

SATURN: Effect of two intensive statin regimens on progression of coronary disease

Kindly supplied by Prof. Stephen Nicholls as an educational resource for PCSK9 Forum

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PCSK9FORUM

Statins: impact on plaque

- Statins have consistently reduced cardiovascular event rates in large randomized controlled clinical trials.
- Imaging studies have shown that statins have a favorable effect on disease progression.
- The effects on plaque burden appear to correlate with both lowering of LDL-C and raising of HDL-C.
- However, no study has compared the effects of maximal dosages of the most efficacious statin regimens on progression of coronary atherosclerosis.

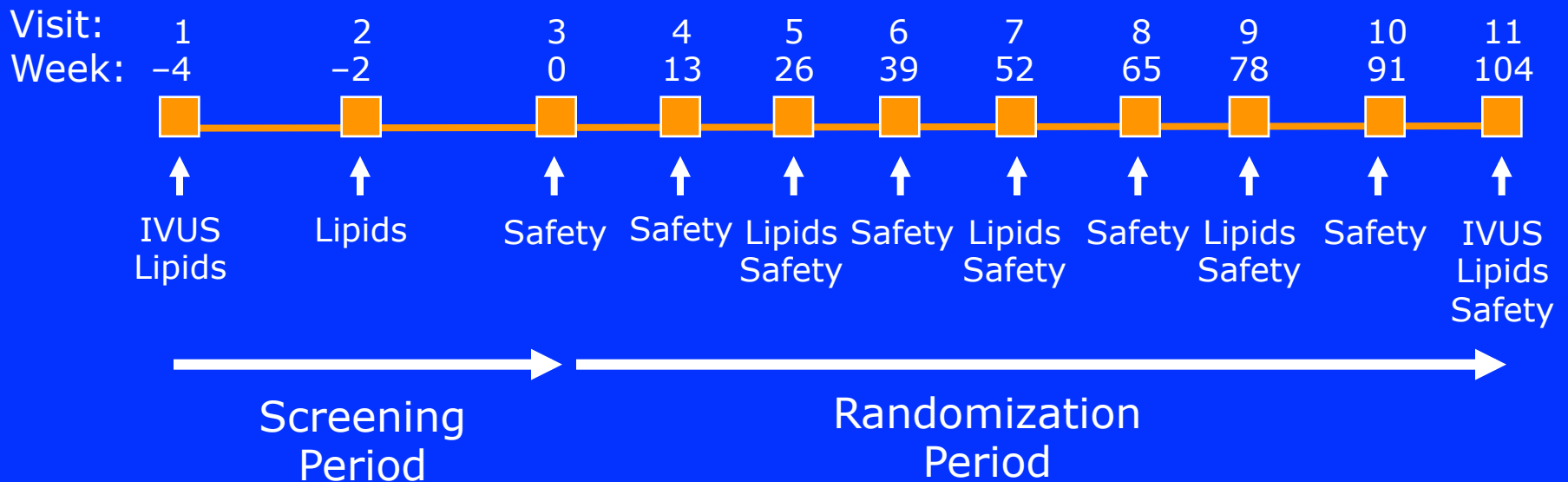
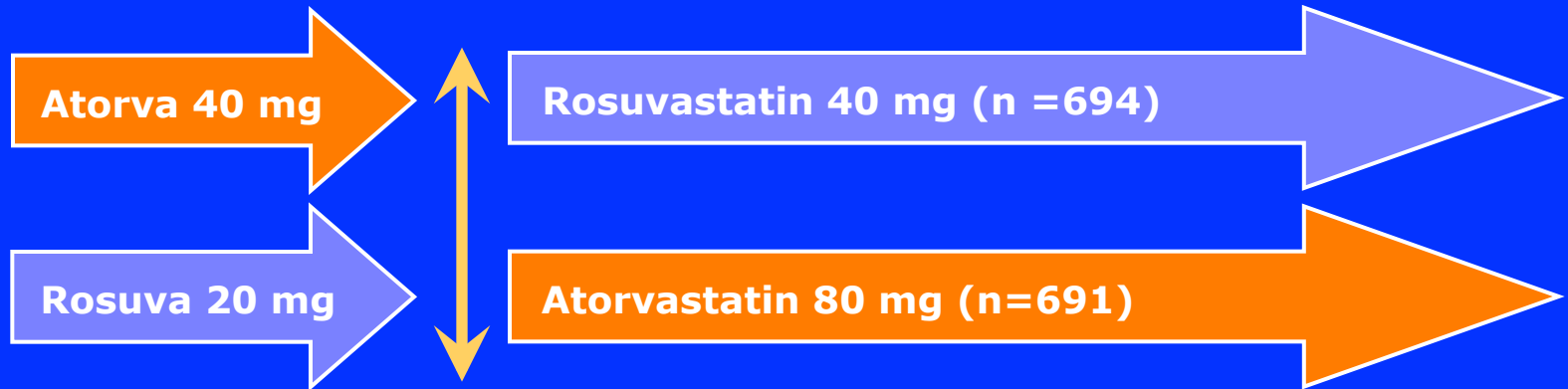
Aim of SATURN

To compare the effects of rosuvastatin 40 mg versus atorvastatin 80 mg on progression of coronary atherosclerosis assessed by intravascular ultrasound.

Study Design

1385 patients with symptomatic CAD (angiographic stenosis >20%)

LDL-C with (>80 mg/dL) or without (>100 mg/dL) statin use last 4 weeks



SATURN Trial: Flow of Patients

4255 patients screened and 1578 patients treated at centers in North America, Europe, South America and Australia

Treatment for 2 weeks with atorvastatin 40 mg or rosuvastatin 20 mg for 2 weeks to achieve LDL-C <116 mg/dL

Atorvastatin 80 mg (n=691)

24 months
treatment

Rosuvastatin 40 mg (n=694)

346 (25%) patients withdrew or did not have an evaluable final IVUS

Follow-up IVUS of originally imaged “target” vessel (n=1039)

Clinical Characteristics

Parameter	Atorvastatin (n=519)	Rosuvastatin (n=520)
Mean age in years	57.9	57.4
Males	74.4%	72.9%
Median Body Mass Index	29.2	28.9
History of Hypertension	70.7%	70.0%
History of Diabetes	16.8%	13.8%
Prior Statin Use	61.5%	58.3%
Concomitant Medications		
Anti-platelet Therapy	97.9%	97.5%
Beta-blockers	61.1%	60.6%
ACE Inhibitors	44.5%	43.5%
Angiotensin Receptor Antagonists	15.8%	16.7%

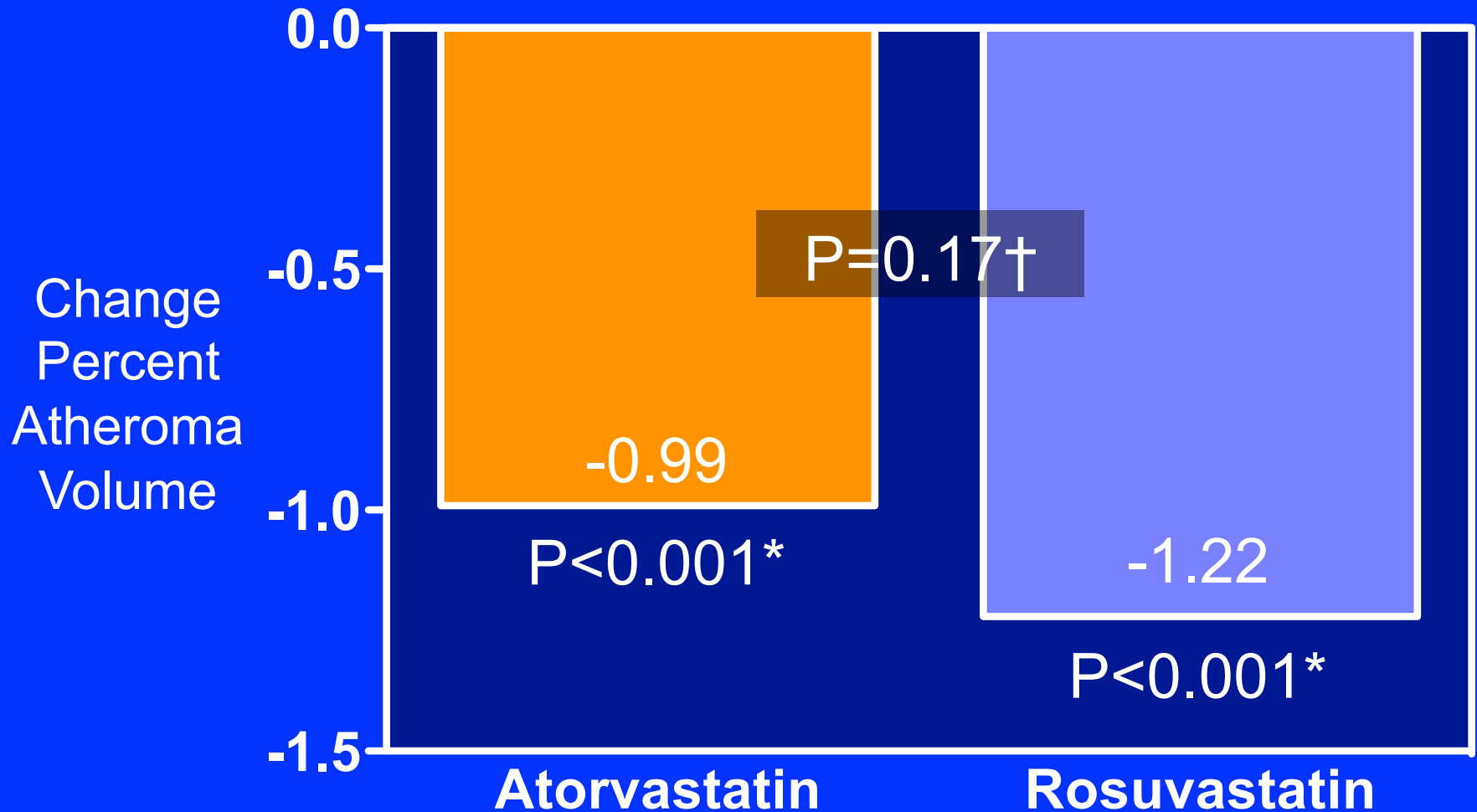
Time-Weighted Lipid Levels and hsCRP

Parameter	Atorvastatin (n=519)	Rosuvastatin (n=520)	P Value
LDL cholesterol (mg/dL)	70.2	62.6	<0.001
HDL cholesterol (mg/dL)	48.6	50.4	0.01
Triglycerides (mg/dL)*	110	120	0.02
LDL:HDL cholesterol	1.5	1.3	<0.01
hsCRP (mg/L)*	1.0	1.1	0.05

Presented as least-square means. *Median values

Primary IVUS Efficacy Parameter

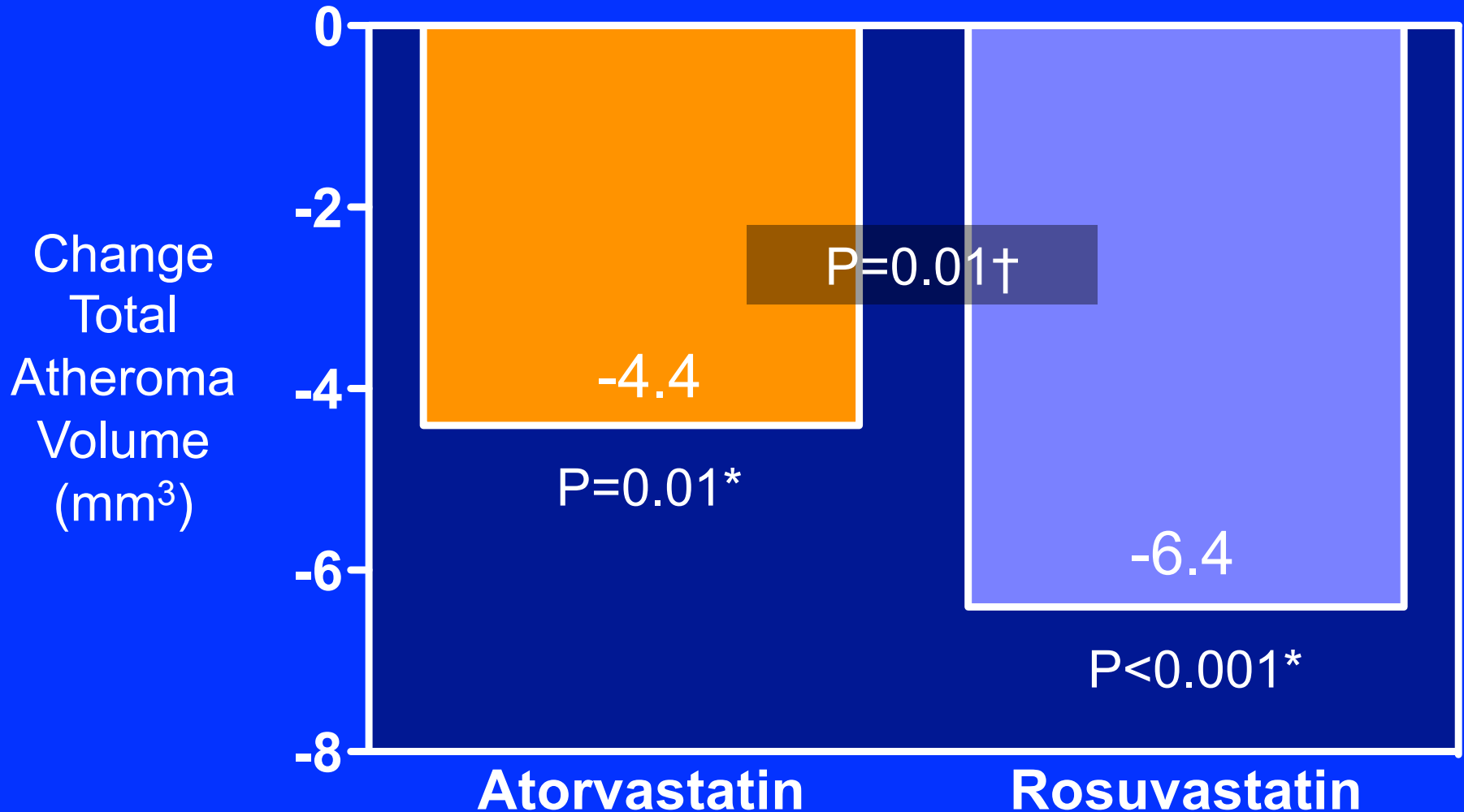
Median Change Percent Atheroma Volume



† comparison between groups. * comparison from baseline

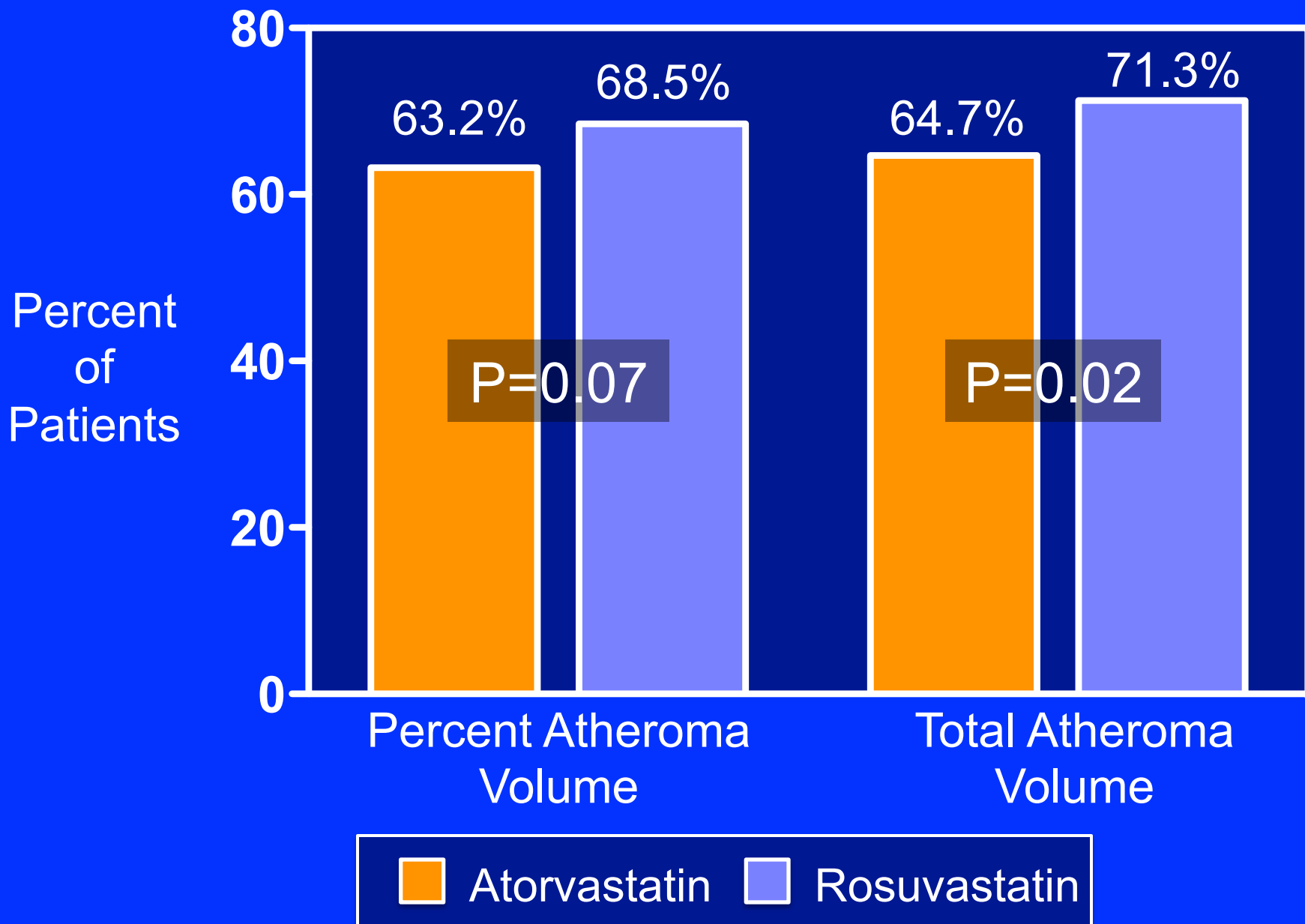
Secondary IVUS Efficacy Parameter

Median Change in Total Atheroma Volume

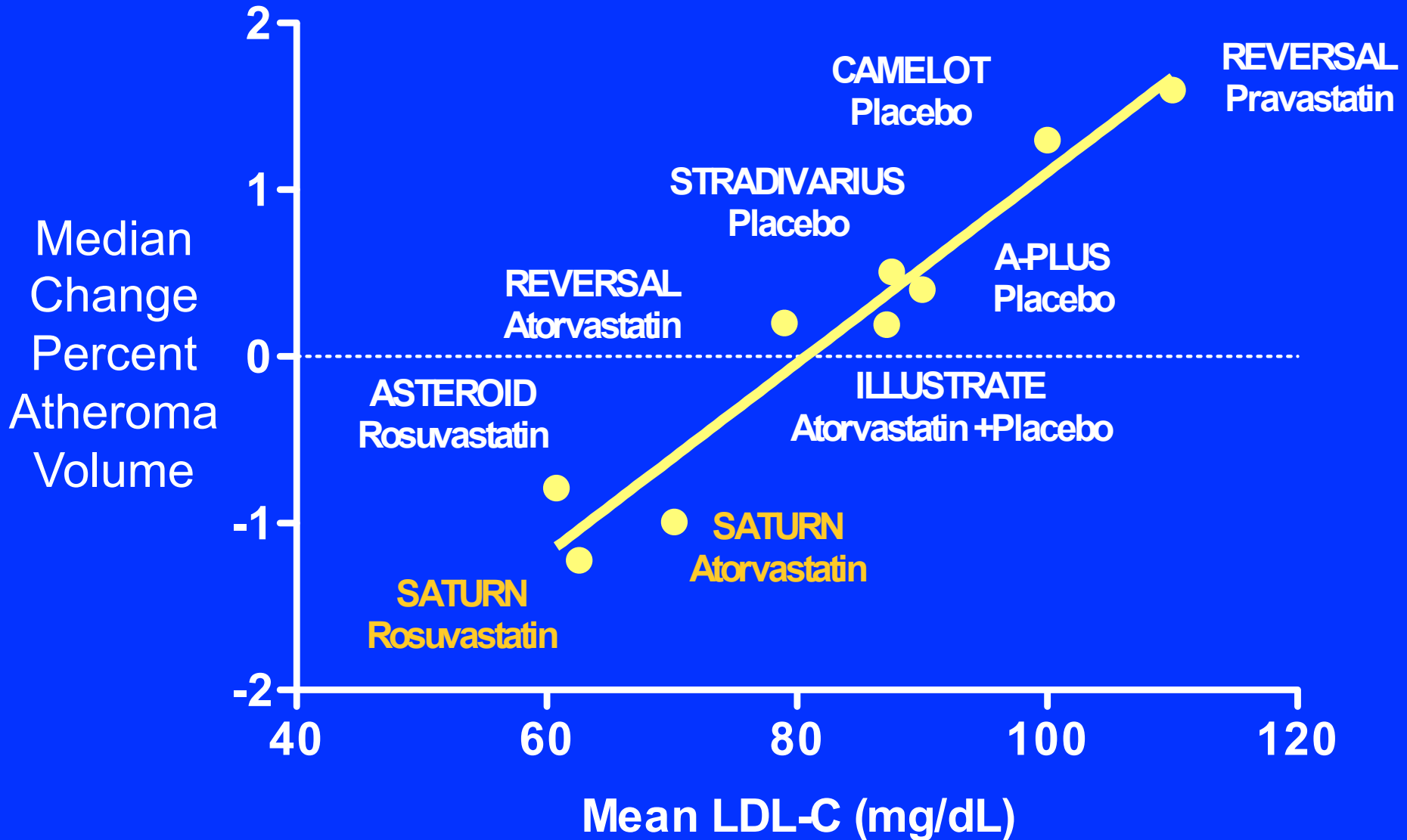


† comparison between groups. * comparison from baseline

Fraction of Patients Exhibiting Regression



LDL-C and Disease Progression



Conclusions

- Maximal statin therapy, achieving optimal LDL-C and HDL-C levels, is well tolerated and promotes extensive disease regression.
- The extent and frequency of regression observed in the SATURN trial is unprecedented.
- The finding that nearly one third of patients continue to progress supports the need to develop additional anti-atherosclerotic therapies.