

PROVE IT - TIMI 22

Protocol Design



Patients stabilized post ACS <10d
Total cholesterol <240 mg/dL (N=4000)

ASA & standard
medical therapy

Pravastatin
40 mg qd

Atorvastatin
80 mg qd

2x2 factorial
design

Follow-up visit day 15

Gatifoxacin
400 mg qd x 10d/mo

Placebo

Placebo

Gatifoxacin
400 mg qd x 10d/mo

Follow-up visit day 30 then q4 months
(average 2 years, minimum 18 months)

1° Endpoint: death, MI, stroke, rehospc for UA, revasc*

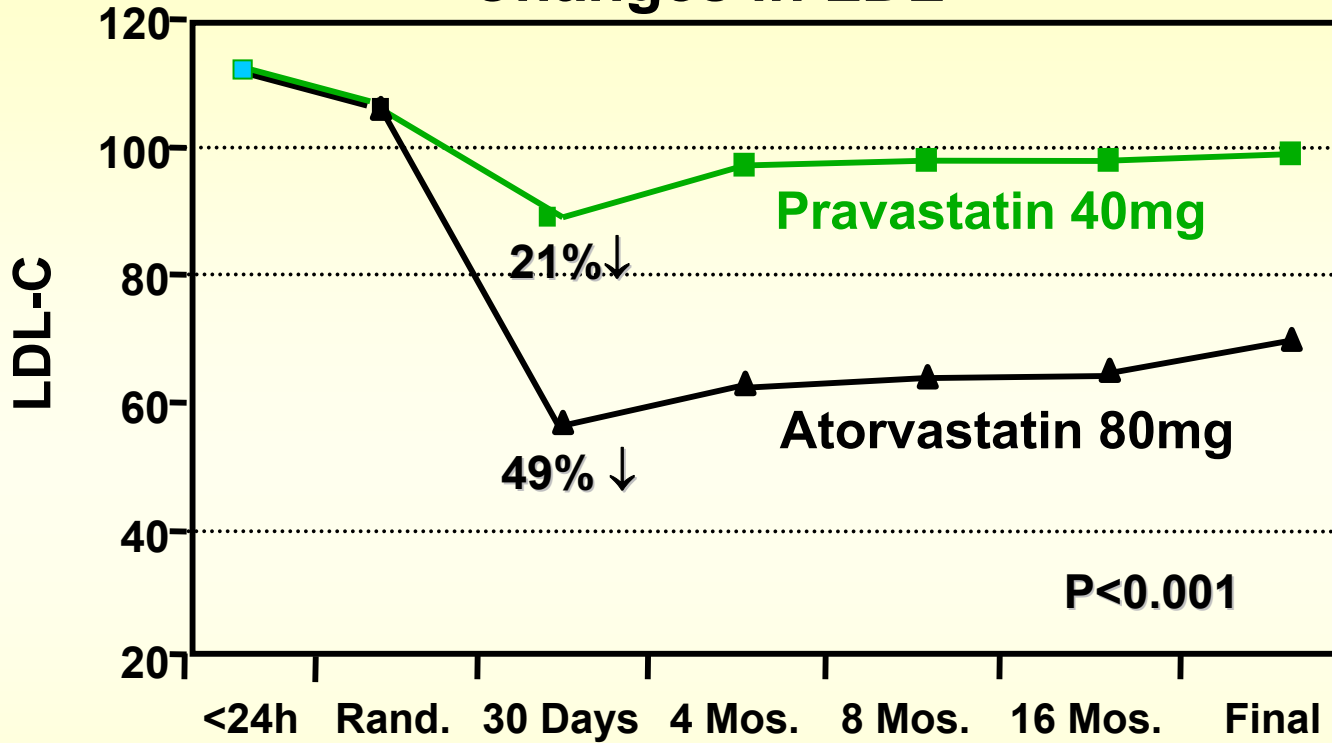
* Revascularization includes only procedures occurring > 30d post randomization

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Lipid Results

Changes in LDL



Median LDL-C (Q1, Q3)
95 mg/dl (79, 113)
62 mg/dl (50, 79)

Note: Changes in LDL-C may differ from prior trials:

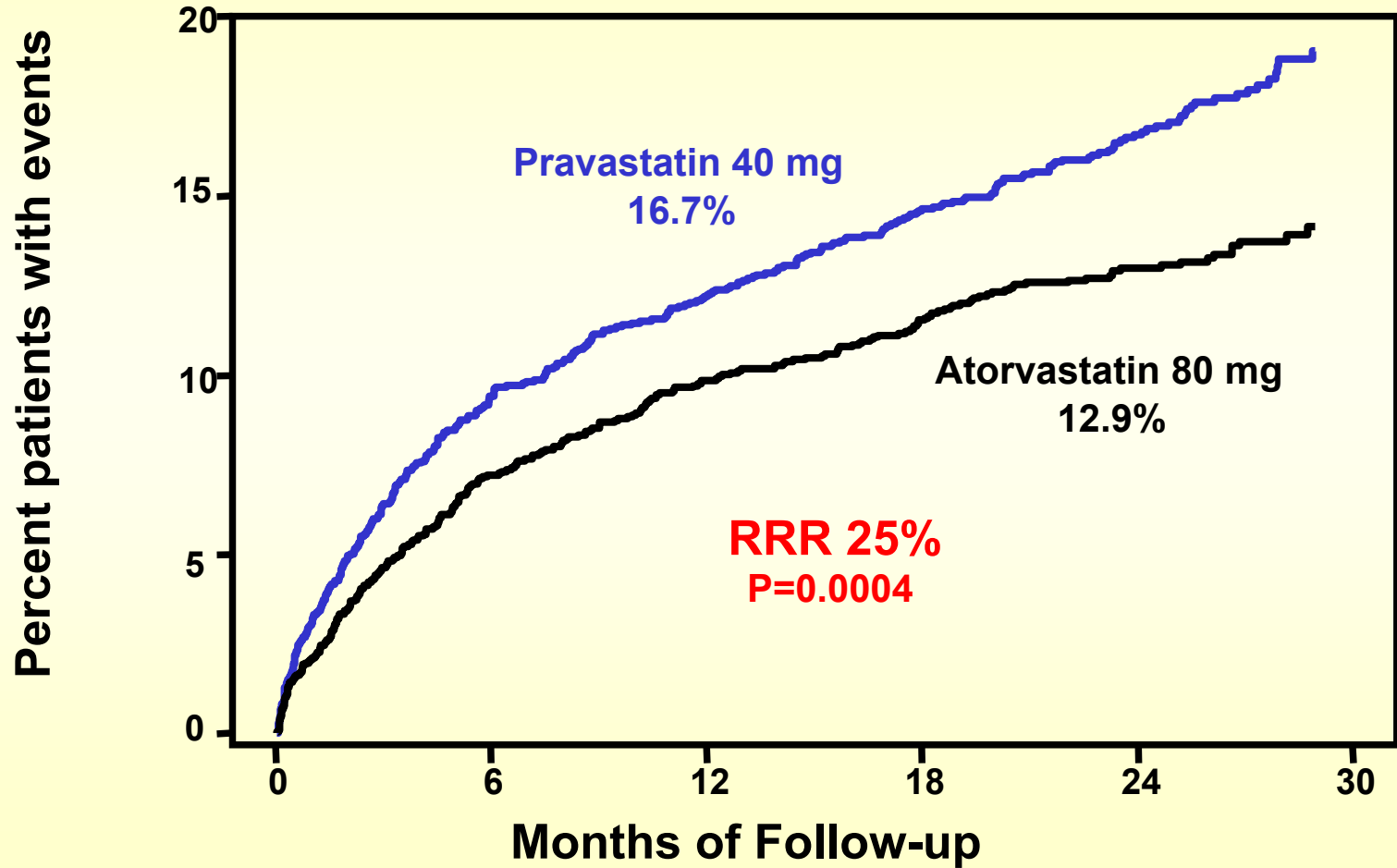
- 25% of patients on statins prior to ACS event
- ACS response lowers LDL-C from true baseline

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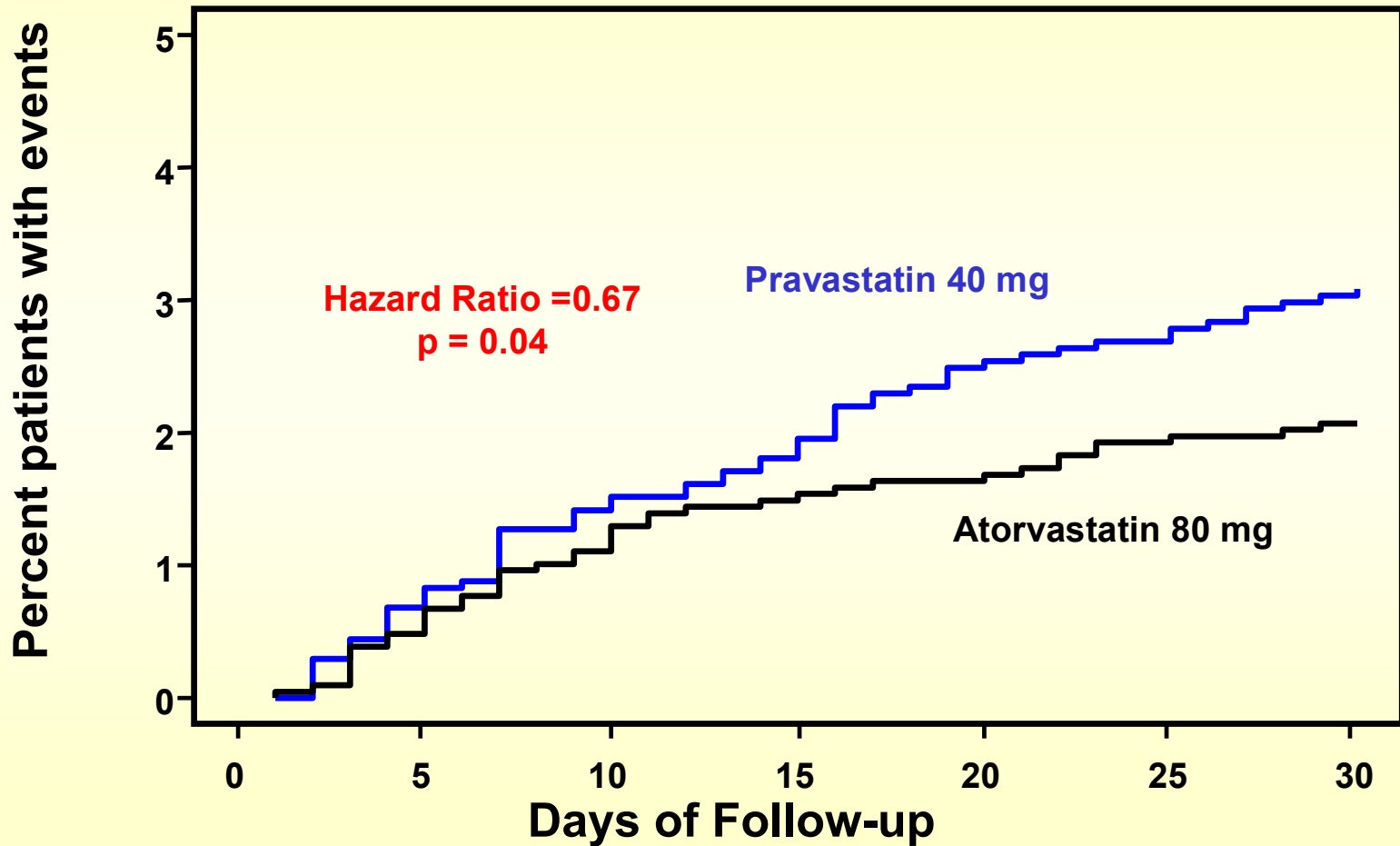
Lipid Results

DEATH, NON-FATAL MI, OR URGENT REVASCULARIZATION



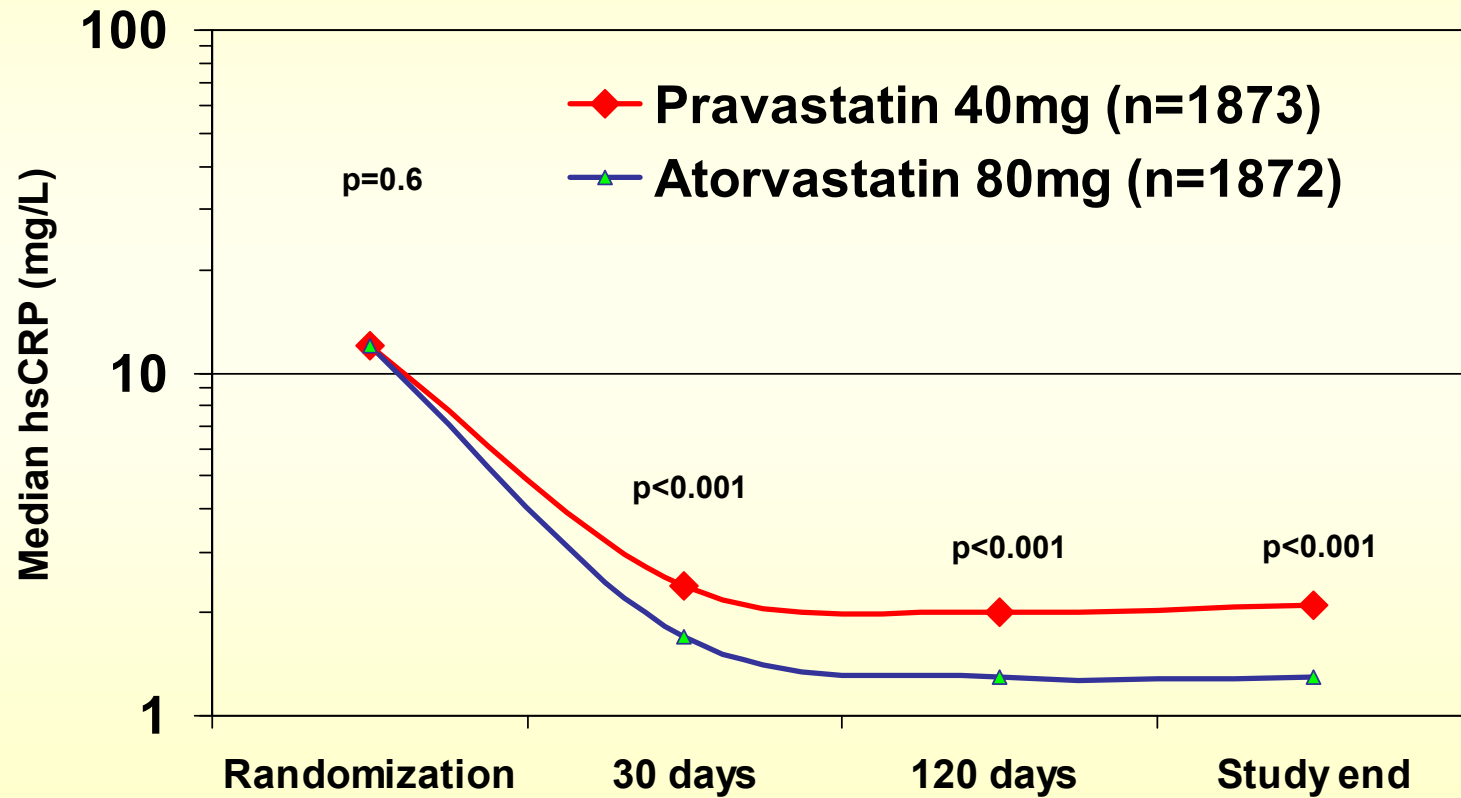
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DEATH, NON-FATAL MI, OR URGENT REVASCULARIZATION AT 30 DAYS



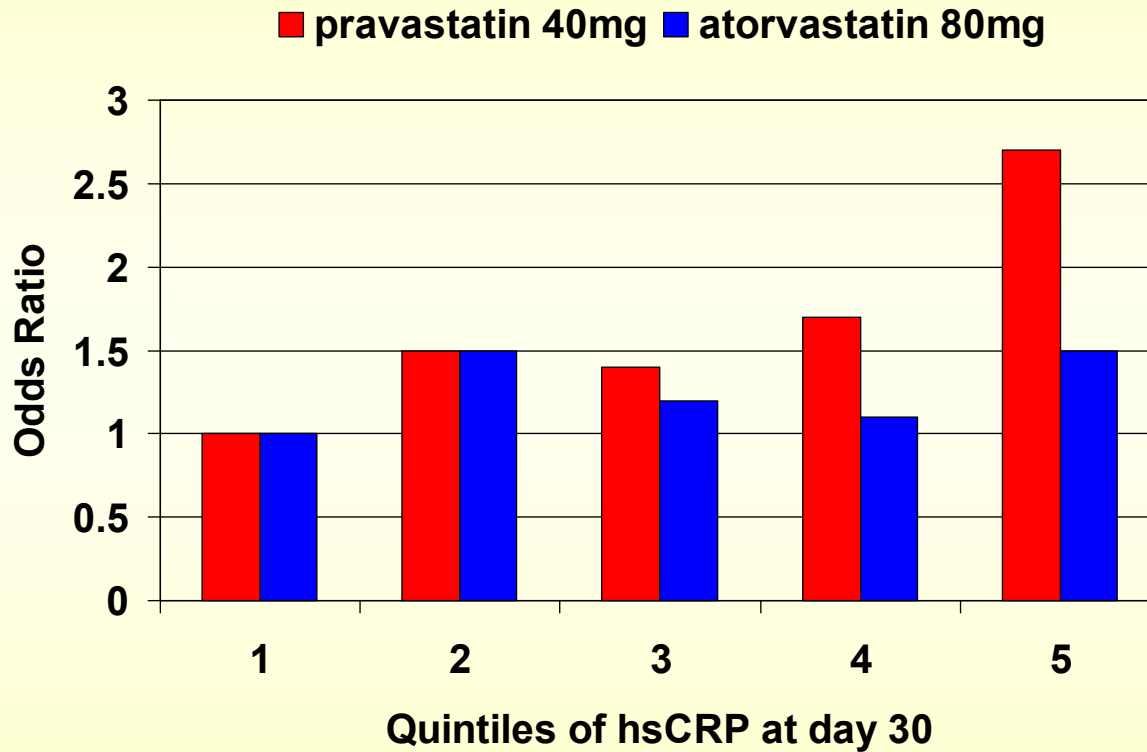
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Median C-reactive protein (hsCRP) levels by treatment



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Risk of Death or MI after Day 30



P=0.005 for prava
P=0.6 for atorva



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Antibiotic Results



Death from Any Cause or a Major CV Event

