Role of Statin: Optimal Treatment for PCI Patients

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Despite improvements in ischemic Sx by PCI, patients continue to have high rates of cardiovascular events.

Interventional cardiologists can be easily preoccupied with problems of restenosis or thrombosis after PCI.

Recently, statin which has reduced morbidity and mortality in cardiovascular disease is being spotlighted in PCI patients.

Pravastatin or Atorvastatin Evaluation and Infection Therapy-Thrombolysis in Myocardial Infarction 22 (PROVE IT-TIMI 22) trial. 2004

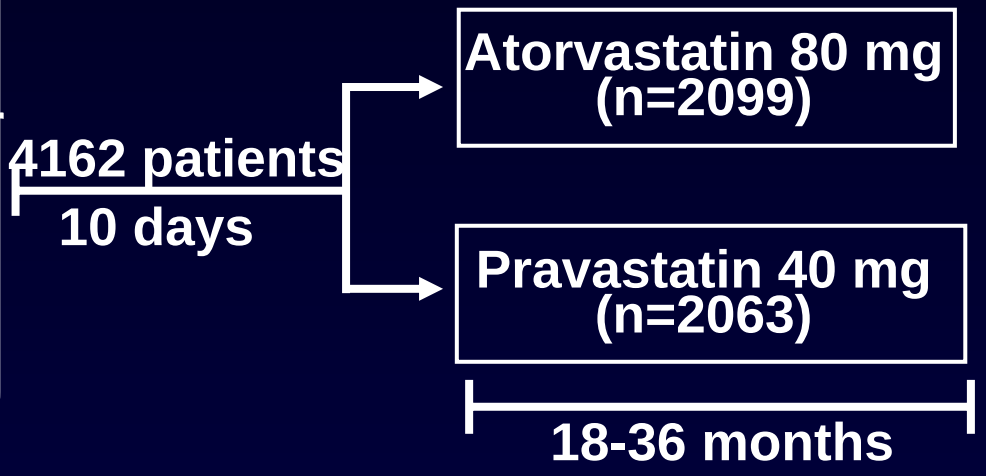
Determining whether there is incremental benefit of reducing LDL-C to <70 mg/dL compared to moderate LDL-C reduction in ACS

Cannon et al. NEJM 2004

Study design

Patient population

- Men and women aged ≥18 years
- Hospitalized with AMI or high-risk UA
- TC ≤240 mg/dL
- Stable condition, enrolled after PCI, if planned



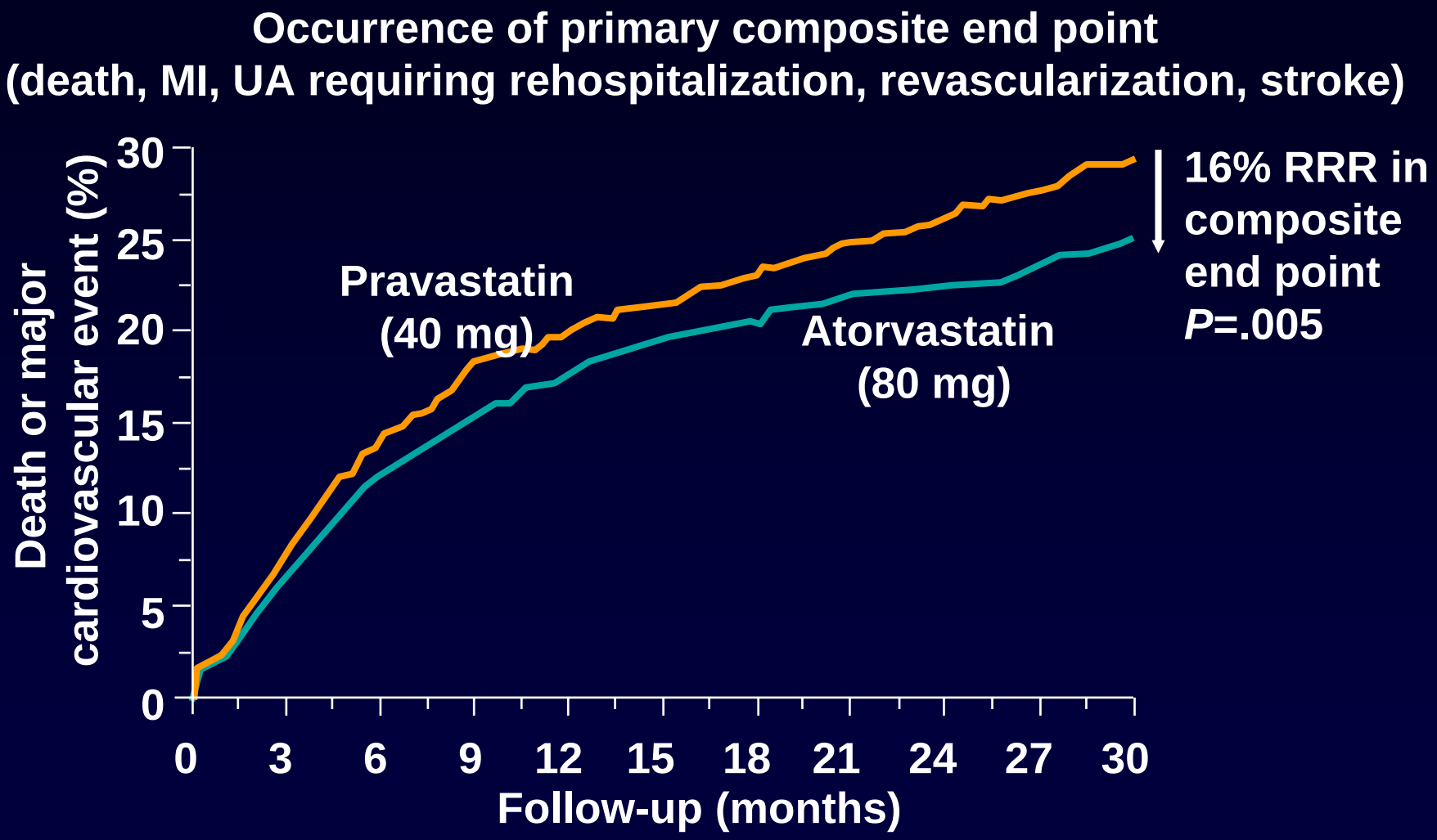
Primary efficacy end point

- Composite of death from any cause, MI, documented UA requiring hospitalization, revascularization, and stroke

Baseline LDL-C: 106 mg/dL

PCI for index ACS: 69%

Study outcome



Phase Z of Aggrastat to Zocor (A to Z) Trial. 2004

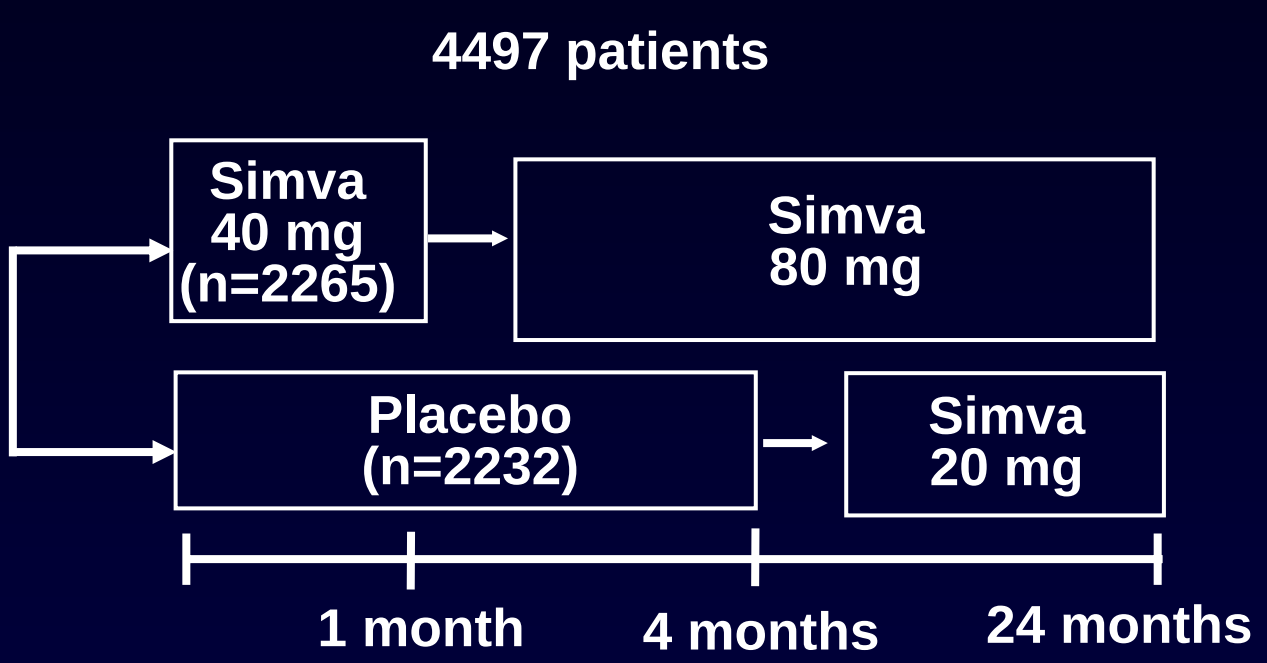
Comparison of aggressive with more moderate and delayed dosing of statin in ACS

de Lemos et al. JAMA 2004

Study design

Patient population

- Men and women aged 21-80 years
- ACS
- TC ≤250 mg/dL
- Met stability criteria
- At least 1 high-risk factor for CVD in addition to cardiac biomarker elevation



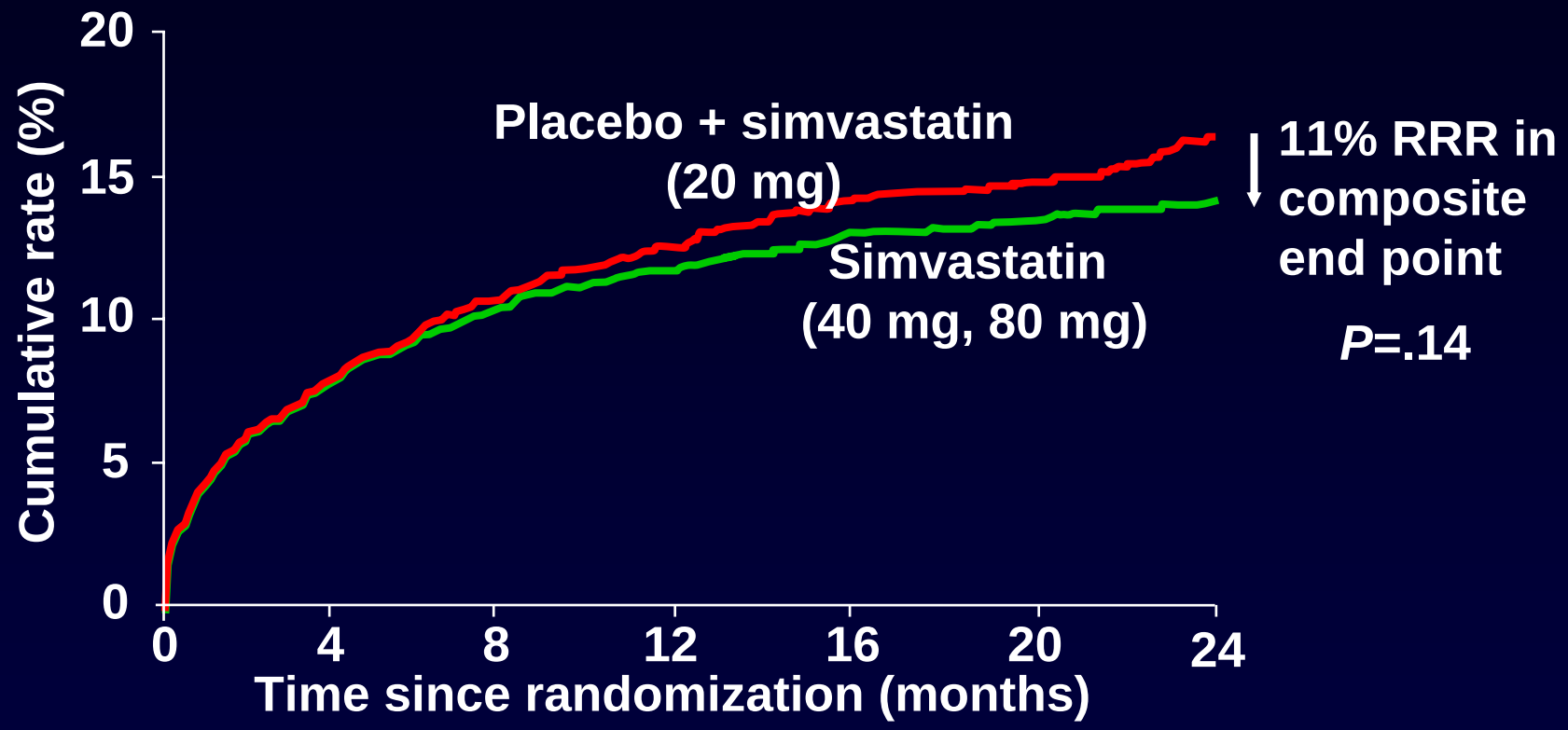
Primary efficacy end point

- Composite of CV death, nonfatal MI, readmission for ACS, and stroke

Baseline LDL-C: 112 mg/dL

PCI for index ACS: 44%

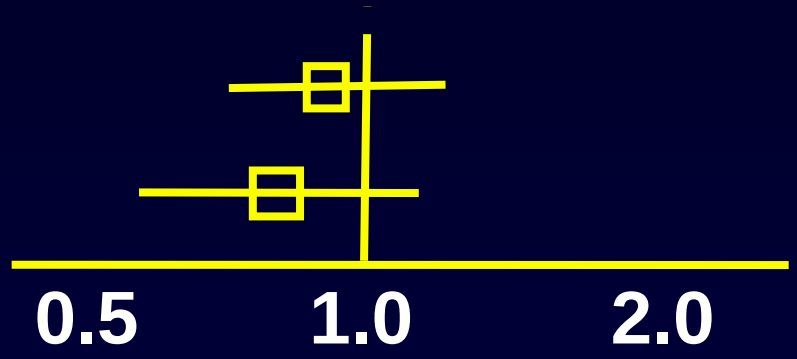
Study outcome



In post hoc analysis, 25% RR in the primary end point in the simva 40/80 mg arm was reported.

Hazard ratio in PCI subgroup

PCI for event	High	Low	RR
No	17.4	19.5	9
Yes	10.7	12.9	17



Statins for PCI Patients

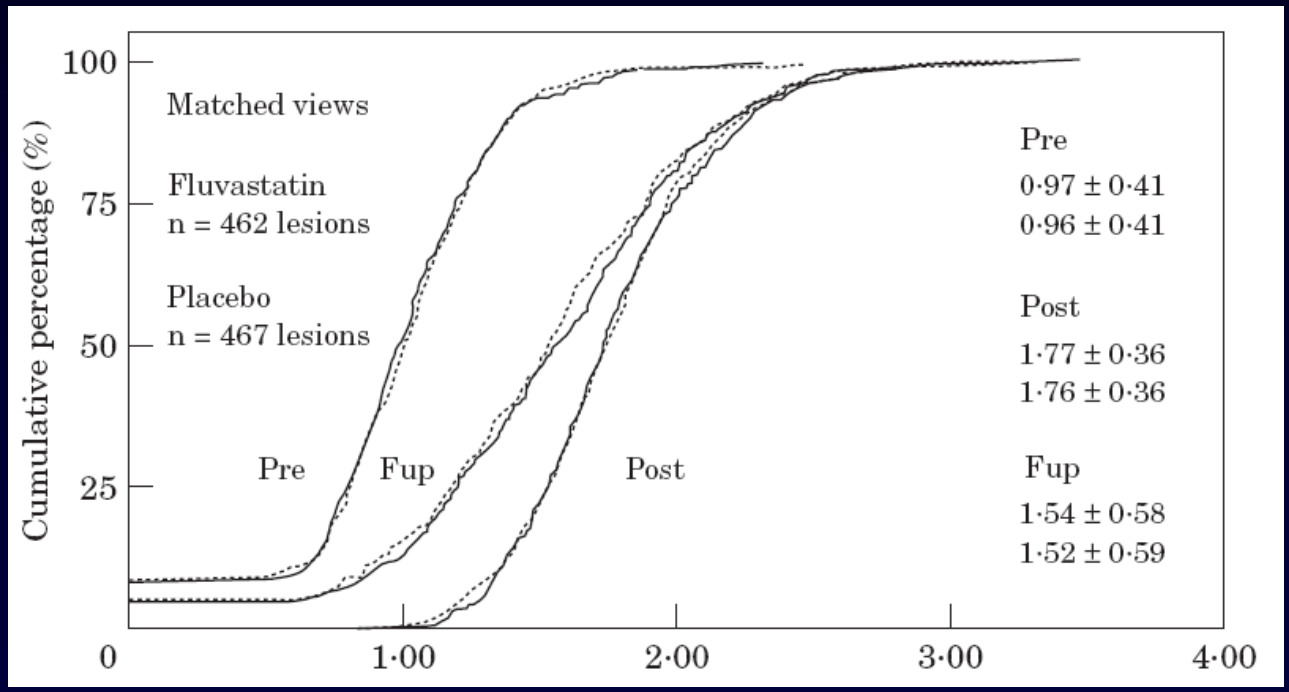
Fluvastatin Angioplasty Restenosis (FLARE) Trial. 1999

- To examine effect of high dose statin on restenosis following PTCA without stenting

Serruys et al. Eur Heart J 1999

- 1054 patients randomized 2-4 weeks before planned PTCA
- Silent ischemia and stable angina
- Fluvastatin 80 mg/d vs placebo for 26 weeks
- Primary end point: angiographic restenosis

A	Fluva	Placebo	p
Restenosis (%)	28	31	0.42



63% reduction in death or non-fatal MI was observed. To confirm these findings, LIPS trial was conducted.

Lescol Intervention and Prevention Study (LIPS). 2002

- To examine high-dose statin in stable, unstable or silent ischemia undergoing PCI

Serruys et al. JAMA 2002

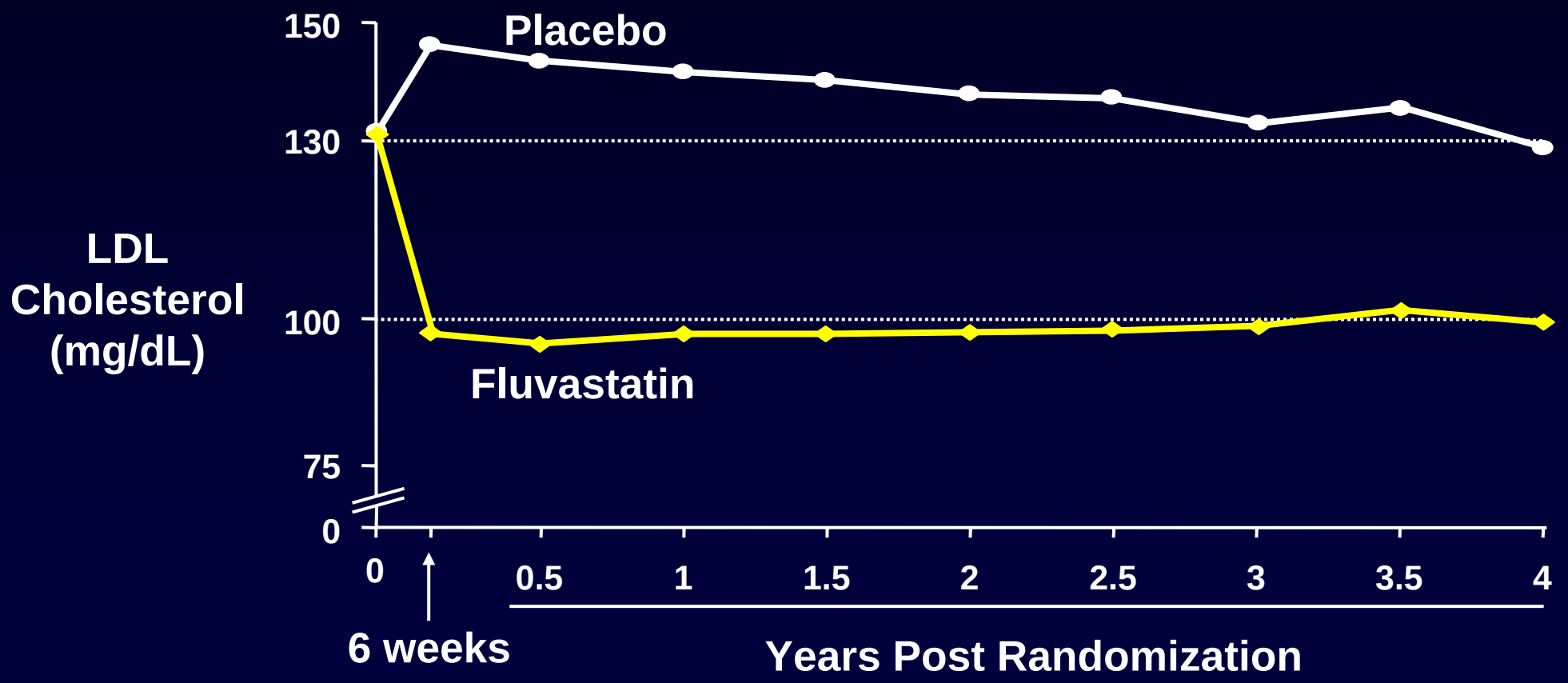
Study design

- Randomized, placebo-controlled, double-blind, multicenter trial in 57 centers in 10 countries
- 1677 subjects receive fluvastatin 80 mg/d or placebo after successful first PCI
- Followed for at least 3 years
- Primary end point: MACE-free survival

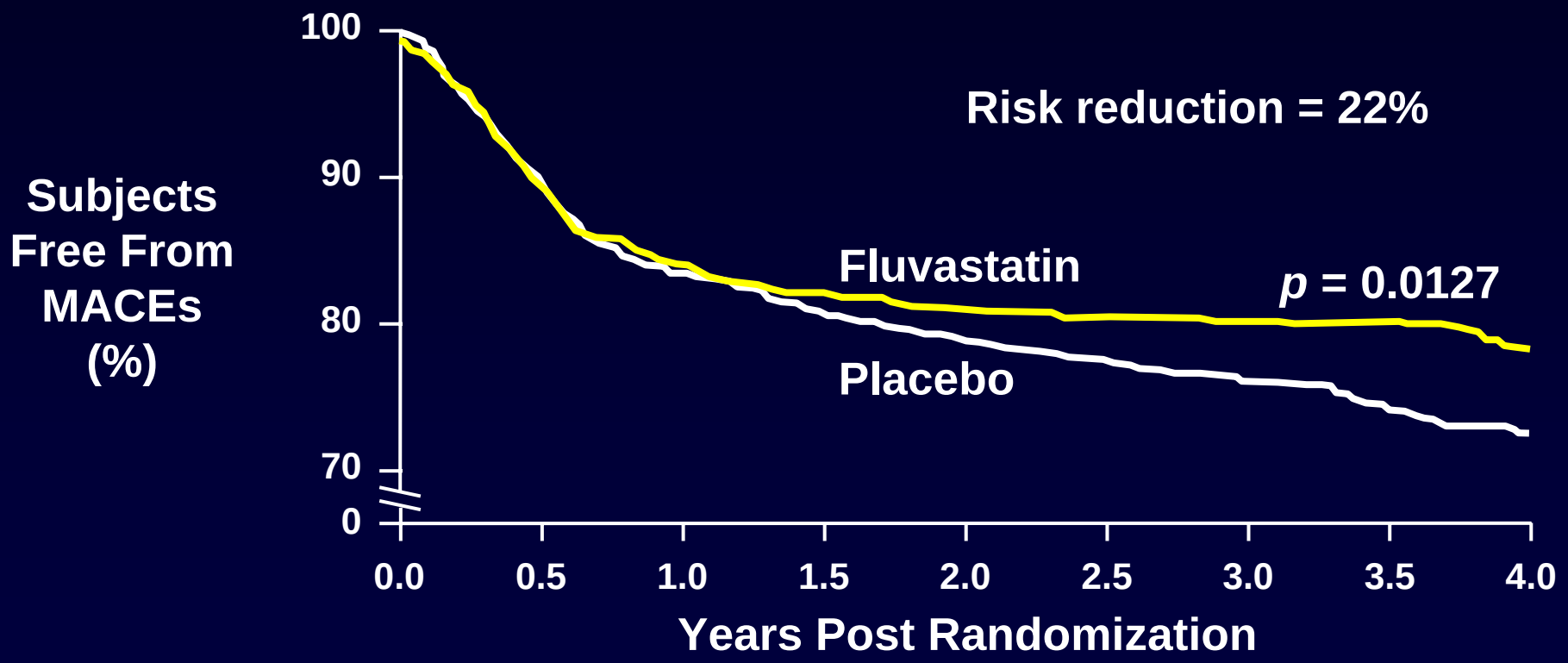
Mean baseline lipid values

	Fluvastatin (mg/dL)	Fluvastatin (mmol/L)	Placebo (mg/dL)	Placebo (mmol/L)
Total cholesterol	200	5.2	199	5.2
LDL cholesterol	131	3.4	132	3.4
HDL cholesterol	38	1.0	37	1.0
Triglycerides	160	1.8	160	1.7

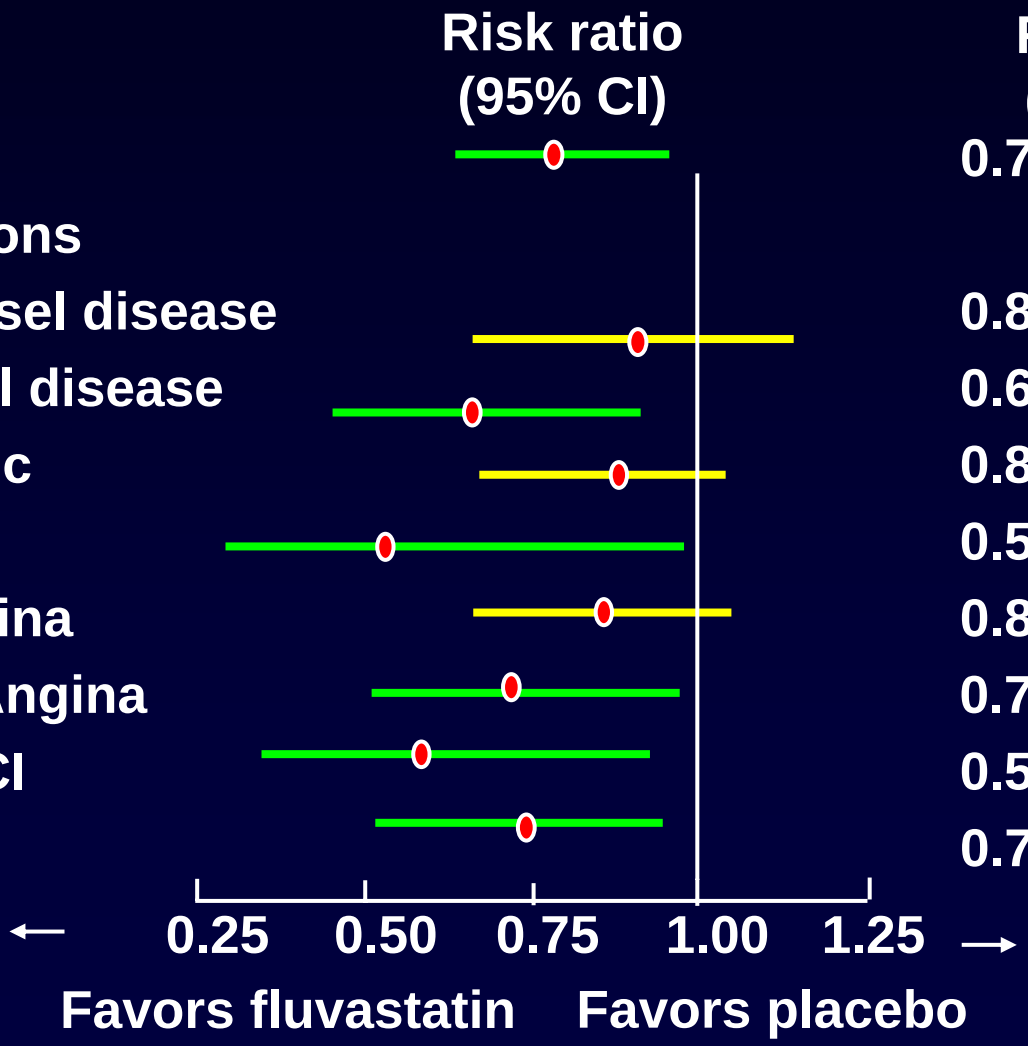
Change in LDL-C levels



Primary end point: MACE-free survival time

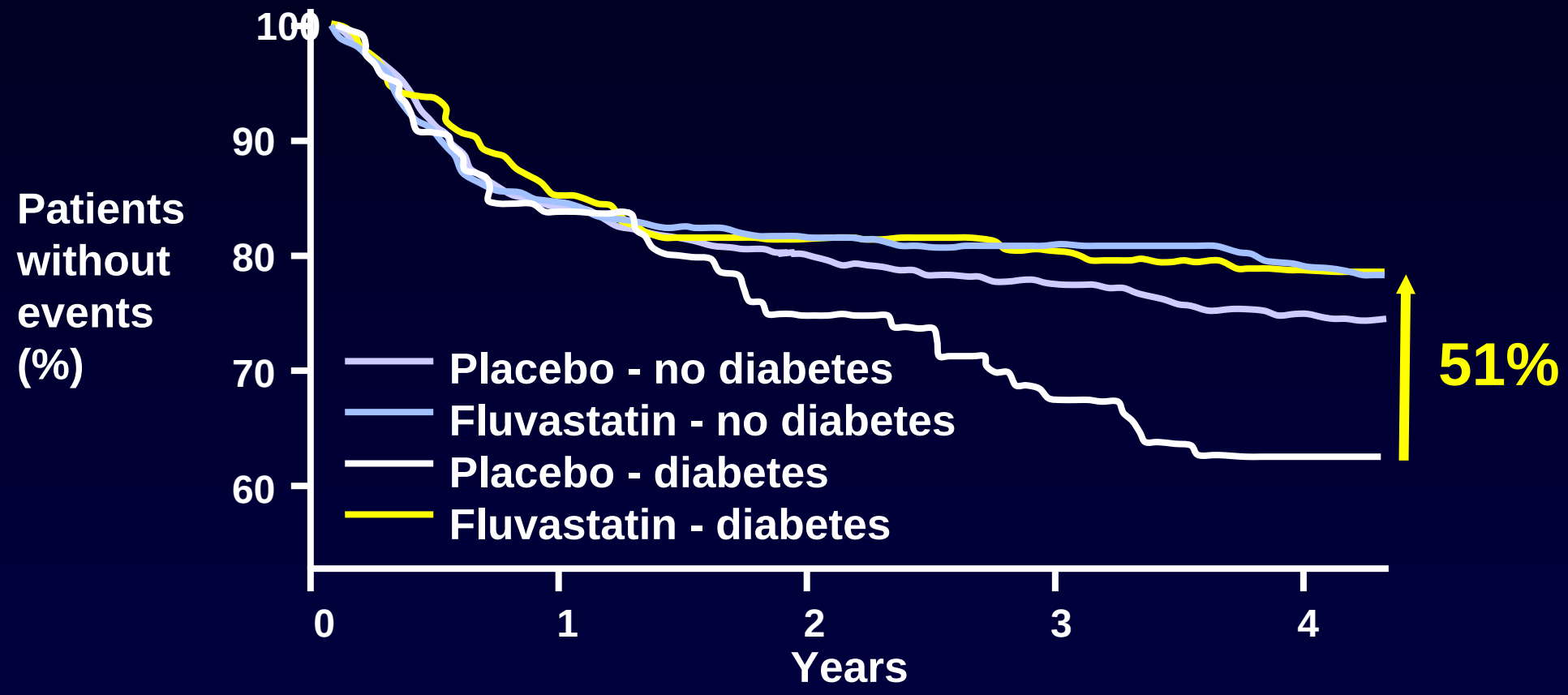


Risk ratios for MACEs in subpopulations (ITT)



	Risk ratio (95% CI)	*p* value
All subjects	0.78 (0.64-0.95)	0.013
Subpopulations		
Single-vessel disease	0.86 (0.66-1.13)	0.278
Multivessel disease	0.66 (0.48-0.91)	0.011
Nondiabetic	0.83 (0.67-1.03)	0.096
Diabetic	0.53 (0.29-0.97)	0.041
Stable angina	0.80 (0.60-1.07)	0.13
Unstable Angina	0.72 (0.54-0.96)	0.03
Balloon PCI	0.57 (0.38-0.84)	0.004
Stent PCI	0.71 (0.54-0.94)	0.02

Effect of fluvastatin on cardiac risk associated with diabetes



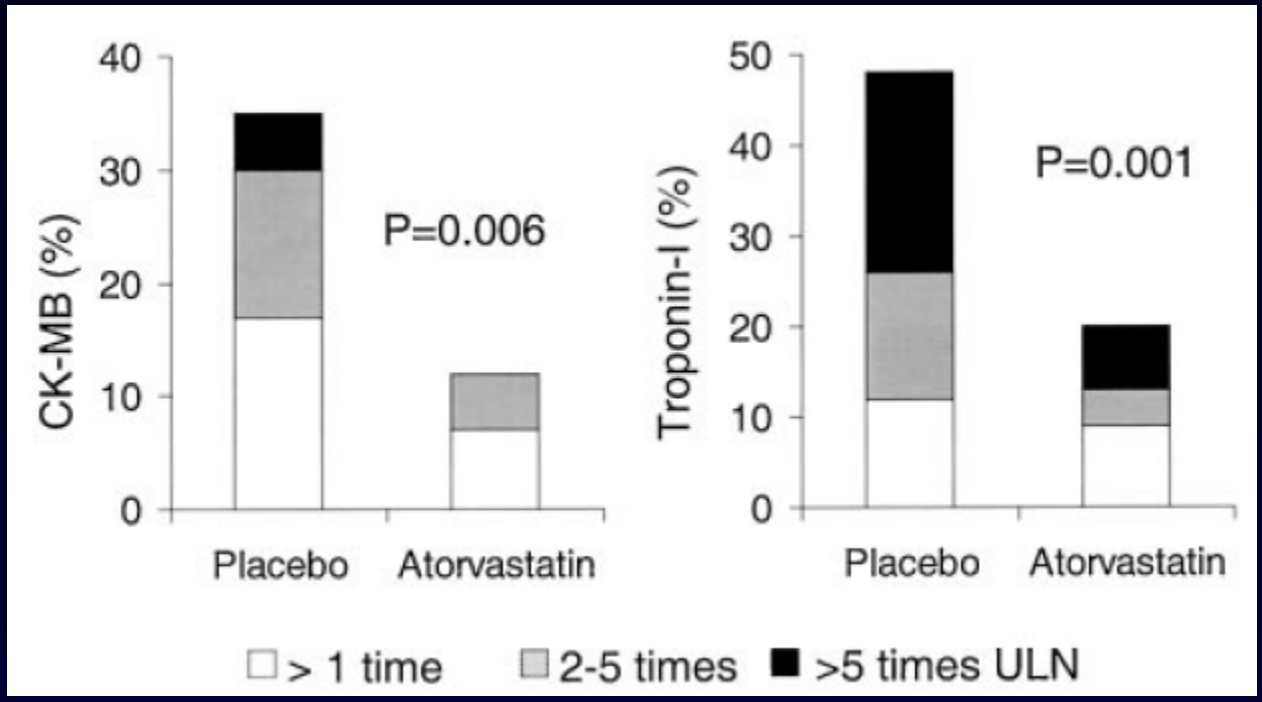
Fluvastatin lowers MACE in DM patients by 51%, to the same level as non-DM patients

Atorvastatin for Reduction of Myocardial Damage during Angioplasty (ARMYDA) Study

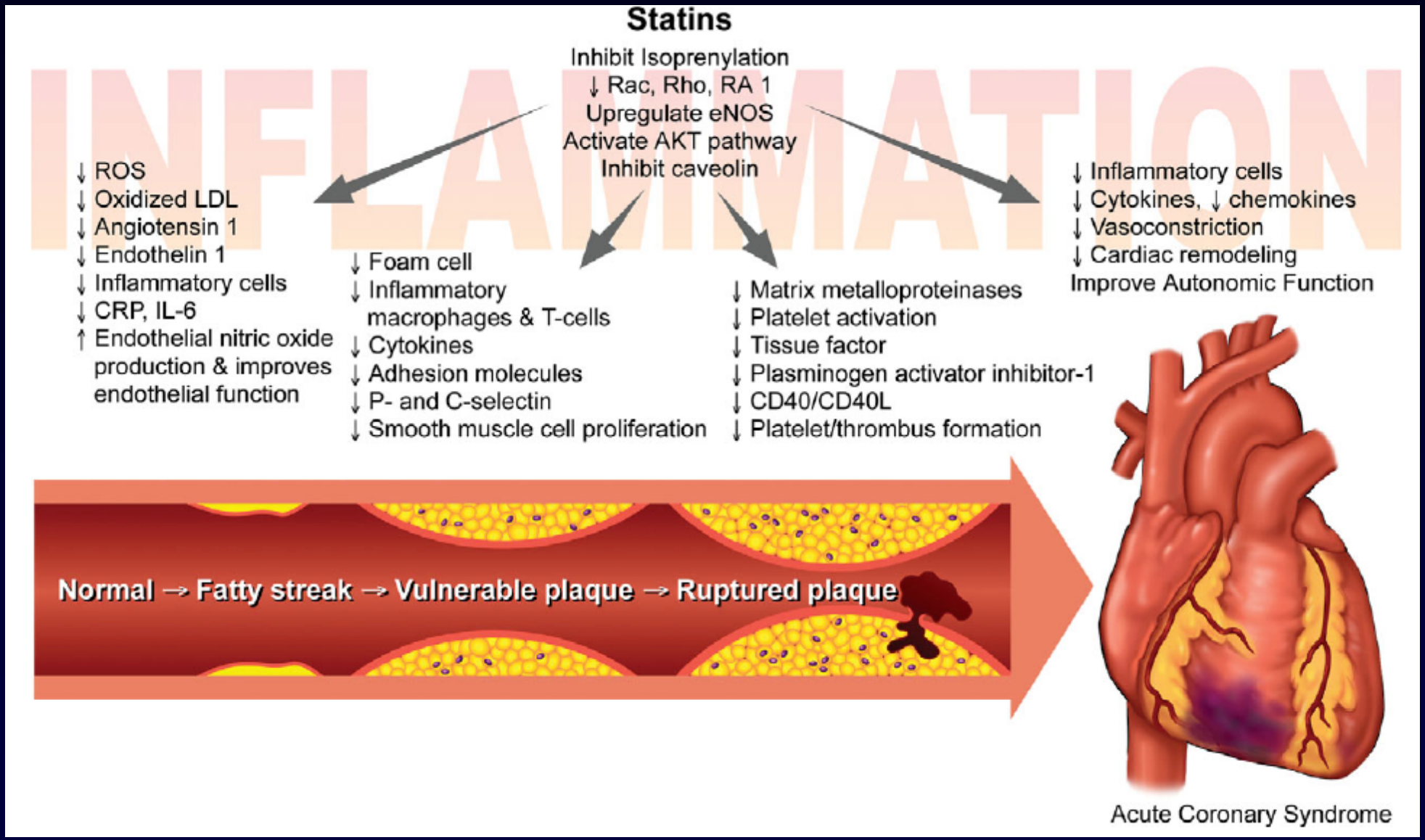
- To confirm that statins may lower risk of procedural myocardial injury

Pasceri et al. Circulation 2004

- 153 patients with stable angina who underwent elective PCI
- Atorvastatin 40mg vs Placebo starting 7 days before PCI
- Primary end-point: MI (CK-MB > 2 UNL at 8 and 24 hrs)



- ***MI by CK-MB was detected in 5% in statin group and 18% of placebo group.***
- ***Pretreatment of atorvastatin 40 mg/d for 7 days reduces procedural MI***



Patel et al. Eur Heart J 2007