JCR
2018. 12. 8

LAMIS
(Livalo® in AMI Study)

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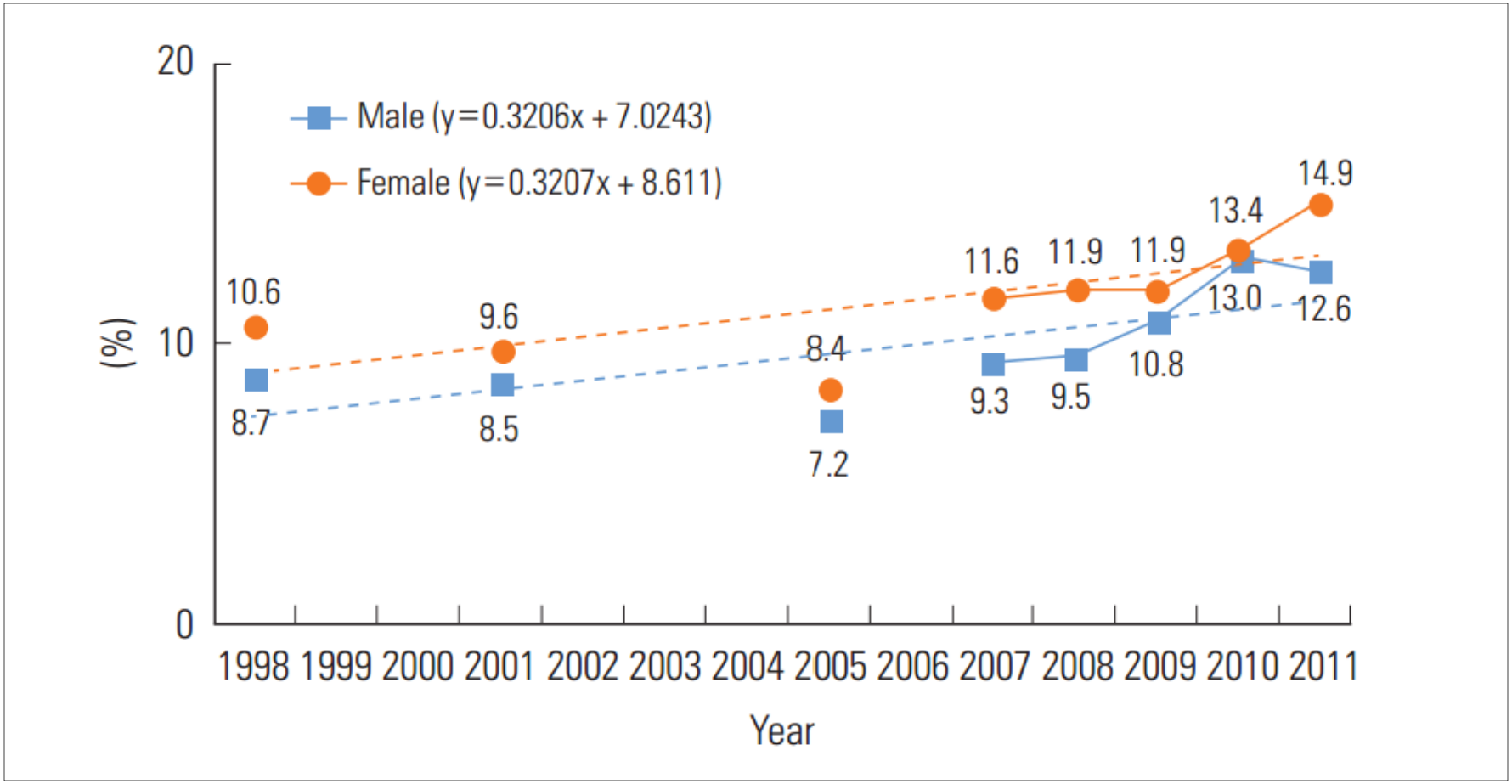
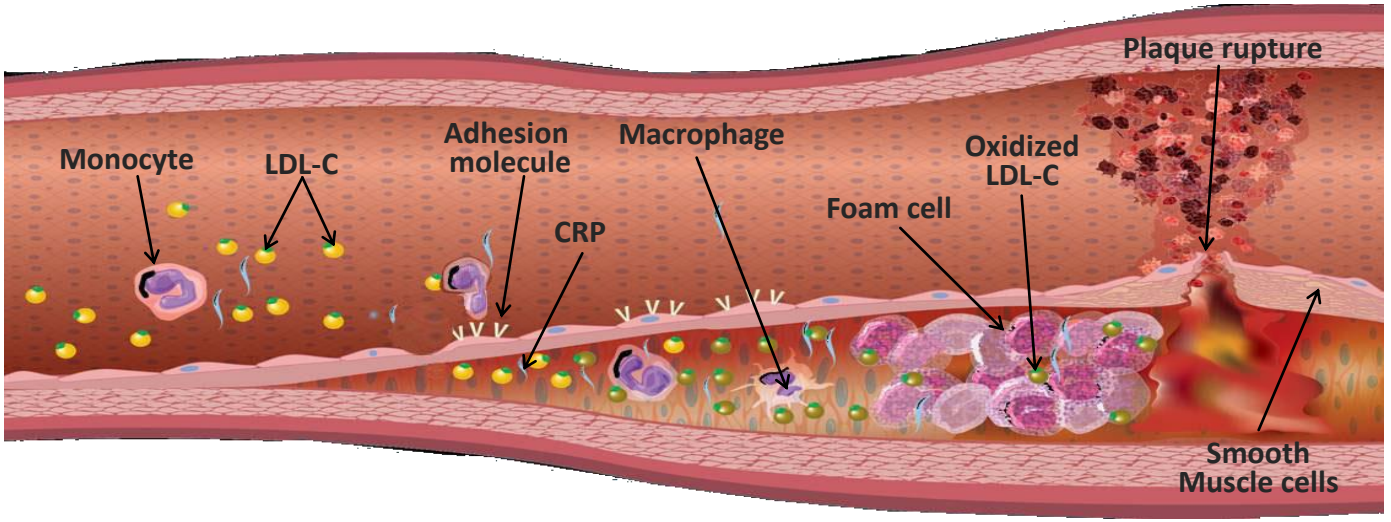
Trend of hypercholesterolemia in Korea

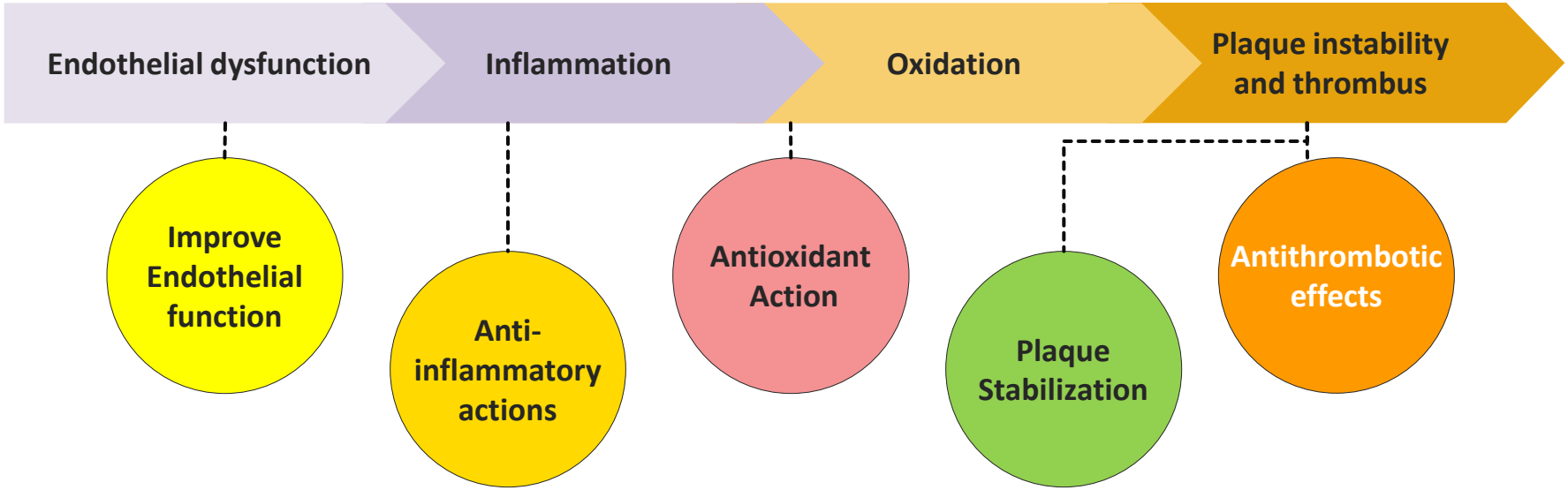
< Prevalence of hypercholesterolemia : Korea health statistics 2011>



Ref. Kim HC, Oh SM. J Prev Med Public Health. 2013;46(4):165-72.

Benefits of Statins Beyond Lipid Lowering



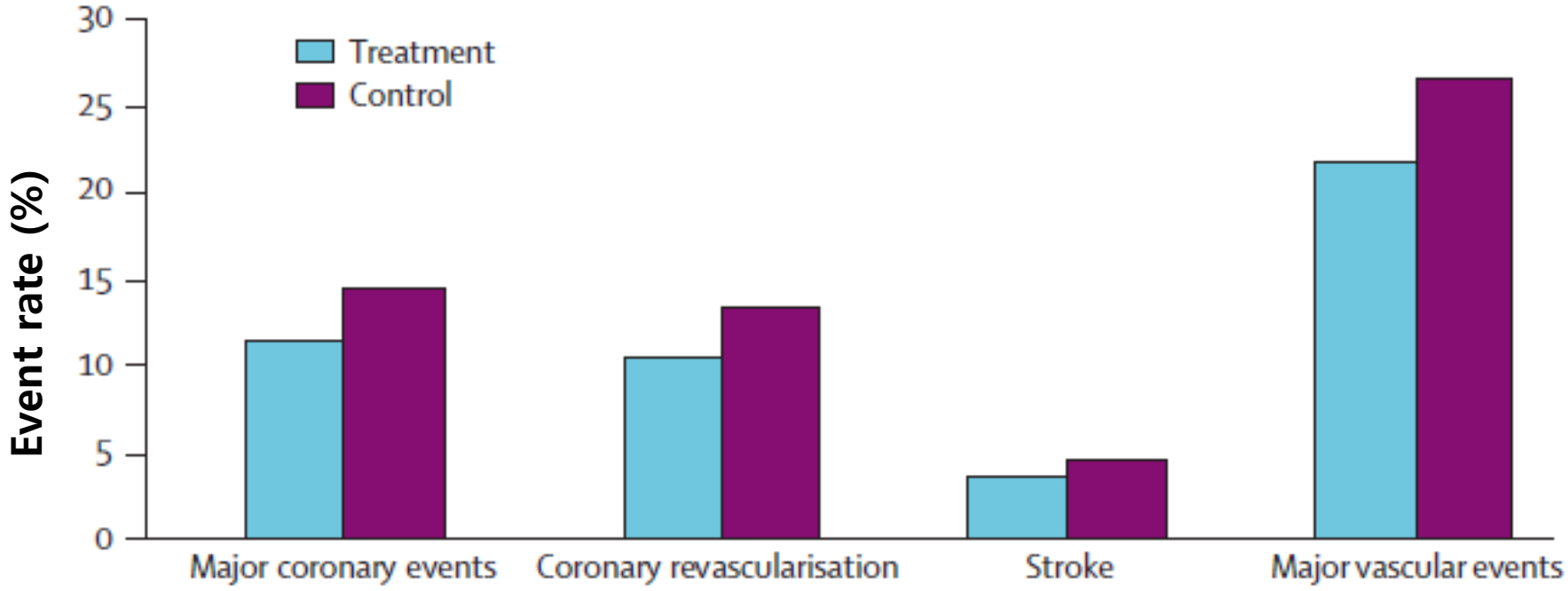


Ref. Libby P, et al. Circulation. 2001;104:365-372.

Benefits on particular vascular outcomes

Participants with previous MI or CHD

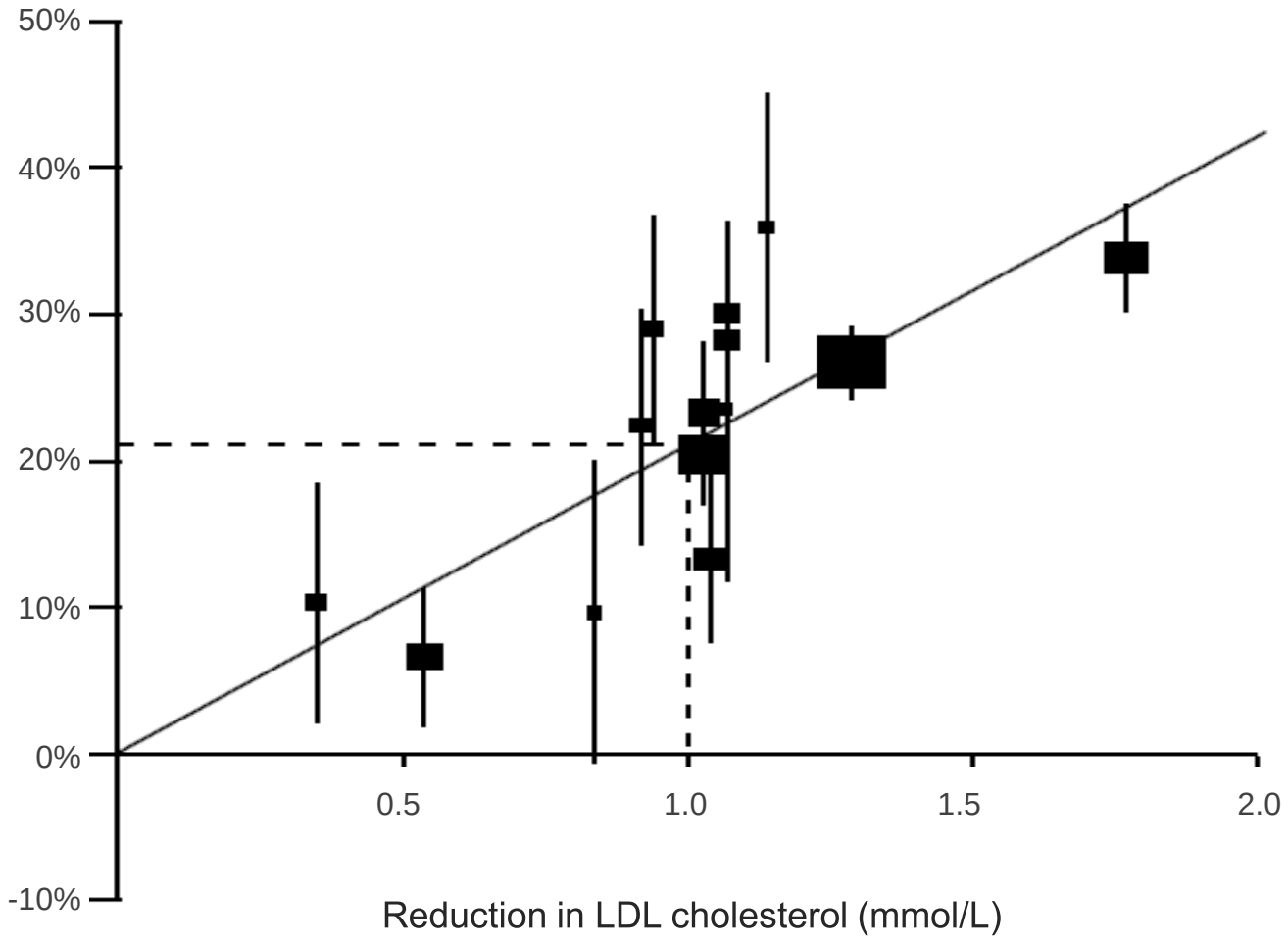
14 randomised trials of statins



	Major coronary events	Coronary revascularisation	Stroke	Major vascular events
Outcomes avoided per 1000 (95% CI)	30 (24–37)	27 (20–34)	8 (4–12)	48 (39–57)

Lancet 2005; 366: 1267–78

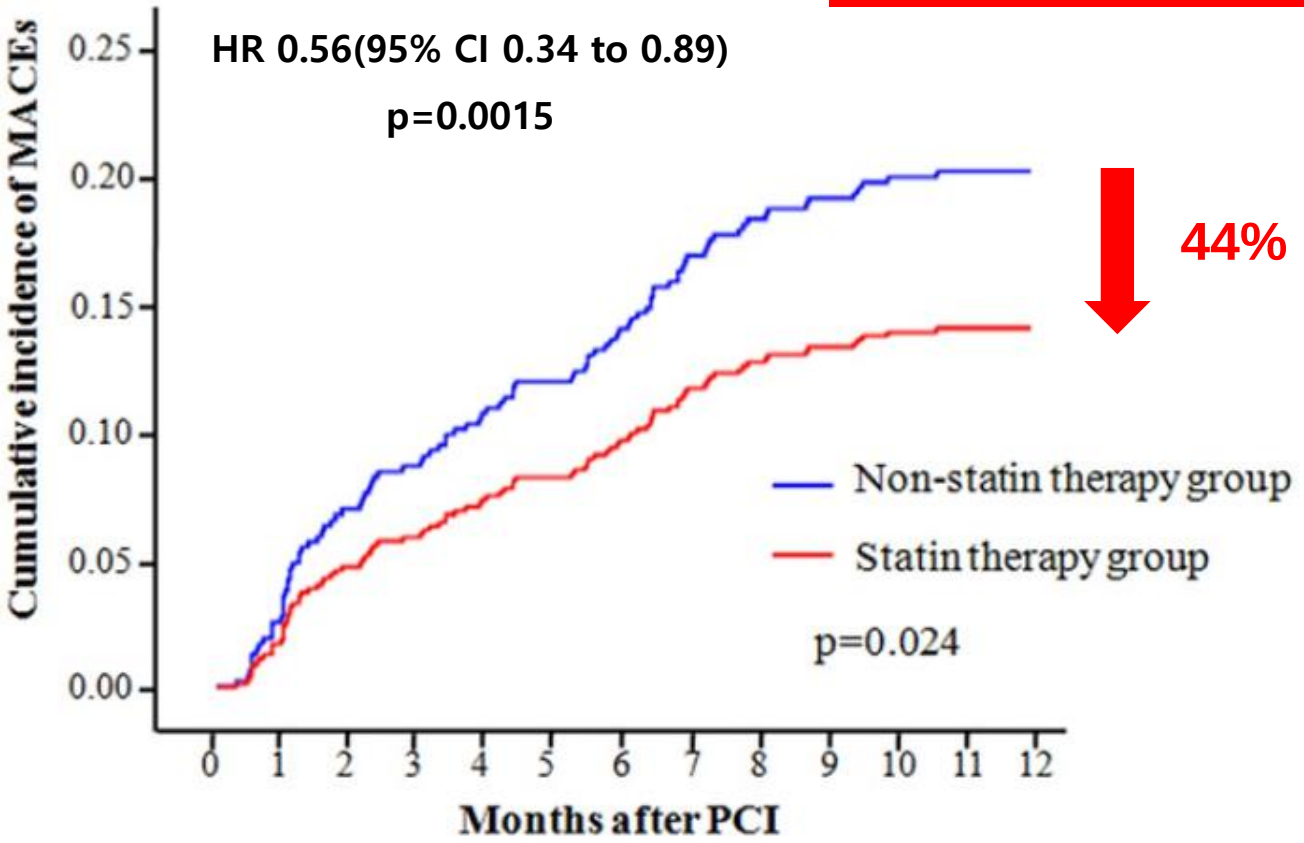
Relation Between the Proportional Reduction in MAJOR VASCULAR EVENTS and Mean Absolute LDL-C Reduction in 14 Statin Trials



Cholesterol Treatment Trialist Collaborators, Lancet 2005;366:1267

Benefit of Statin Therapy (Korean AMI)

Patients < LDL-C 70mg/dL



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

J Am Coll Cardiol 2011;58:1664–71

2018 ACC/AHA guideline

High-Intensity Statin Therapy	Moderate-Intensity Statin Therapy	Low-Intensity Statin Therapy
Daily dose lowers LDL–C on average, by approximately **≥50%**	Daily dose lowers LDL–C on average, by approximately **30-49%**	Daily dose lowers LDL–C on average, **by <30%**
• Atorvastatin (40†)–80 mg Rosuvastatin 20 (40) mg	• **Pitavastatin 1,2,4 mg** • Atorvastatin 10 (20) mg • Rosuvastatin (5) 10 mg • Simvastatin 20–40 mg‡ • Pravastatin 40 (80) mg • Lovastatin 40 mg • Fluvastatin XL 80 mg • Fluvastatin 40 mg bid	• Simvastatin 10 mg • Pravastatin 10–20 mg • Lovastatin 20 mg • Fluvastatin 20–40 mg

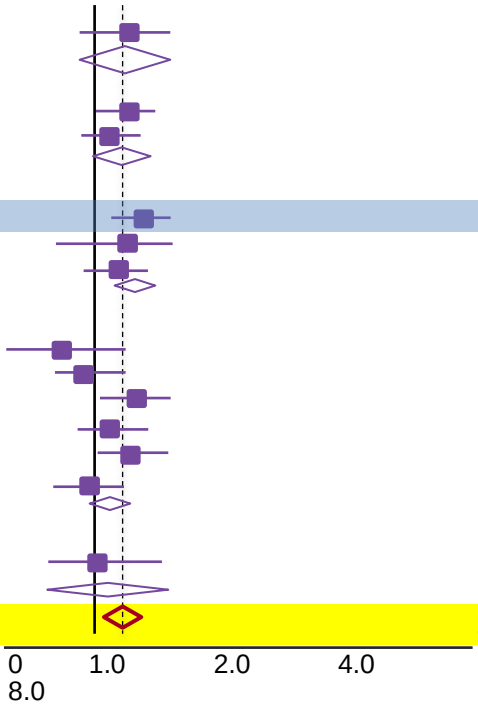
†LDL-C lowering that should occur with the dosage listed below each intensity.
‡Evidence from 1 RCT only: down titration if unable to tolerate atorvastatin 80 mg in the IDEAL (Incremental Decrease through Aggressive Lipid Lowering) study (S3.2.1-3).
§Although simvastatin 80 mg was evaluated in RCTs, initiation of simvastatin 80 mg or titration to 80 mg is not recommended by the FDA because of the increased risk of myopathy, including rhabdomyolysis.

Issue of statin : DM safety

Risk of NOD by Statin

Association between different statins and development of diabetes (Meta-analysis of 13 statin trials with 91,140 participants)

	N	Statin	Placebo or control	OR (95% CI)	Weight (%)
Atorvastatin					
ASCOT-LLA	7,773	154	134	1.14 (0.89-1.46)	7.07
				1.14 (0.89-1.46)	7.07
Simvastatin					
HPS	14,573	335	293	1.15 (0.98-1.35)	13.91
4S	4,242	198	193	1.03 (0.84-1.28)	8.88
Subtotal (I^2=0.0%, P=0.445)				1.11 (0.97-1.26)	22.80
Rosuvastatin					
JUPITER	17,802	270	216	1.26 (1.04-1.51)	11.32
CORONA	3,534	100	88	1.14 (0.84-1.55)	4.65
GISSI HF	3,378	225	215	1.10 (0.89-1.35)	9.50
Subtotal (I^2=0.0%, P=0.607)				1.18 (1.04-1.33)	25.46
Pravastatin					
WOSCOPS	5,974	75	93	0.79 (0.58-1.10)	4.24
LIPID	6,997	126	138	0.91 (0.71-1.17)	6.53
PROSPER	5,023	165	127	1.32 (1.03-1.69)	6.94
MEGA	6,086	172	164	1.07 (0.86-1.35)	8.03
ALLHAT-LLT	6,087	238	212	1.15 (0.95-1.41)	10.23
GISSI PREVENZIONE	3,460	96	105	0.89 (0.67-1.20)	4.94
Subtotal (I^2=47.5%, P=0.090)				1.03 (0.90-1.19)	40.91
Lovastatin					
AFCAPS/TexCAPS	6,211	72	74	0.98 (0.70-1.38)	3.76
				0.98 (0.70-1.38)	3.76
Overall (*P*=11.2%)				**1.09 (1.02-1.17)**	**100.0**



In view of the overwhelming benefit of statins for reduction of CV events, the small absolute risk for development of diabetes is outweighed by CV benefit in the short and medium term in individuals for whom statin therapy is recommended.

Study design; This was to search Medline, Embase, and the Cochrane Central Register of Controlled Trials from 1994 to 2009, for randomised controlled endpoint trials of statins. This was to identify 13 statin trials with 91,140 participants, of whom 4,278 (2,226 assigned statins and 2,052 assigned control treatment) developed diabetes during a mean of 4 years. This was aimed to establish by a meta-analysis of published and unpublished data whether any relation exists between statin use and development of diabetes.

OR, odds ratio; CI, confidence interval; CV, cardiovascular.

1. Satter N, et al. Lancet. 2010;375:735-742.

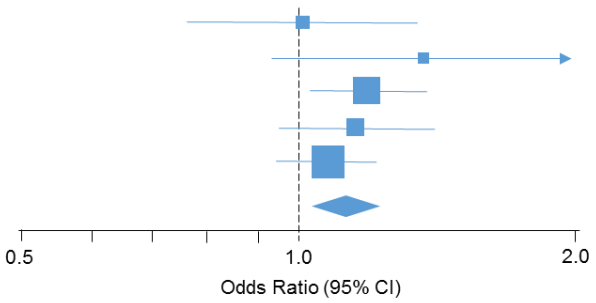
META-analysis 2011

- **The use of intensive-dose statin therapy compared with moderate-dose statin therapy was associated with a higher incidence of new-onset diabetes (OR, 1.12)**

- Figure) Meta-analysis of New-Onset Diabetes and First Major Cardiovascular Events in 5 Large Trials Comparing Intensive-Dose to Moderate-Dose Statin Therapy

Incident Diabetes	Cases / Total, No. (%)		OR (95% CI)
	Intensive Dose	Moderate Dose	
PROVE-IT-TIMI 22, 2004	101 / 1707 (5.9)	99 / 1688 (5.9)	1.01 (0.76-1.34)
A to Z, 2004	65 / 1768 (3.7)	47 / 1736 (2.7)	1.37 (0.94-2.01)
TNT, 2005	418 / 3798 (11.0)	358 / 3797 (9.4)	1.19 (1.02-1.38)
IDEAL, 2005	240 / 3737 (6.4)	209 / 3724 (5.6)	1.15 (0.95-1.40)
SEARCH, 2010	625 / 5398 (11.6)	587 / 5399 (10.9)	1.07 (0.95-1.21)
Pooled odds ratio	**1449 / 16408 (8.8)**	**1300 / 16344 (8.0)**	**1.12 (1.04-1.22)**

Heterogeneity: I^2 = 0%; P =.60



Data Sources: In 5 statin trials with 32 752 participants without diabetes at baseline

JAMA. 2011;305(24):2556-2564.

Management of Dyslipidemia

Statin Safety Recommendations

Recommendation	NHLBI Grade
Safety	
1. To maximize the safety of statins, selection of the appropriate statin and dose in men and nonpregnant/nonnursing women should be based on patient characteristics, level of ASCVD* risk, and potential for adverse effects. Moderate-intensity statin therapy should be used in individuals in whom high-intensity statin therapy would otherwise be recommended when characteristics predisposing them to statin-associated adverse effects are present. Characteristics predisposing individuals to statin adverse effects include, but are not limited to: • Multiple or serious comorbidities, including impaired renal or hepatic function. • History of previous statin intolerance or muscle disorders. • Unexplained ALT elevations >3 times ULN. • Patient characteristics or concomitant use of drugs affecting statin metabolism. • >75 years of age. Additional characteristics that may **modify the decision to use higher statin intensities** may include, but are not limited to: • History of hemorrhagic stroke. **• Asian ancestry.**	**A (strong)** There is high certainty based on evidence that the net benefit† is substantial.

2018 Racial/Ethnic Issues in Evaluation, Risk Decisions, and Treatment of ASCVD Risk

	Asian Americans
ASCVD issues informed by race/ethnicity	ASCVD risk in people of South Asian and East Asian origin varies by country of origin; individuals from South Asia (see below) have increased ASCVD risk.
Lipid issues informed by race/ethnicity	Asian Americans have lower levels of HDL-C than whites. There is higher prevalence of LDL-C among Asian Indians, Filipinos, Japanese, and Vietnamese than among whites. An increased prevalence of high TG was seen in all Asian American subgroups.
Intensity of statin therapy and response to LDL-C lowering	Japanese patients may be sensitive to statin dosing. In an open-label, randomized primary-prevention trial, Japanese participants had a reduction in CVD events with low-intensity doses of pravastatin as compared with placebo. **In a secondary-prevention trial, Japanese participants with CAD benefitted from a moderate-intensity dose of pitavastatin.**
Safety	Higher rosuvastatin plasma levels are seen in Japanese, Chinese, Malay, and Asian Indians as compared with whites. FDA recommends a lower starting dose (5 mg of rosuvastatin in Asians versus 10 mg in whites). Caution is urged as dose is uptitrated.

*The term Asian characterizes a diverse portion of the world's population. Individuals from Bangladesh, India, Nepal, Pakistan, and Sri Lanka make up most of the South Asian group (S.4.5.1-26). **Individuals from Japan, Korea, and China make up most of the East Asian group.**


Pitavastatin, the Balanced Statin
LAMIS
Livalo® in Acute Myocardial Infarction Study
Seung-Woon Rha[1], Soon Yong Suh[1,3], Tae Hoon Ahn[1], Jang Ho Bae[1], Seung Ho Hur[2], In Ho Chae[6], Jong Hyun Kim[7], Kyeong Ho Yun[8], Sang Wook Kim[9], Kee Sik Kim[10], Mi Hee Kim[11], Ji Eun Oh[11], Young Joon Hong[2], Myung Ho Jeong[2]*
(LAMIS Investigators)
University[1], ChonNam University[2], Gachon University[3], KonYang University[4], KeiMyung University[5], Seoul National University[6], Han Seo Hospital[7], Kwang University[8], Chung Ang University[9], Catholic University of Daegu[10], Chung Wae Pharm[11]
* CI of LAMIS Investigators
2011 (In Press)
2011/07/16

LAMIS-I: Background

- **There are very limited data regarding role of statin in managing AMI patients, especially in DES era.**
- **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 LAMIS-I, we evaluated the efficacy and safety of administration of Pitavastatin in AMI pts as a substudy of Korea Acute Myocardial Infarction Registry (KAMIR).

LAMIS I (Publication)

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

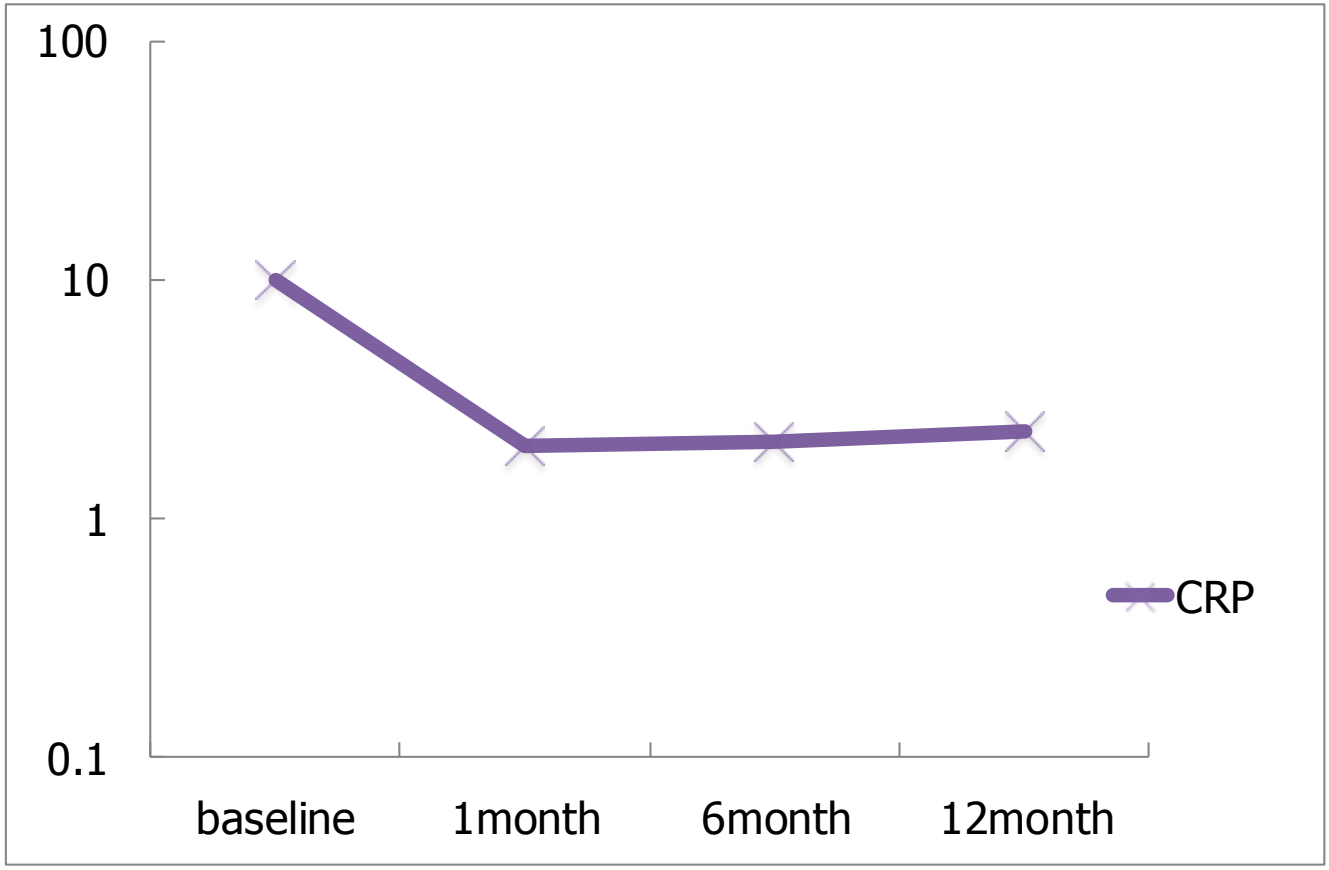
Pitavastatin is a potent lipophilic statin and may play an important role in acute myocardial infarction (AMI) but there have been limited data on the safety and efficacy of pitavastatin in AMI. This study consisted of 1,039 consecutive patients with AMI (74.0% men, mean age 61.4 ± 12.6 years) who presented 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)

LDL-C target attainment

	Pre discharge (N=1007)	1-month (N=540)	6-month (N=438)	12-month (N=319)
LDL-C target attainment (N, %)	274 (27.2%)	378 (70.0%)	293 (66.9%)	225 (70.5%)
Diabetic patients	78 (31.7%)	96 (74.4%)	62 (69.7%)	45 (67.2%)
Non diabetic patients	196 (25.9%)	281 (68.7%)	231 (66.6%)	180 (71.7%)

70.5% patients had achieved the LDL-C target defined by the NCEP criteria and LDL-C target attainment for diabetic patients was 67.2%

Pleiotropic Effects of LIVALO®(LAMIS I study)



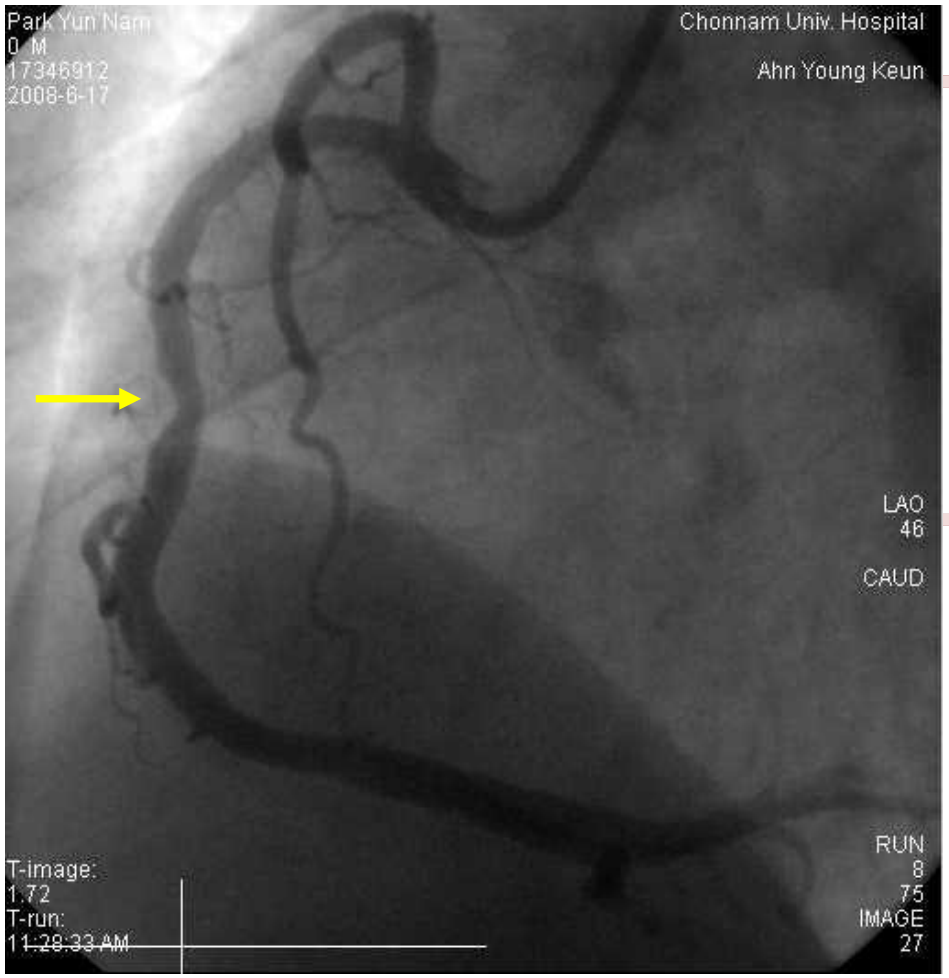
hs-CRP, was remarkably high at baseline but normalized during the first 1 month and sustained up to 12-month follow up

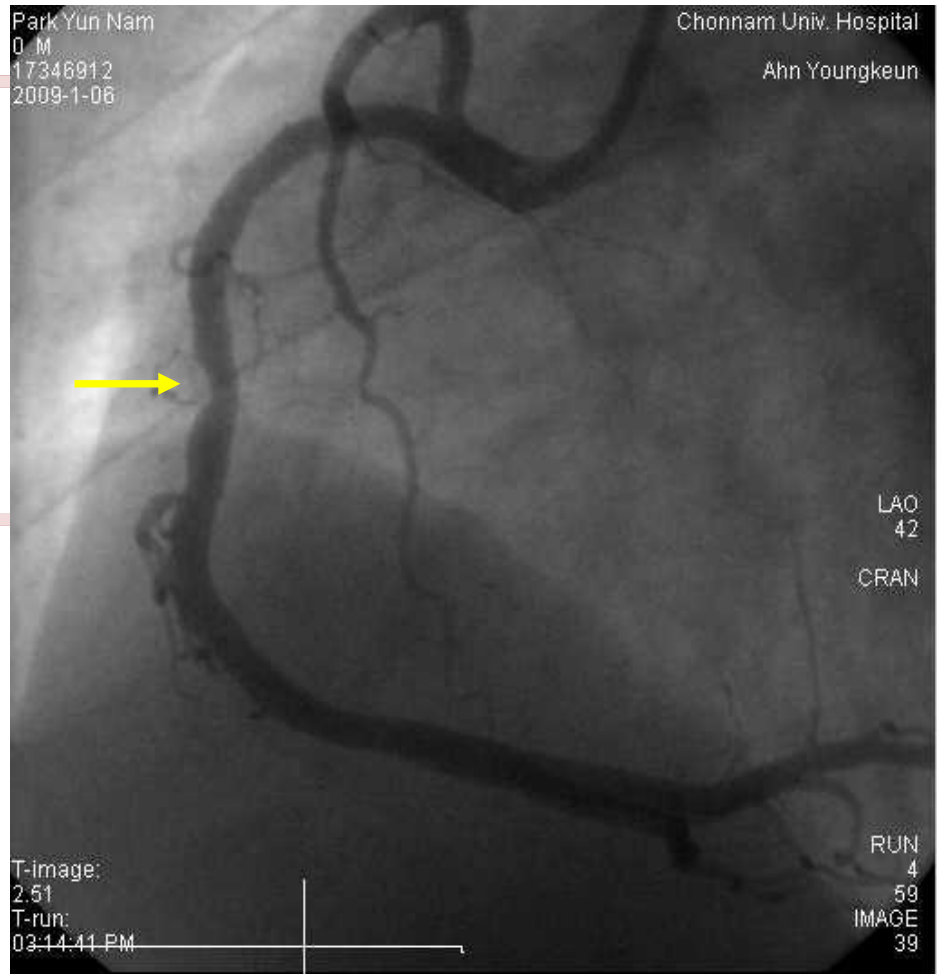
Pleiotropic Effects of LIVALO®(LAMIS I study)

Variables	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 infarction			
STEMI	1 (0.1%)	5 (0.5%)	8 (0.9%)
NSTEMI	1 (0.1%)	5 (0.5%)	6 (0.7%)
Repeat PCI			
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 graft	0	0	2 (0.2%)
Total major adverse cardiac event	8 (0.8%)	34 (3.5%)	66 (7.3%)

Pitavastatin 2mg

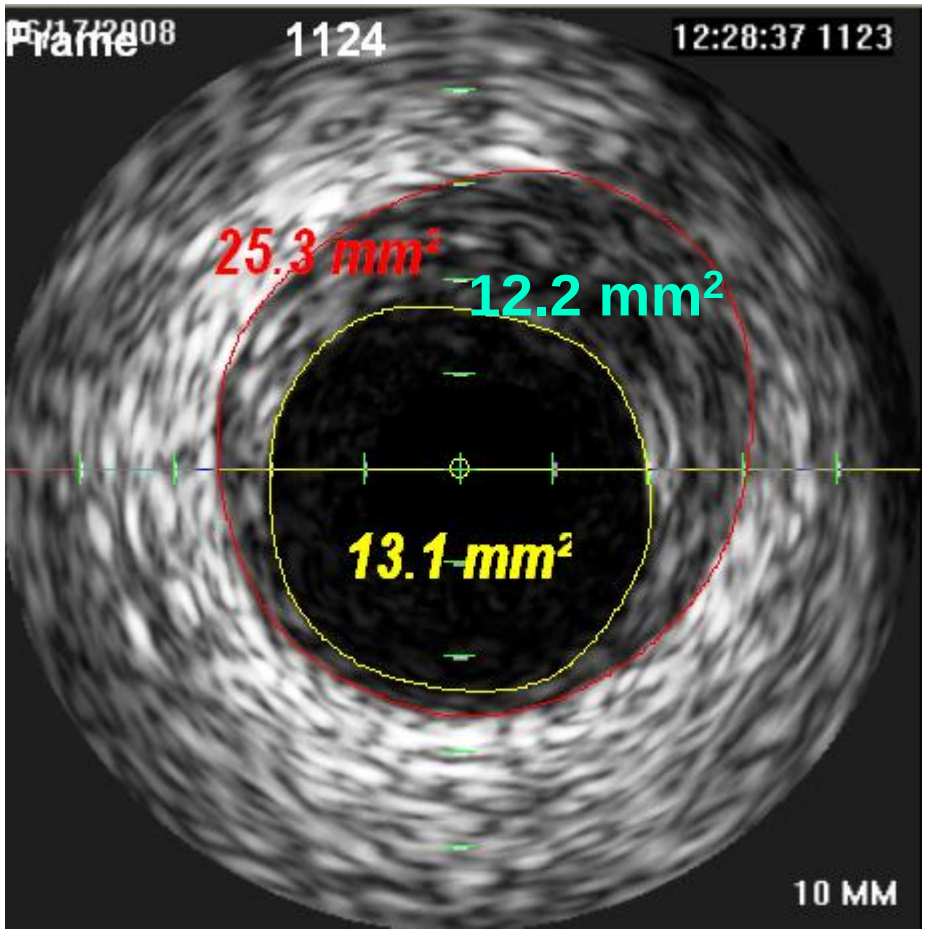
Baseline → **Follow up**

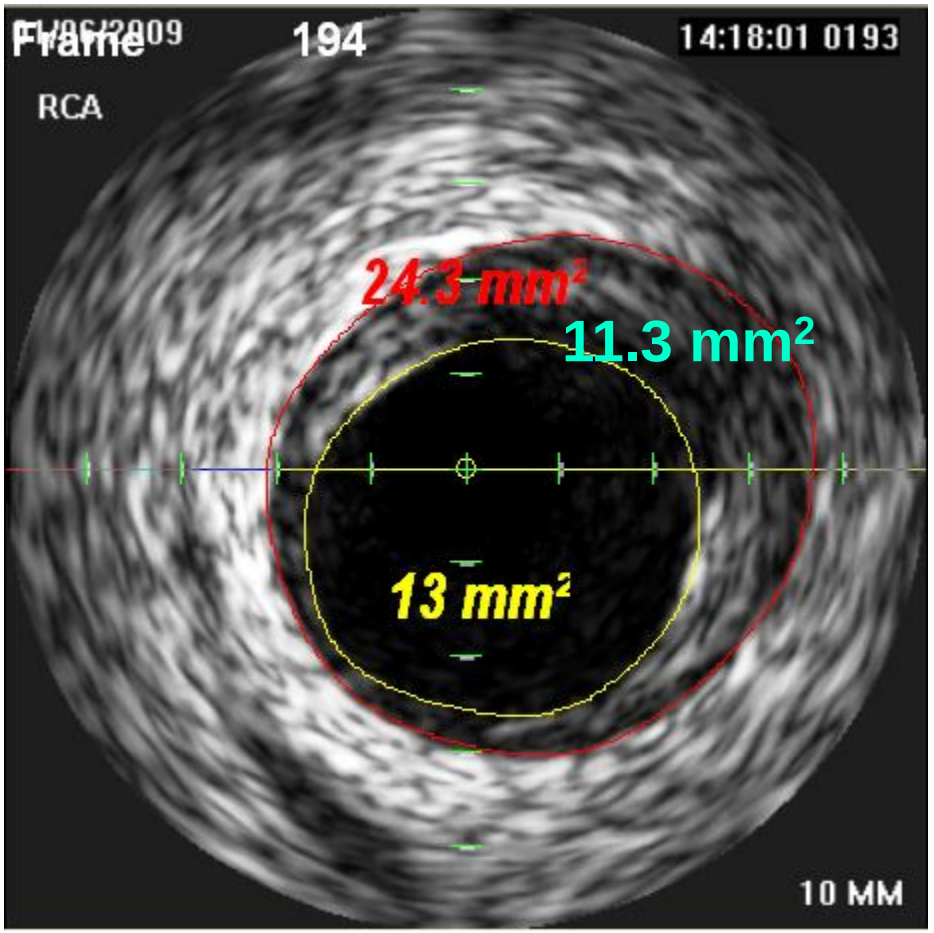




Pitavastatin 2mg

Baseline → **Follow up**



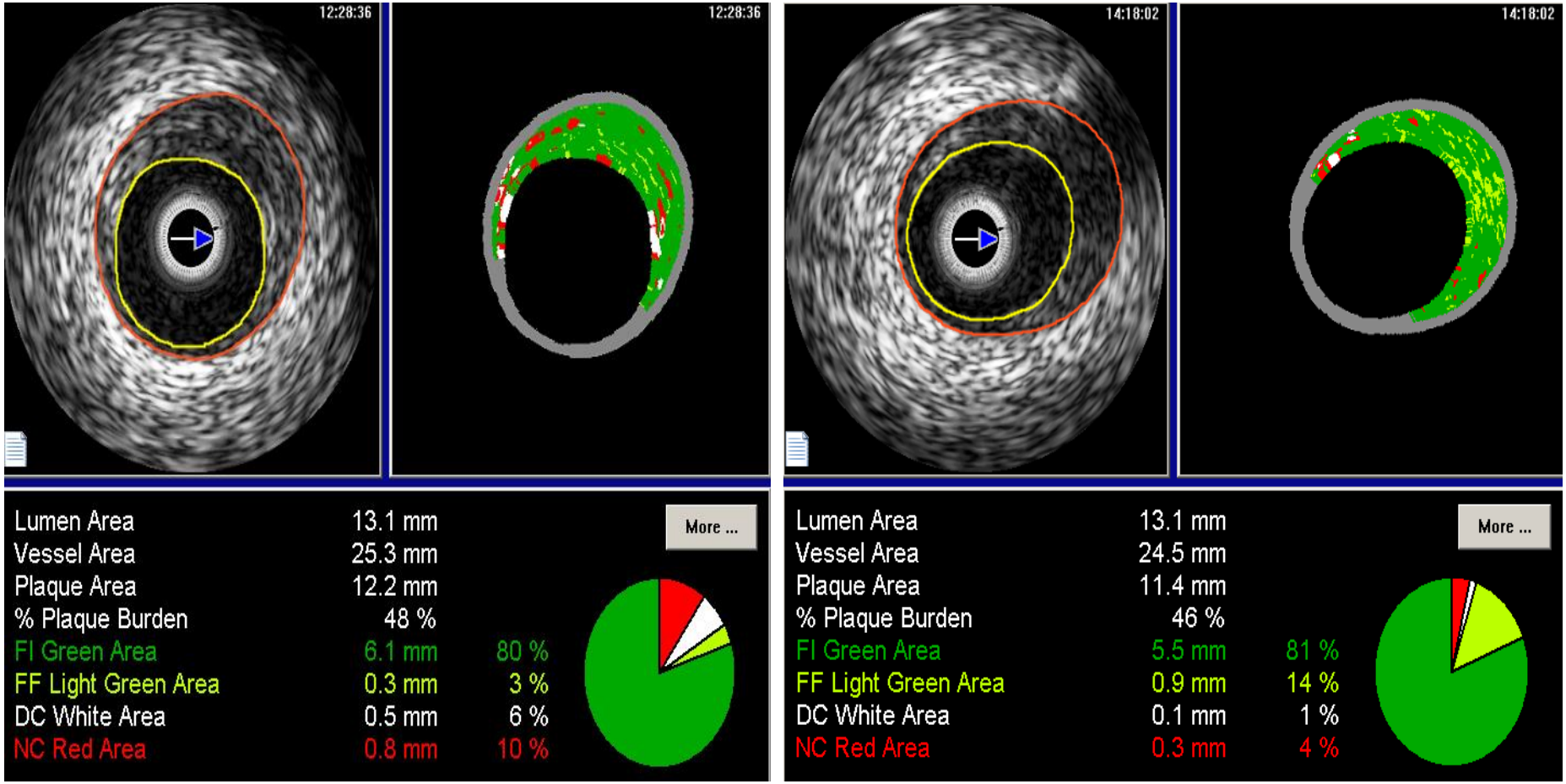


Plaque burden 48%

Plaque burden 46%

Pitavastatin 2mg

Baseline → **Follow up**



LAMIS I (Publication)

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Original article

Effect of pitavastatin treatment on changes of plaque volume and composition according to the reduction of high-sensitivity C-reactive protein levels

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ABSTRACT

Background: There are few data regarding the effect of statins on regression and compositional changes of plaque according to the reduction in high-sensitivity C-reactive protein (hs-CRP) levels in acute myocardial infarction (AMI) patients.

Methods: We used serial virtual histology-intravascular ultrasound to assess the efficacy of pitavastatin (dosage: 2 mg/day) on plaque regression and compositional changes according to the degree of reduction in hs-CRP levels from baseline to follow-up [≥1 mg/dl ($n=62$) vs. <1 mg/dl ($n=32$)] in non-intervened non-infarct related artery in AMI patients who were enrolled in the Livalo in acute myocardial infarction study (LAMIS).

Results: Total atheroma and percent atheroma volumes decreased more significantly in patients with reduction in hs-CRP ≥1 mg/dl compared with those with reduction in hs-CRP <1 mg/dl ($-1.7 \pm 12.4\ mm^3$ vs. $+2.7 \pm 7.8\ mm^3$, $p<0.015$, and $-0.4 \pm 3.4\%$ vs. $+0.4 \pm 4.8\%$, $p<0.001$, respectively). Absolute and %necrotic core volumes decreased more significantly in patients with reduction in hs-CRP ≥1 mg/dl compared with those with reduction in hs-CRP <1 mg/dl ($-0.4 \pm 3.5\ mm^3$ vs. $+1.9 \pm 3.4\ mm^3$, $p=0.038$, and $-1.1 \pm 4.9\%$ vs. $+2.7 \pm 4.7\%$, $p=0.016$, respectively). Reduction in hs-CRP ≥1 mg/dl at follow-up was the independent predictor of reduction of percent atheroma volume and %necrotic core volume at follow-up [odds ratio (OR), 2.228; 95% confidence interval (CI), 1.390–2.977, $p=0.016$, and OR, 2.204; 95% CI, 1.512–2.916, $p=0.020$, respectively].

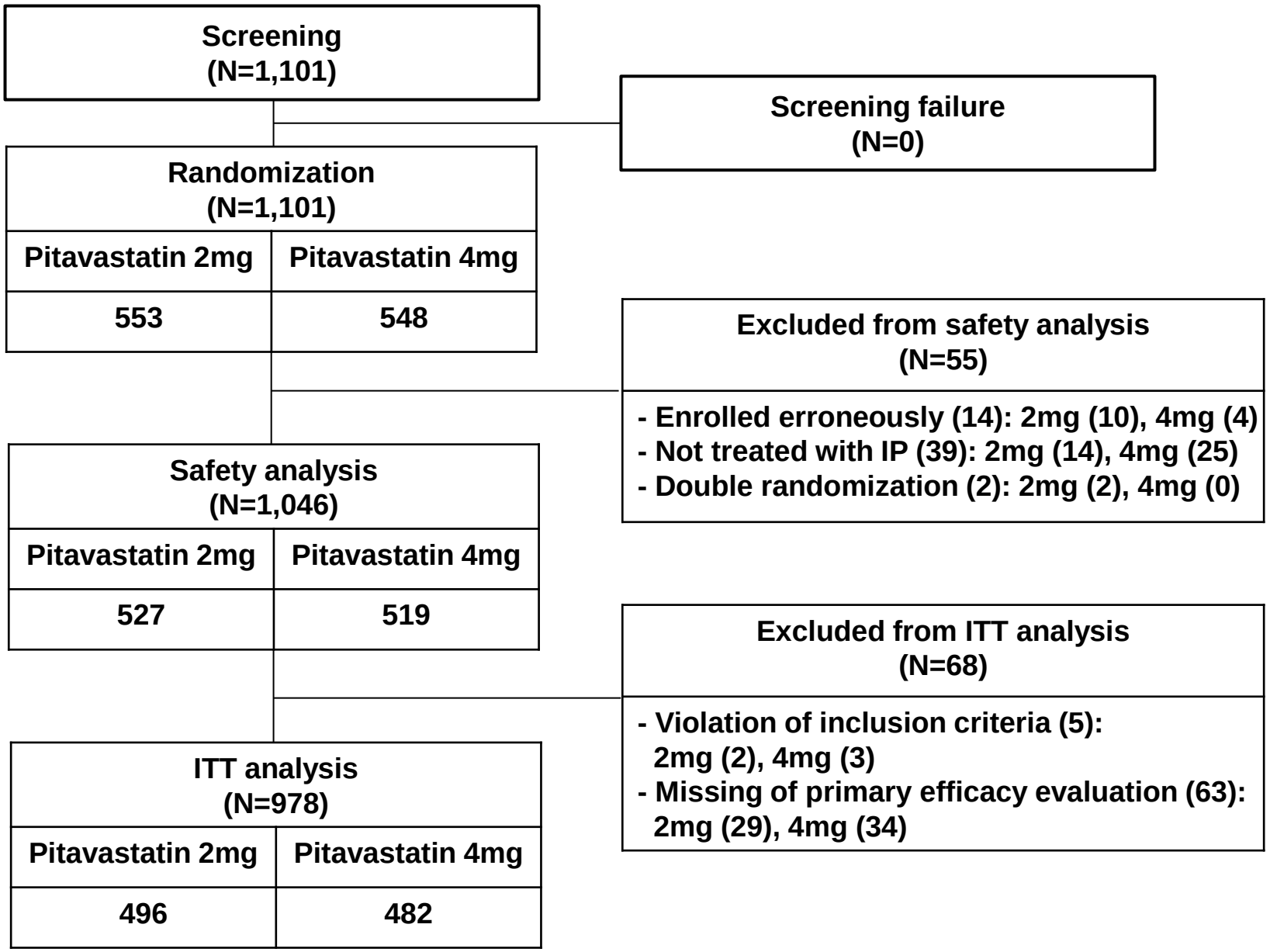
Conclusions: Reduction in hs-CRP levels in AMI patients plays an important role in the beneficial effects of statins on the regression and compositional change of coronary plaque.

LAMIS-II: Study objective

- So far, there are very limited data regarding comparison of the efficacy and safety of different doses of pitavastatins in AMI patients.

- Therefore, the aim of LAMIS-II was to evaluate efficacy and safety and influence on glucose tolerance of different doses of pitavastatins in AMI patients.

DESIGN


Screening
(N=1,101)
Screening failure
(N=0)
Randomization
(N=1,101)
Pitavastatin 2mg
Pitavastatin 4mg
553
548
Excluded from safety analysis
(N=55)
- Enrolled erroneously (14): 2mg (10), 4mg (4)
- Not treated with IP (39): 2mg (14), 4mg (25)
- Double randomization (2): 2mg (2), 4mg (0)
Safety analysis
(N=1,046)
Pitavastatin 2mg
Pitavastatin 4mg
527
519
Excluded from ITT analysis
(N=68)
- Violation of inclusion criteria (5):
2mg (2), 4mg (3)
- Missing of primary efficacy evaluation (63):
2mg (29), 4mg (34)
ITT analysis
(N=978)
Pitavastatin 2mg
Pitavastatin 4mg
496
482

DESIGN- Endpoint

1. Primary endpoint

Target lesion revascularization (TLR)-MACE: composite of cardiac death, nonfatal MI, TLR, and hospitalization for unstable angina, heart failure or arrhythmic events at 12-month follow-up

2. Secondary endpoint

a) Target vessel revascularization (TVR)-MACE: composite of all-cause death, nonfatal MI, TVR, and hospitalization for unstable angina, heart failure or arrhythmic events at 12-month follow-up

b) Changes of lipid profiles from baseline to 12-month follow-up

c) Changes of FPG and HbA1c from baseline to 12-month follow-up

BASELINE CHARACTERISTICS

Variable	Total (n = 978)	Pitavastatin 2 mg (n = 496)	Pitavastatin 4 mg (n = 482)	*p* value
Age, yr	61.06 ± 11.87	61.41 ± 11.97	60.70 ± 11.78	0.345
Sex				0.852
Male	731 (74.7)	372 (75.0)	359 (74.5)	
Female	247 (25.3)	124 (25.0)	123 (25.5)	
Diagnosis				0.781
STEMI	578 (59.1)	291 (58.7)	287 (59.5)	
NSTEMI	400 (40.9)	205 (41.3)	195 (40.5)	
Hypertension	459 (46.9)	237 (47.8)	222 (46.1)	0.404
Diabetes mellitus	254 (26.0)	133 (26.8)	121 (25.1)	0.542
Hypercholesterolemia	419 (42.8)	205 (41.3)	214 (44.4)	0.023
Current smoker	465 (47.6)	255 (51.4)	210 (43.6)	0.002
History of myocardial infarction	38 (3.9)	18 (3.6)	20 (4.2)	0.929
Thrombolysis	2 (5.3)	2 (11.1)	0	
PCI	30 (79.0)	15 (83.3)	15 (75.0)	
CABG	2 (5.3)	1 (5.6)	1 (5.0)	
Medical therapy	1 (2.6)	0	1 (5.0)	
Unknown	5 (13.2)	2 (11.1)	3 (15.0)	
History of angina	584 (59.7)	296 (59.7)	288 (59.8)	0.792
Family history of CHD	74 (7.6)	41 (8.3)	33 (6.9)	0.325
Body mass index, kg/m^2	24.25 ± 3.21	24.26 ± 3.18	24.25 ± 3.25	0.934
< 25	597 (61.0)	290 (58.5)	307 (63.7)	0.102
≥ 25	380 (38.9)	205 (41.3)	175 (36.3)	
LVEF, %	54.58 ± 10.37	54.58 ± 10.59	54.59 ± 10.16	0.982
CK, ng/mL	572.58 ± 1,087.64	567.02 ± 1,048.63	577.60 ± 1,144.17	0.879
CK-MB, ng/mL	56.44 ± 99.58	52.42 ± 87.43	59.48 ± 121.38	0.305

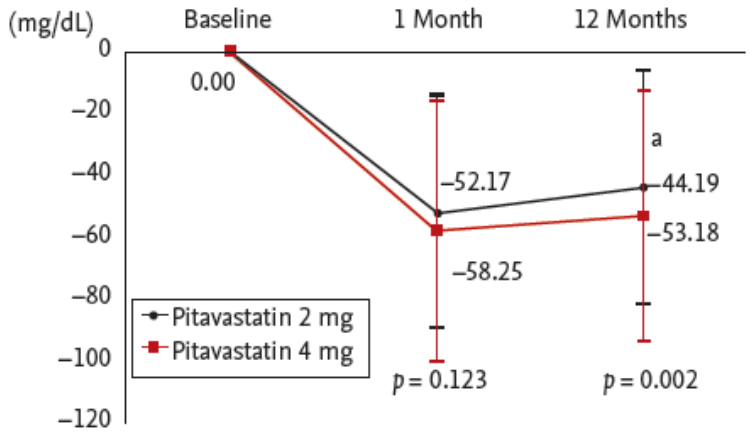
BASELINE CHARACTERISTICS

Variable	Total (n = 978)	Pitavastatin 2 mg (n = 496)	Pitavastatin 4 mg (n = 482)	*p* value
Prior history of statin therapy	98 (10.0)	48 (9.7)	50 (10.4)	0.783
Pitavastatin	6 (6.1)	3 (6.3)	3 (6.0)	
Rosuvastatin	11 (11.2)	7 (14.6)	4 (8.0)	
Fluvastatin	1 (1.0)	1 (2.1)	0	
Atorvastatin	57 (58.2)	26 (54.2)	31 (62.0)	
Simvastatin	8 (8.2)	2 (4.2)	6 (12.0)	
Unknown	15 (15.3)	9 (18.8)	6 (12.0)	
Door to PCI time, hr				0.559
Within 12	680 (69.5)	343 (69.2)	337 (69.9)	
12–24	161 (16.5)	79 (15.9)	82 (17.0)	
24–48	81 (8.3)	47 (9.5)	34 (7.1)	
Over 48	56 (5.7)	27 (5.4)	29 (6.0)	
Discharge medications				
Aspirin	944 (95.5)	480 (96.8)	464 (96.3)	0.664
Clopidogrel	915 (92.5)	459 (92.5)	446 (92.5)	0.996
Cilostazol	201 (20.6)	100 (20.2)	101 (21.0)	0.759
Prasugrel	31 (3.2)	16 (3.2)	15 (3.1)	0.919
β-Blocker	756 (77.3)	383 (77.2)	373 (77.4)	0.950
Renin-angiotensin system blockers	731 (74.7)	373 (75.2)	358 (74.3)	0.739

Values are presented as mean ± SD or number (%).
STEMI, ST segment myocardial infarction; NSTEMI, non-ST segment myocardial infarction; PCI, percutaneous coronary intervention; CABG, coronary artery bypass graft; CHD, coronary heart disease; LVEF, left ventricular ejection fraction; CK, creatine kinase; MB, myocardial band.

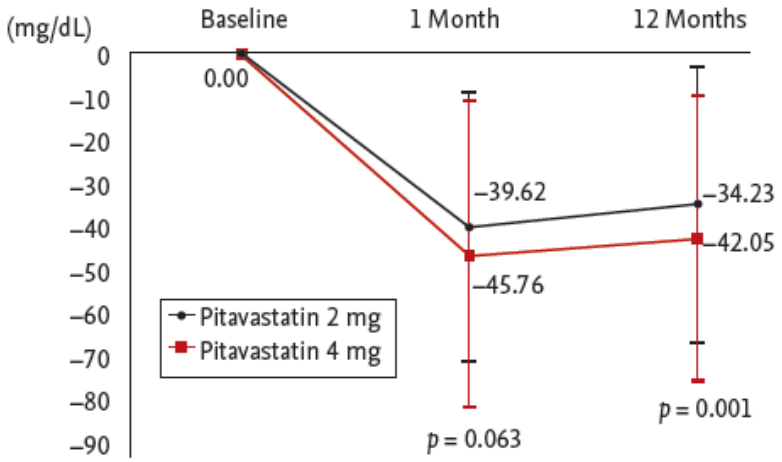
RESULTS (Lipid profile)

Change in TC



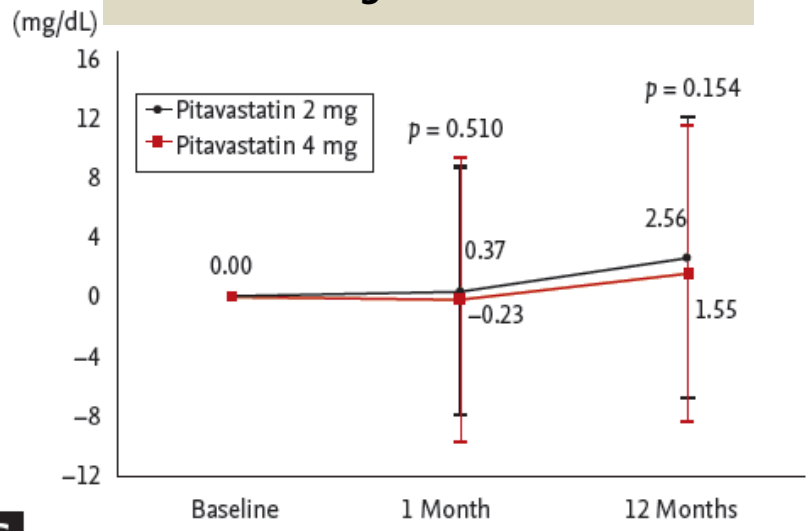
A

Change in LDL-C



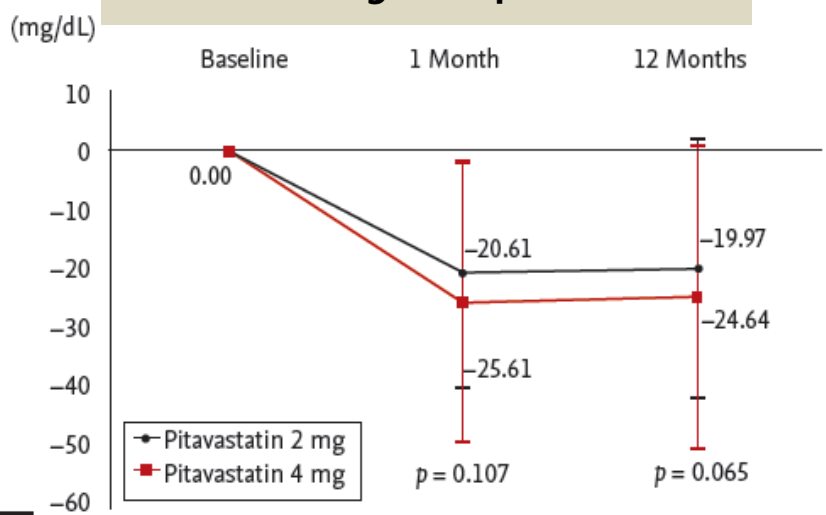
B

Change in HDL-C



C

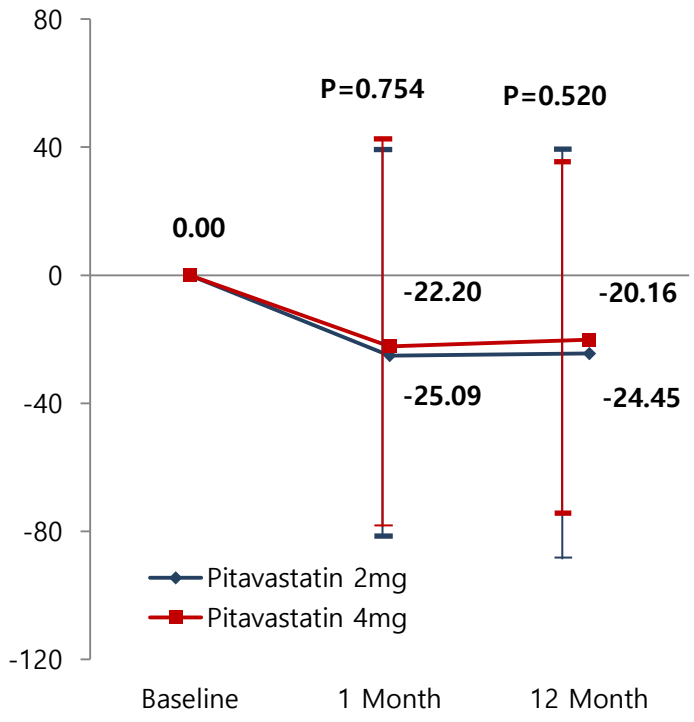
Change in ApoB



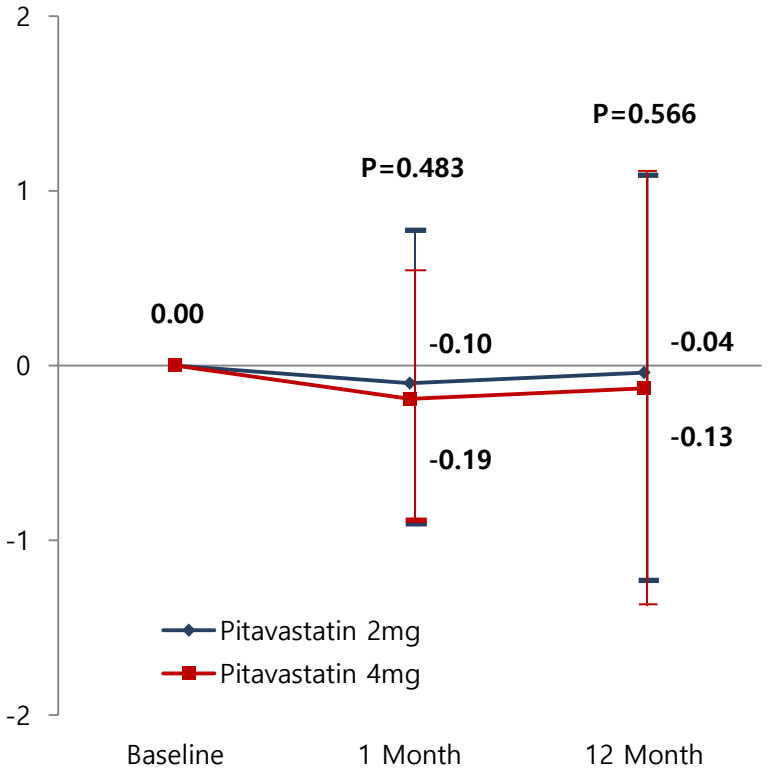
D

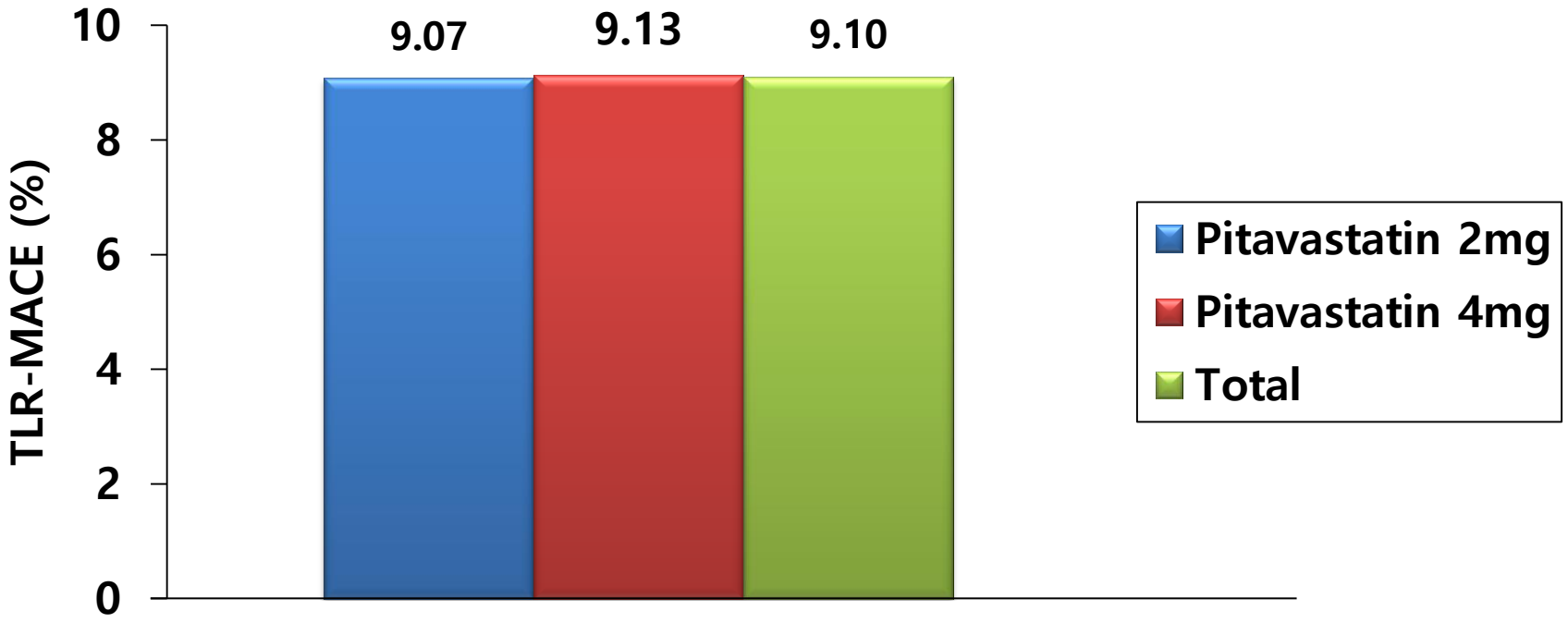
RESULTS (Glucose tolerance)

Fasting Plasma Glucose



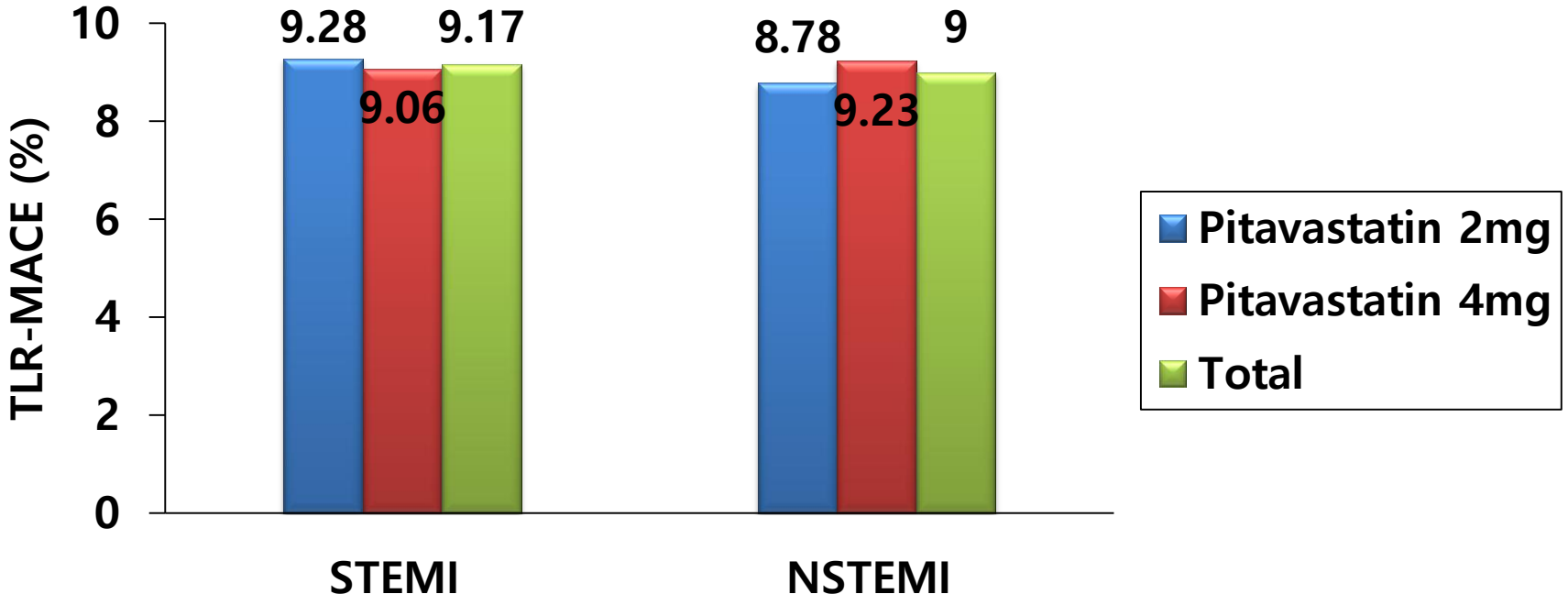
HbA1c





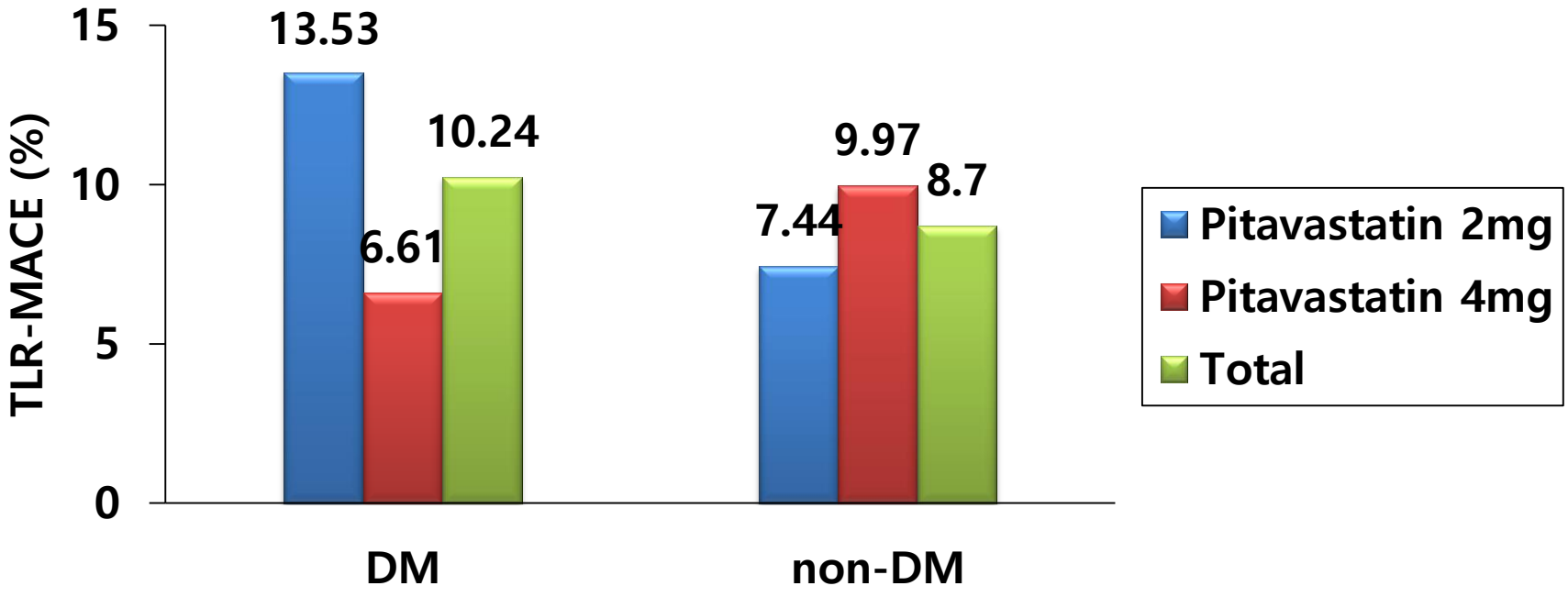
TLR-MACE	Pitavastatin 2mg		Pitavastatin 4mg		Total		odds ratio*	*p* value
	Total N	N (%)	Total N	N (%)	Total N	N (%)		
	496	45 (9.07)	482	44 (9.13)	978	89 (9.10)	0.993	0.976

* Odds ratio for pitavastatin 2mg vs. pitavastatin 4mg



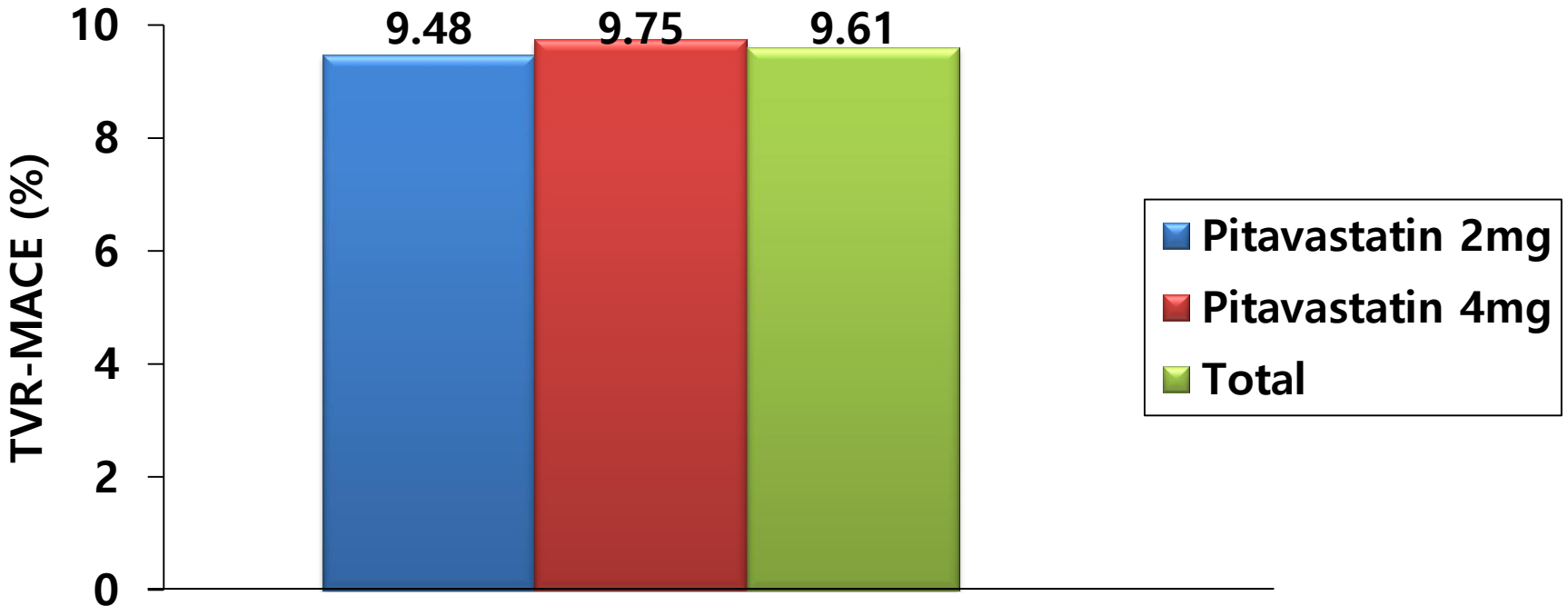
	Pitavastatin 2mg		Pitavastatin 4mg		Total		odds ratio*	*p* value
	Total N	N (%)	Total N	N (%)	Total N	N (%)		
STEMI	291	27 (9.28)	287	26 (9.06)	578	53 (9.17)	1.027	0.927
NSTEMI	205	18 (8.78)	195	18 (9.23)	400	36 (9.00)	0.947	0.875

* Odds ratio for pitavastatin 2mg vs. pitavastatin 4mg



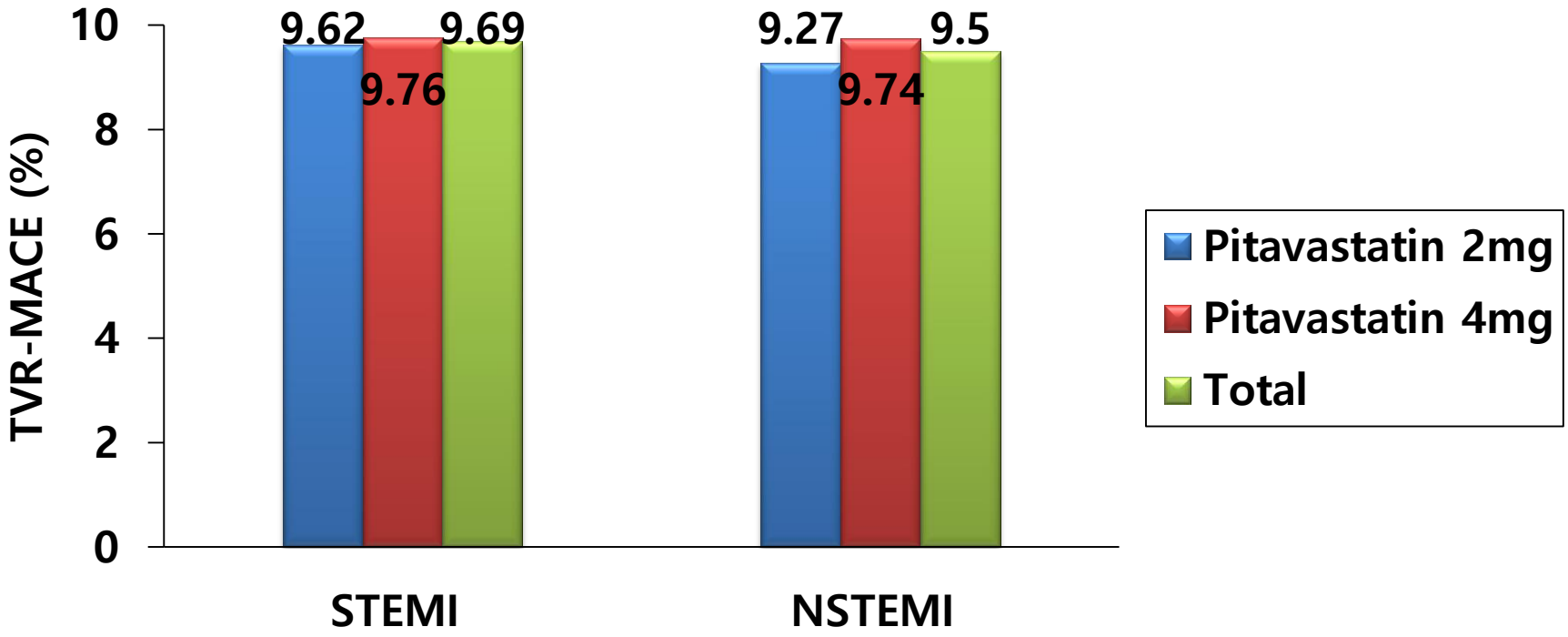
	Pitavastatin 2mg		Pitavastatin 4mg		Total		odds ratio*	*p* value
	Total N	N (%)	Total N	N (%)	Total N	N (%)		
DM	133	18 (13.53)	121	8 (6.61)	254	26 (10.24)	2.211	0.070
non-DM	363	27 (7.44)	361	36 (9.97)	724	63 (8.70)	0.725	0.227

* Odds ratio for pitavastatin 2mg vs. pitavastatin 4mg



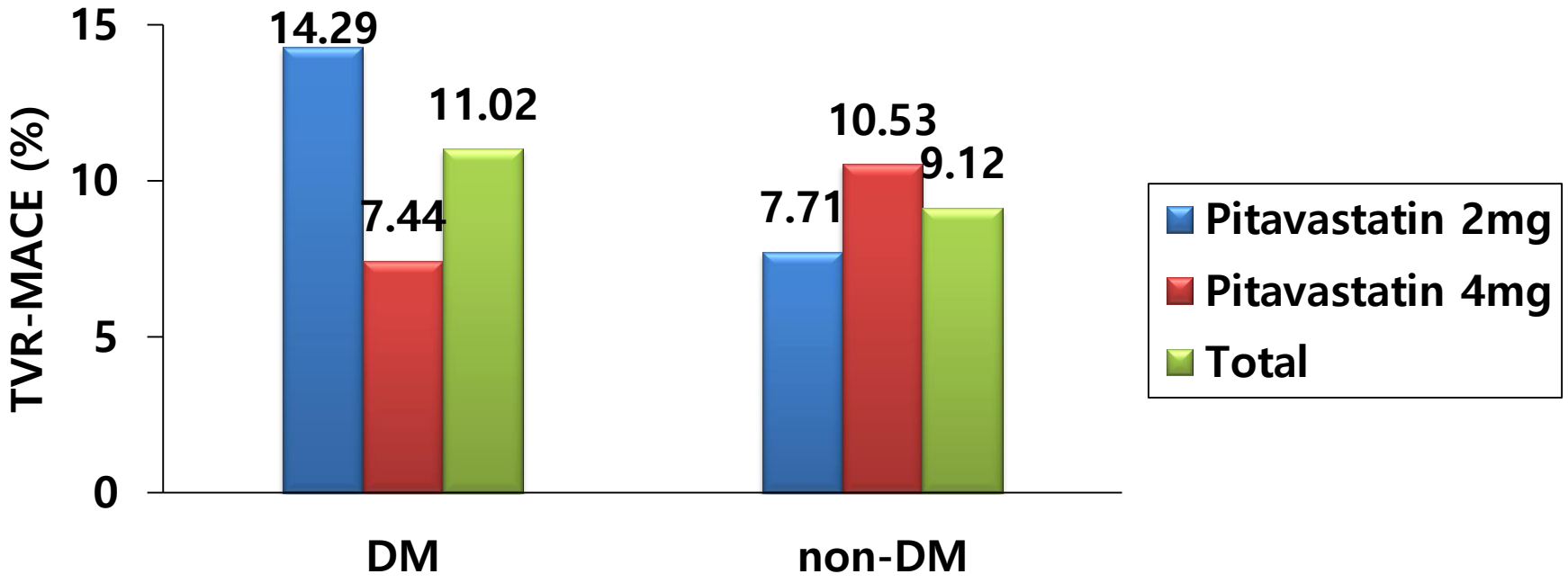
	Pitavastatin 2mg		Pitavastatin 4mg		Total		odds ratio*	*p* value
	Total N	N(%)	Total N	N(%)	Total N	N(%)		
TVR-MACE	496	47(9.48)	482	47(9.75)	978	94(9.61)	0.969	0.884

* Odds ratio for pitavastatin 2mg vs. pitavastatin 4mg



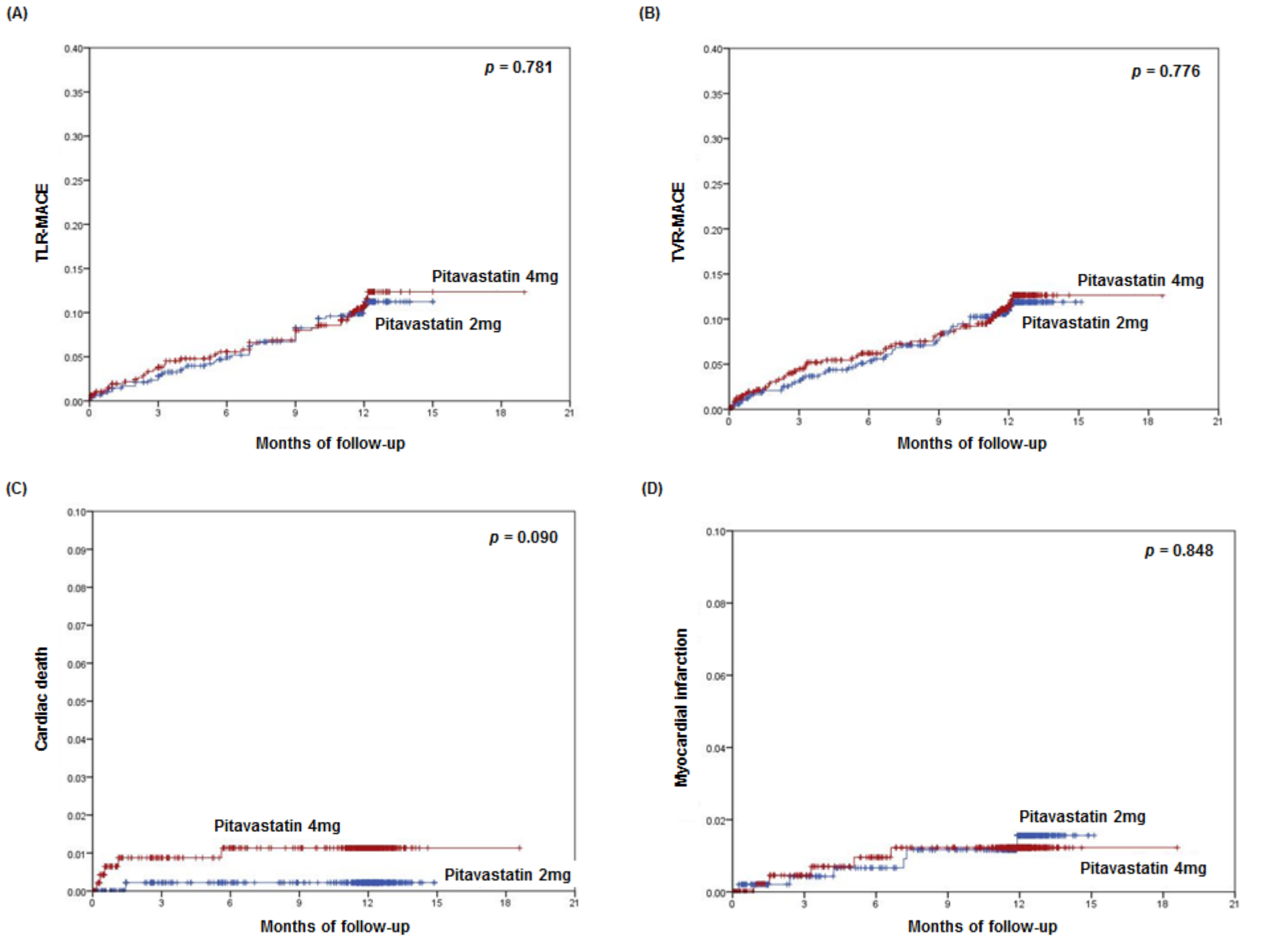
	Pitavastatin 2mg		Pitavastatin 4mg		Total		odds ratio*	*p* value
	Total N	N(%)	Total N	N(%)	Total N	N(%)		
STEMI	291	28(9.62)	287	28(9.76)	578	56(9.69)	0.985	0.957
NSTEMI	205	19(9.27)	195	19(9.74)	400	38(9.50)	0.946	0.871

* Odds ratio for pitavastatin 2mg vs. pitavastatin 4mg



	Pitavastatin 2mg		Pitavastatin 4mg		Total		odds ratio*	*p* value
	Total N	N(%)	Total N	N(%)	Total N	N(%)		
DM	133	19(14.29)	121	9(7.44)	254	28(11.02)	2.074	0.082
non-DM	363	28(7.71)	361	38(10.53)	724	66(9.12)	0.710	0.189

* Odds ratio for pitavastatin 2mg vs. pitavastatin 4mg


(A)
p = 0.781
TLR-MACE
Pitavastatin 4mg
Pitavastatin 2mg
Months of follow-up
(B)
p = 0.776
TVR-MACE
Pitavastatin 4mg
Pitavastatin 2mg
Months of follow-up
(C)
p = 0.090
Cardiac death
Pitavastatin 4mg
Pitavastatin 2mg
Months of follow-up
(D)
p = 0.848
Myocardial infarction
Pitavastatin 2mg
Pitavastatin 4mg
Months of follow-up

LAMIS II (Publication)

ORIGINAL ARTICLE

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KJIM

Efficacy and safety of pitavastatins in patients with acute myocardial infarction: Livalo in Acute Myocardial Infarction Study (LAMIS) II

Young Joon Hong[1], Myung Ho Jeong[1], Jang Ho Bae[2], Seok Kyu Oh[3], Seung Woon Rha[4], Seung Ho Hur[5], Sung Yun Lee[6], Sang Wook Kim[7], Kwang Soo Cha[8], In Ho Chae[9], Tae Hoon Ahn[10], and Kee Sik Kim[11]

Efficacy and safety of different doses of pitavastatins in patients with acute myocardial infarction- Livalo® in Acute Myocardial Infarction Study (LAMIS)-II

Department of Cardiology, 1Chonnam National University Hospital, Gwangju; 2Konyang University Hospital, Daejeon; 3Wonkwang University Hospital, Iksan; 4Korea University Guro Hospital, Seoul; 5Keimyung University Dongsan Medical Center, Daegu; 6Inje University Ilsan Paik Hospital, Goyang; 7Chung-Ang University Hospital, Seoul; 8Pusan National University Hospital, Busan; 9Seoul National University Bundang Hospital, Seongnam; 10Gachon University Gil Medical Center, Incheon; 11Daegu Catholic University Medical Center, Daegu, Korea

LAMIS III

To evaluate the efficacy and safety of combination of pitavastatin / valsartan (Livalo-V®) in AMI patients

LAMIS III Enrollment

No.	Site No	Site Name	PI	IRB Approval/ Contract date	Contract	Enrollment	ongoing	D/O	Comp	Enroll Rate(%)
1	1	전남대병원	홍영준	2017-05-23/ 2017-07-21	100	67	67	-	-	67%
2	3	전북대병원	이상록	2017-04-24/ 2017-07-04	100	46	40	6	-	46%
3	4	원광대병원	윤경호	2017-04-24/ 2017-07-13	30	23	16	3	4	76.6%
4	11	신촌세브란스	김중선	2017-08-20/ 2017-09-19	50	16	16	-	-	32%
5	20	고대구로병원	나승운	2017-11-19/ 2018-03-27	100	11(▲2)	11	-	-	11%
6	2	중앙대병원	김상욱	2017-05-30/ 2017-07-11	30	8	8	-	-	26.6%
7	8	고신대복음병원	허정호	2018-02-22/ 2018-04-24	50	4	4	-	-	8%
8	16	분당서울대병원	채인호	2017-07-10/ 2018-03-02	30	4	3	1	-	13.3%
9	14	조선대병원	박근호	2017-08-29/ 2017-11-24	30	4	4	-	-	13.3%
10	12	순천향천안병원	신원용	2017-05-31/ 2017-10-24	50	2	2	-	-	4%
11	19	건대충주병원	최웅길	2017-09-19/ 2017-11-14	50	2	2	-	-	4%
12	7	강동경희대병원	조진만	2017-11-10/ 2017-12-15	50	1	1	-	-	2%
13	5	영남대병원	김웅	2017-11-06/ 2018-02-01	100					
14	18	청주성모병원	양용모	2017-10-24/ 2018-05-30	50	-	-	-	-	
15	6	대구가톨릭병원	김기식	2018-06-20/ 2018-10-17	50	-	-	-	-	-
16	21	일산병원	오성진	2018-09-12/ 2018-10-30	50	-	-	-	-	-
17	22	을지대학교병원	김원호	심의중/검토중	100		-	-	-	-
					1020	188(▲2)	174	10	4	188/905 (20.7%)

CONCLUSION

(1) The incidences of cardiac mortality and all-cause mortality were very low after pitavastatin treatment.

(2) Pitavastatin treatment reduced LDL-C and FPG effectively from baseline to 12-month follow-up.

(3) The incidences of TLR-MACE and TVR-MACE were not significantly different between 2 and 4 mg of pitavastatin groups.

(4) Pitavastatin was not adversely affect glucose metabolism or diabetes development compared with placebo or other statins.

Thank You For Your Attention