미복용	36
선정기준위반	4
이상반응	3
존재하지 않는 피험자	1
중복 등록된 피험자	10
타병원 전원	4
퇴원 전 사망	10
추적관찰 실패	20
피험자 참여형태	
임상시험 완료	901
중도 탈락	138

Baseline Demographics and Risk Factors

Characteristics	Pitavastatin (N=1039)
Age (years)	61.4 ± 12.6
Male (%)	769 (74.0%)
BMI (kg/m^2)	24.2 ± 3.2
Diabetes	251 (24.2%)
Hypertension	480 (46.3%)
Dyslipidemia	102 (9.8%)
Statin use	50 (4.9%)
Prior history of CAD	114 (11.0%)
Family history of CAD	52 (5.0%)
Current smoking	499 (48.3%)

Vital Signs and Biochemical Profiles

SBP (mmHg)	116.6 ± 19.4
DBP (mmHg)	71.7 ± 12.4
HR (/min)	74.5 ± 14.3
Total cholesterol (mg/dl)	190.9 ± 42.4
Triglyceride (mg/dl)	125.2 ± 91.4
HDL-C (mg/dl)	45.2 ± 11.8
LDL-C (mg/dl)	122.1 ± 37.1
hs-CRP (mg/l)	10.0 ± 29.8
CK, maximum (IU/l)	1129.5 ± 2135.0

Clinical Presentation of AMI

Type of AMI	Pitavastatin (N=1039)
STEMI	660 (63.8%)
NSTEMI	375 (36.2%)
Killip classification	
Class I	817 (80.0%)
Class II	154 (15.1%)
Class III	34 (3.3%)
Class IV	16 (1.6%)
Onset time of AMI	
Within 12 hr	781 (75.6%)
Within 24 hr	93 (9.0%)
Within 48 hr	44 (4.3%)

AMI Management

Angiographic findings	**(N=1022)**
LM disease	12
1 vessel disease	458
2 vessel disease	341
3 vessel disease	185
No significant stenosis	26
Treatment	**(N=1014)**
PCI	959
Thrombolysis	51
CABG	4
Stage of revascularization	**(N=982)**
No revascularization of IRA	58
Revascularization of single IRA	511
Revascularization of only IRA in multivessel	153

Serial Biochemical Markers

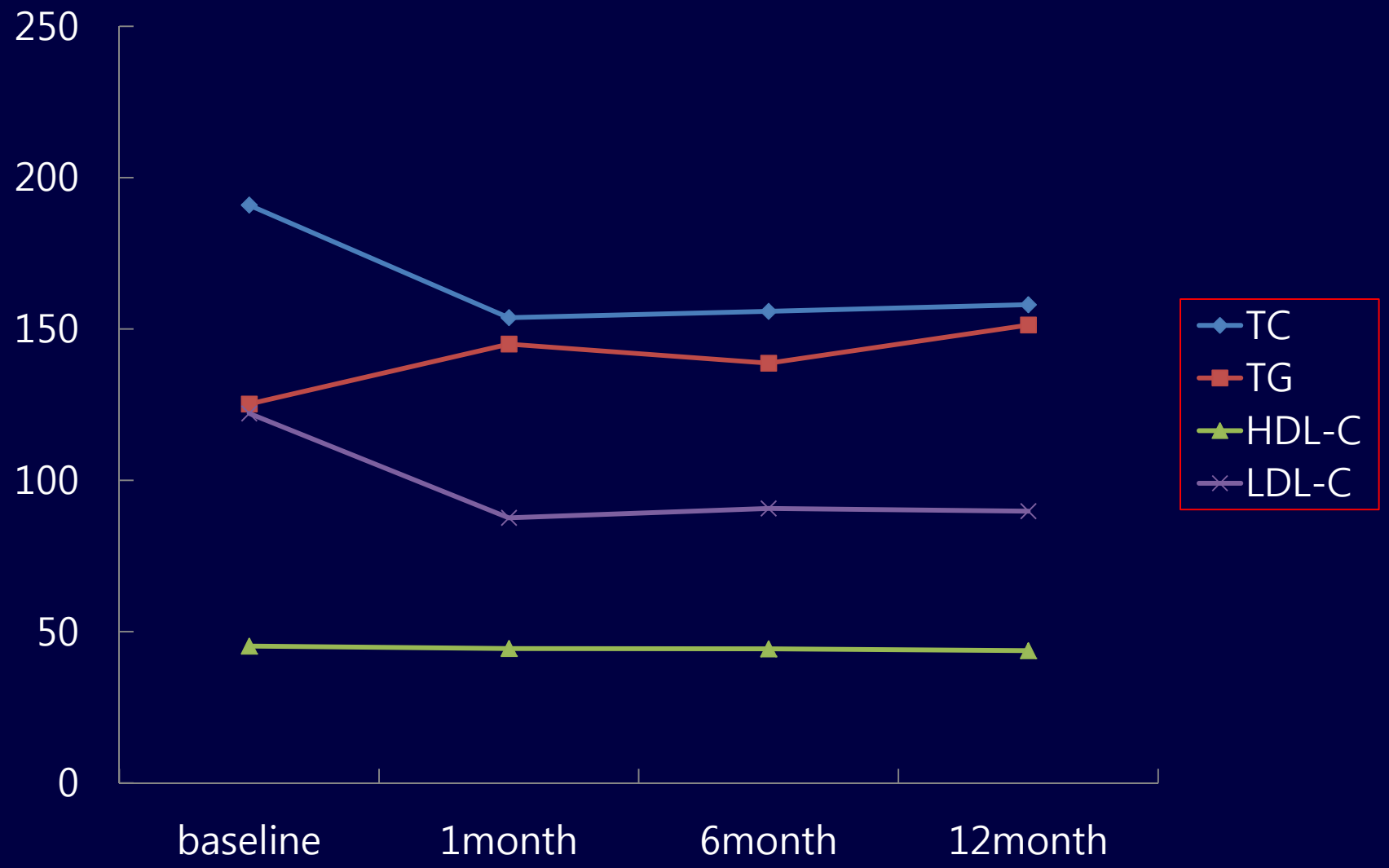
	Predischarge	1 month	6 month	12 month
Total cholesteroal (mg/dl)	190.9 ± 42.4	153.7 ± 29.4	155.8 ± 34.1	158.0 ± 34.9
TG (mg/dl)	125.2 ± 91.4	145.0 ± 108.4	138.7 ± 76.5	151.3± 152.0
HDL-C (mg/dl)	45.2 ± 11.8	44.4 ± 10.5	44.3 ± 11.1	43.7 ± 9.5
LDL-C (mg/dl)	122.1 ± 37.1	87.6 ± 24.9	90.7 ± 27.4	89.8 ± 28.4
CK (IU/l)	1129.5 ± 2135.0	105.1 ± 95.4	120.3 ± 97.2	117.0 ± 78.6
GOT (IU/l)	90.5 ± 139.4	25.1 ± 17.4	25.5 ± 26.1	24.9 ± 9.8
GPT (IU/l)	40.0 ± 44.1	27.8 ± 25.9	26.7 ± 29.1	26.2 ± 15.9
hs-CRP (mg/l)	10.0 ± 29.8	2.0 ± 6.8	2.1 ± 9.4	2.3 ± 13.1

LDL-C Target Attaintments by NCEP ATPIII guideline

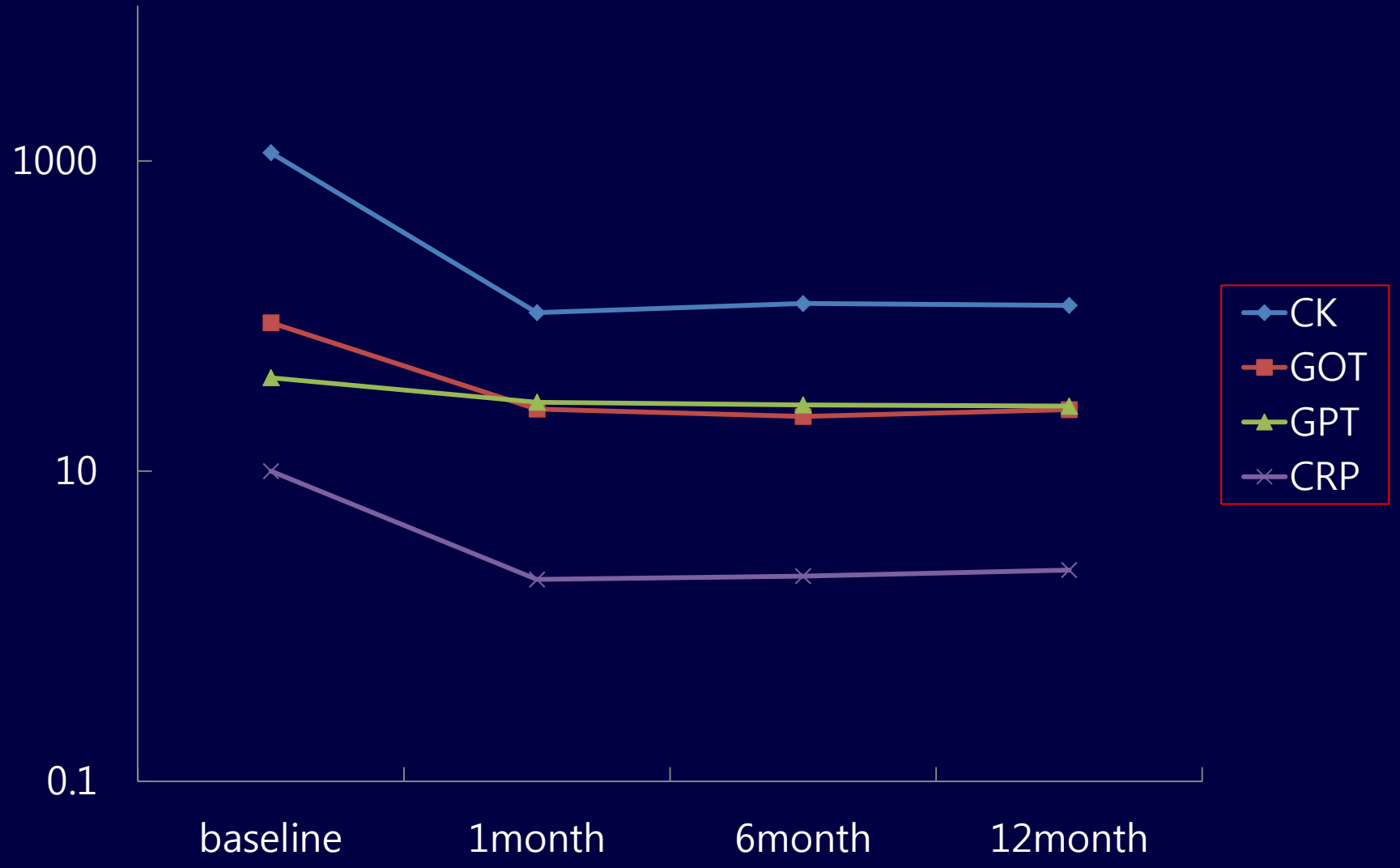
LDL-C	Pre discharge (n=524)		1 Month (n=524)		6 Month (n=252)		12 Month (n=203)	
	n	%	n	%	n	%	n	%
< 100mg/dL	139	26.53	368	70.23	163	64.68	146	71.92
≥100mg/dL	385	73.47	156	29.77	89	35.32	57	28.08

LDL-C	Pre discharge (n=524)	1 Month (n=524)		6 Month (n=252)		12 Month (n=203)	
	n	n	%	n	%	n	%
달성	385	252	65.45	112	59.26	107	68.15
비달성		133	34.55	77	40.74	50	31.85

Change in Lipid Profiles



Change in Biochemical markers



Cumulative Clinical Outcomes up to 12 months

Variables , N (%)	1 month N = 1039	6 month N = 963	12 month N = 901
Total death	8 (0.8%)	20 (2.1%)	32 (3.6%)
Cardiac Death	6 (0.6%)	13 (1.4%)	19 (2.1%)
Non cardiac death	2 (0.2%)	7 (0.7%)	13 (1.4%)
Recurrent Myocardial infaction			
STEMI	1 (0.1%)	5 (0.5%)	8 (0.9%)
NSTEMI	1 (0.1%)	5 (0.5%)	6 (0.7%)
Repeat PCI			
TLR	1 (0.1%)	18 (1.8%)	42 (4.7%)
TVR	2 (0.1%)	26 (2.7%)	59 (6.5%)
CABG	0	0	2 (0.2%)

Multiple logistic regression analysis for major adverse cardiac event (MACE) at 12 month follow up

Variable		Odds Ratio	95% CI		p-value
Age		1.01	0.993	1.030	NS
BMI		0.941	0.878	1.008	NS
Onset time of AMI	Within 12hr	-	-	-	NS
	Within 24hr	0.576	0.225	1.476	
	Within 48hr	1.083	0.371	3.160	
	Over 48hr	1.967	1.106	3.496	
DM		2.464	1.581	3.840	< 0.001

Overall summary of treatment emergent adverse events

Category	Number (%) of patients	Number (%) of events
With any TEAE	220 (21.2%)	318 (30.6%)
With any serious TEAE		42
Death or life threatening		17
Need admission		24
other		1
With any TRAE	14 (1.4%)	20 (1.92%)

TEAE; Treatment emergent adverse event, TRAE; treatment related adverse event.

Incidence of treatment related adverse event (TRAE) by systemic organ class (1)

TRAE	Number of events
Cental and peripheral nervous system disorders	
cramps legs	1
dizziness	1
Gastro-intestinal system disorders	
abdominal pain	1
constipation	1
diarrhea	1
vomitting	1
Liver and biliary system disorders	
GOT increased	4

Incidence of treatment related adverse event (TRAE) by systemic organ class (2)

TRAE	Number of events
Metabolic and nutritional disorders	
Creatine phosphokinase increased	1
Muscluoskeltal system disorders	
myalgia	3
skeletal pain	1
Respiratory system disorder	
coughing	1

LAMIS-1 Summary

Favorable 1-year Clinical Outcomes

- 리바로를 1년간 투여한 AMI 환자 1,039명 중 7.3%인 66명에서 MACE가 발생하였음.
- 당뇨병 유무는 AMI환자의 MACE발생에 유의한 영향을 미치는 것으로 관찰되었음.

Improving Lipid Profile and Pleiotrophic Effect

- LDL-C이 100 이상인 환자의 68%, 100 미만인 환자의 72% 가 리바로 2mg 투여 12개월째 목표치에 도달하였음.
- CRP 저하-Pleiotrophic Effect

Excellent Safety

- 발생한 이상반응의 대부분은 경증의 중등증이었음. (근골격계 이상반응: 4명)
- CK수치가 정상 수치에서 증가한 비율은 단 3명이었음.

LAMIS-1 Summary

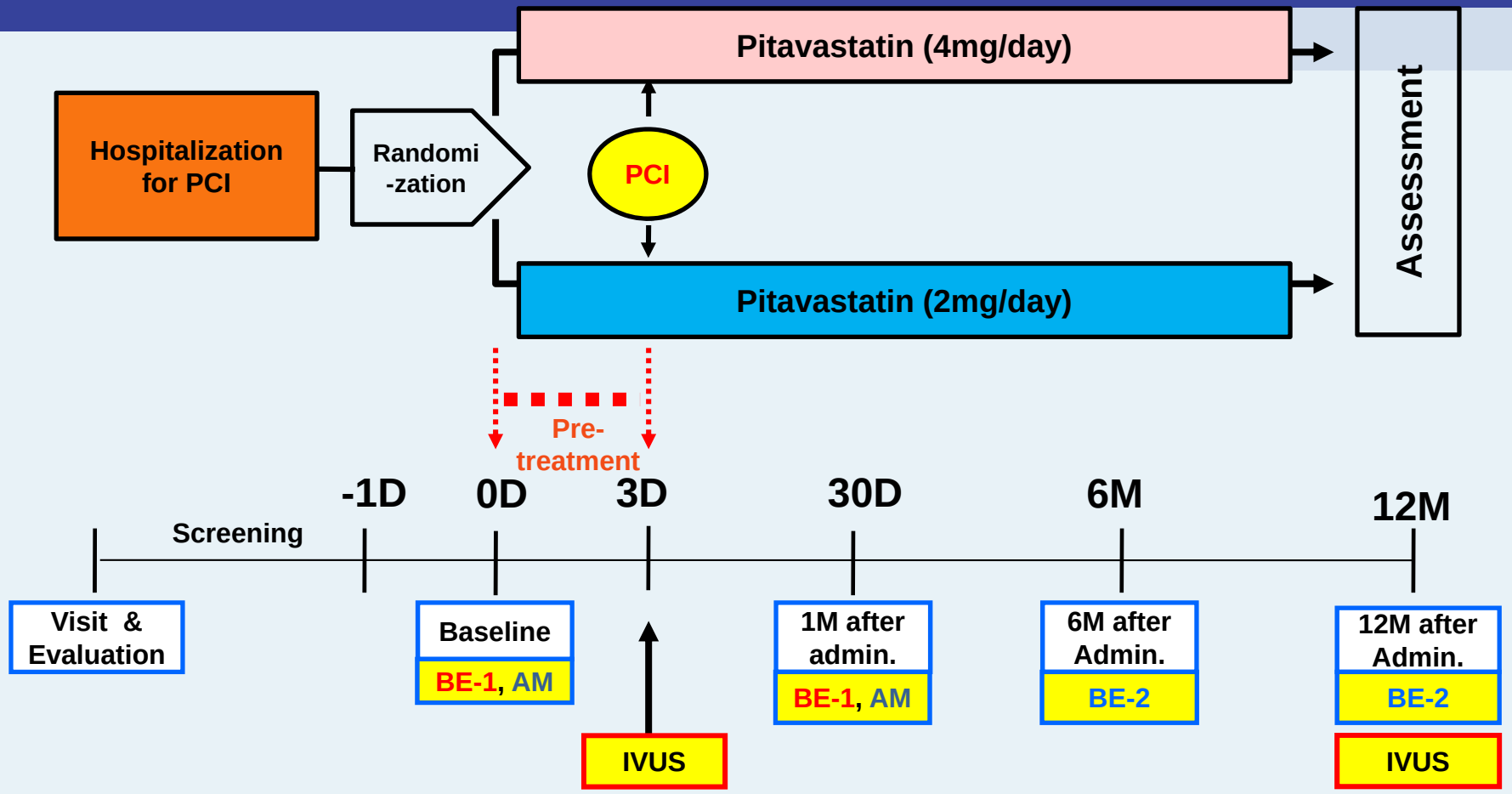
1. Major clinical outcomes in AMI pts who received routine Pitavastatin (LIVALO) were excellent up to 12 months.

2. Long-term administration of Pitavastatin in pts with AMI was safe and effective in reducing future cardiovascular events.

LAMIS-1 Conclusion

Routine administration of 2mg Pitavastatin daily in pts with AMI showed 71.9% LDL-C target attainments with good tolerance and associated with favorable clinical outcomes up to 12 months.

LAMIS-2 Study Design



Blood examination-1(BE-1): Lipids, LDH, CK, AST/ALT, Creatine Kinase-MB(mass), Troponin-I(mass), Myoglobin, hsCRP

Blood examination-2(BE-2): Lipids, LDH, CK, AST/ALT, Myoglobin, hsCRP

Soluble adhesion molecules(AM): VCAM-1, ICAM-1, E-selectin

LAMIS-2 Investigators

기관명	7월	8월	9월	10월	11월	12월	1월	진행
1. 전남대학교병원	1	1	0	8	17	15	7	**46**
2.가천의대길병원	1	0	0	0	1	1	0	**3**
3.건양대병원	0	0	0	0	0	0	0	**0**
4.계명대병원	6	11	12	8	6	14	4	**47**
5.고대구로병원	0	0	0	0	3	1	1	**2**
6.대구가톨릭병원	0	4	2	0	0	0	0	**6**
7.분당서울대병원	2	4	3	3	6	2	0	**20**
8.원광대병원	2	5	8	11	2	6	6	**37**
9.중앙대학교병원	0	1	0	1	0	2	1	**5**
10.일산백병원	0	0	0	0	1	2	3	**6**
11.부산대병원	0	0	0	0	0	1	0	**1**
월별합계	12	26	25	31	36	44	22	173

National PI; Prof MH Jeong

Research Fellow 2010

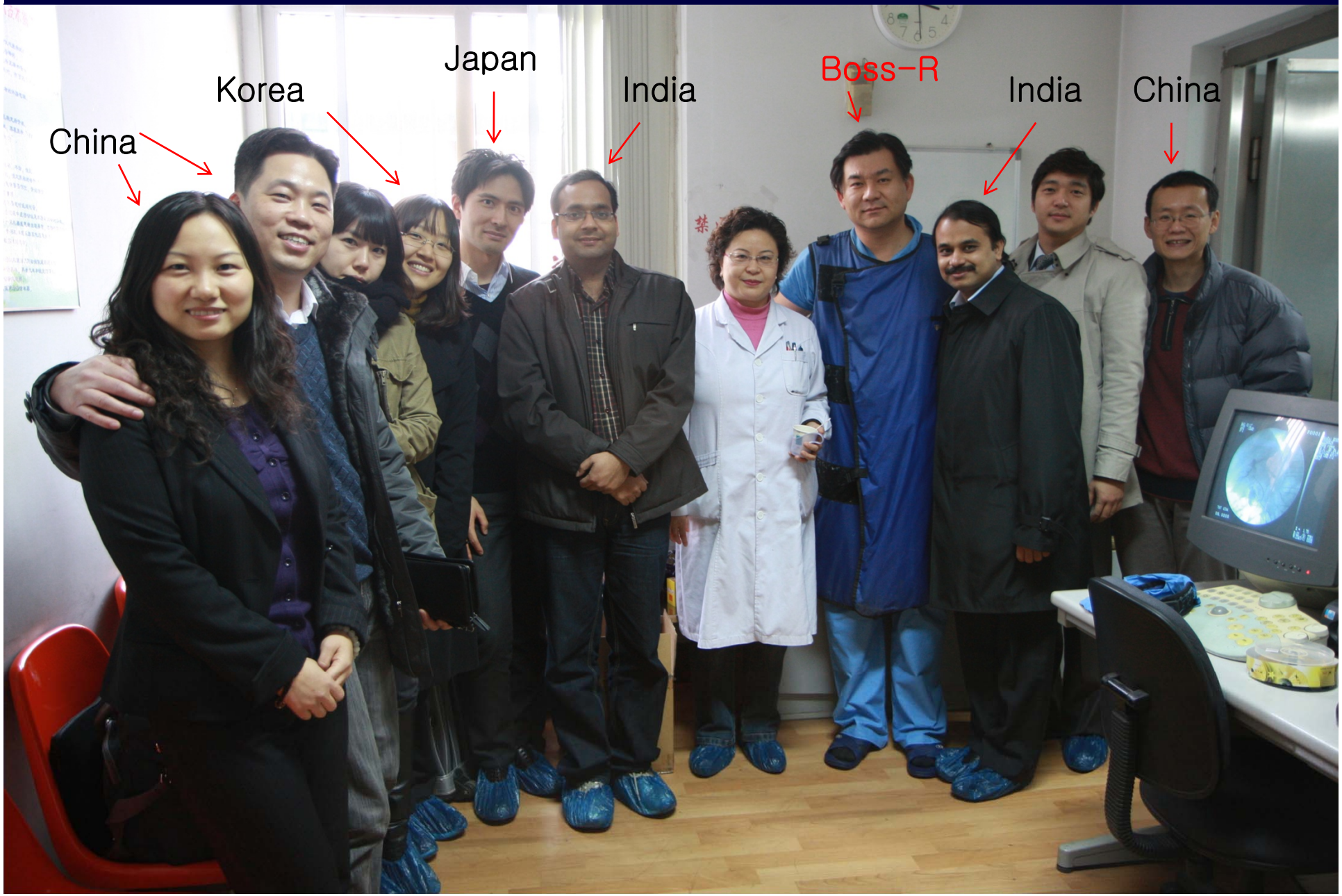
Kanhaiya L Poddar

Meera Kumari

Research Fellow 2011

Amro Elnagar, Benha University Hospital, Egypt

R Family at Tianjin 2009



Research Family Members

Korea University Guro Hospital (KUGH)

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)

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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

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

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.

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
Diagnosis			
STEMI	1696 (55.5)	676 (63.4)	<0.001
NSTEMI	1362 (44.5)	390 (36.6)	<0.001
Hypertension	1465 (48.2)	495 (46.6)	0.375
Untreatment	187 (6.2)	73 (6.9)	0.405
treatment	1260 (41.4)	403 (37.9)	0.046
DM	896 (29.6)	261 (24.5)	0.002
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
Dyslipidemia	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
Smoking	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
IHD (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
PreviousCABG	30 (1.0)	3 (0.3)	0.030
Family Hx of IHD	173 (5.7)	55 (5.2)	0.522
Multi Vessle disease	1489 (58.1)	544 (50.8)	<0.001
LM lesion	113 (4.4)	12 (1.1)	<0.001

Baseline Characteristics(3)

Variable, n (%)	No statin (N=3011 pts)	Pitavastatin (N=1070 pts)	p-value
KillipClass			
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)	-
Post LVEF	50.9 ±12.7	52.7 ±11.4	<0.001
Total Cholesterol	174.1 ±43.6	190.5 ±42.2	<0.001
Triglyceraide	123.3 ±91.9	126.3 ±92.0	0.376
HDL-C	44.8 ±13.9	45.2 ±11.8	0.378
LDL-C	108.3 ±42.3	121.8 ±36.8	<0.001
hs-CRP	8.8 ±35.4	9.9 ±30.2	0.394
CK	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
Medication			
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
STEMI			
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)	-
NSTEMI			
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
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

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 (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).

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

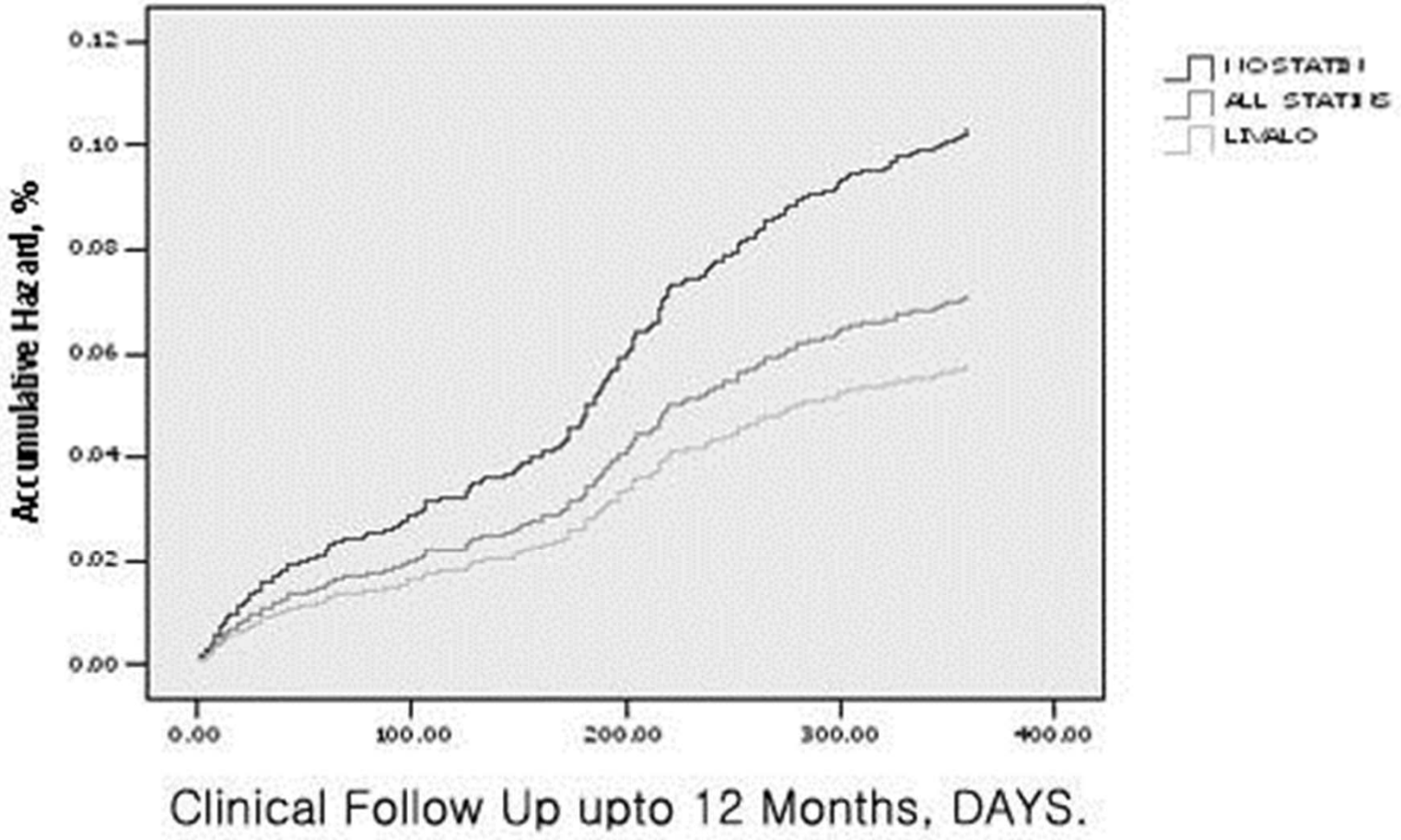
Methods

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).

CCI Program

Complex Cardiovascular Intervention Program

COURSE OVERVIEW

- Instructor : Dr. Rha Seung Woon
- Technical Improvement in Complex Coronary & Peripheral Intervention
- Clinical Research in Cardiovascular Field

REGISTRATION

Personal Information

Name _____

Hospital & Specialty _____

E-mail address _____

Telephone/Mobile _____

Areas of Interests

- ☐ How to get out of trouble (procedural complication)
- ☐ How to get accesses in difficult CTO Case
- ☐ Current treatment strategies and device selection
- ☐ Clinical Research in Cardiovascular Field

Research Fellow & Visiting Professor 2011

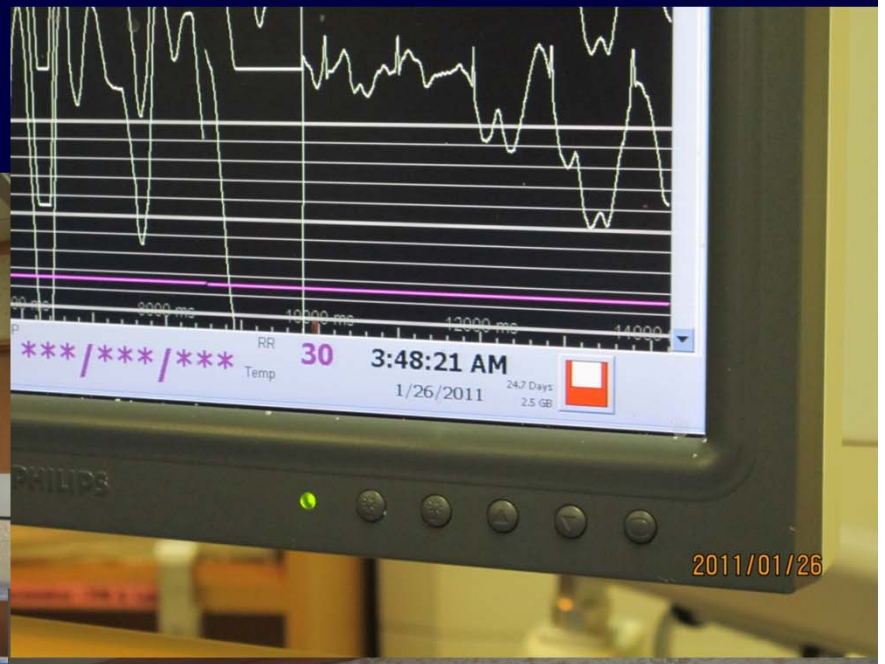
Dr Amro Elnagar from Egypt, Korean Visiting Professors

Korean Visiting Professors

Prof. Park SH & Cho YH's Live

Visiting Professor 2011

Never give up & Until tired or expire…



Korean Visiting Professors

CCI Program & Visiting Professors

1. 천안 순천향대 병원; 박상호 (Mentor)
2. 관동의대 명지병원; 조윤형 (Mentor)
3. 을지의대 노원을지병원; 박지영
4. 원광대 군포병원; 김연경
5. 부천 순천향대 병원; 조윤행
6. 강북삼성병원; 김병진
7. 건국대 충주병원; 최웅길

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1. 원주의대; 윤영진
2. 인하대병원; 우성일
3. 명지병원; 봉정민
4. 강북삼성병원; 공준혁 (흉부외과)

Summary & Conclusion

1. Introduction; ACS in DES Era & Statins
2. Pitavastatin (Livalo) in AMI Study (LAMIS)
   ; insights from LAMIS-1
   Excellent efficacy and safety in AMI pts
3. LAMIS-2; ongoing
4. Pitavastatin (Livalo) vs. No Statin in KAMIR

** *Pitavastatin was crucial, essential and absolutely needed in pts with AMI in DES era!!*

Thank You for Your Attention!!