

**Secondary Endpoint Results:**

In AFCAPS/TexCAPS, time to first event of the following secondary endpoints was evaluated: (1) coronary revascularization procedures, (2) new onset unstable angina, (3) fatal and nonfatal MIs, (4) fatal and nonfatal cardiovascular events, (5) fatal and nonfatal coronary events, (6) cardiovascular mortality, and (7) CHD mortality. Two of the secondary endpoints were components of the primary endpoint.

**Coronary Revascularization Procedures**

Coronary revascularization procedures included CABG, PTCA, stent placement, atherectomies, and coronary laser therapy. The incidence rate was 3.2% (106 procedures) for the lovastatin group and 4.8% (157 procedures) for the placebo group with a relative risk of 0.67.

The subgroup results are consistent with the results seen for the primary endpoint; very few events were seen for women (a total of 15) and most of the effect is seen in patients with 2 or more risk factors.

Table 14. Results for Coronary Revascularization Procedures

	Lovastatin	Placebo	Relative Risk	95% CI	P-value
All patients	106/3304 (3.2%)	157/3301 (4.8%)	0.67	0.52, 0.86	.001
Gender					
Male	99/2805 (3.5%)	149/2803 (5.3%)	0.66	0.51, 0.85	.001
Female	7/499 (1.4%)	8/498 (1.6%)	0.89	0.32, 2.45	.89
Age					
<65	66/2589 (2.4%)	108/2600 (4.2%)	0.57	0.42, 0.78	.0005
≥65	37/612 (6.1%)	45/594 (7.6%)	0.80	0.52, 1.23	.30
Baseline LDL					
<130	7/348 (2.0%)	17/343 (5.0%)	0.41	0.17, 0.98	.05
≥130	99/2956 (3.4%)	140/2958 (4.7%)	0.70	0.54, 0.91	.007
Baseline LDL					
<160	74/2402 (3.1%)	102/2381 (4.3%)	0.71	0.53, 0.96	.03
≥160	32/902 (3.6%)	55/920 (6.0%)	0.59	0.38, 0.91	.02
Risk factors					
1	27/1242 (2.2%)	34/1229 (2.8%)	0.79	0.45, 1.31	.36
≥2	79/2063 (3.8%)	123/2072 (5.9%)	0.64	0.48, 0.84	.002

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### New Onset Unstable Angina

Unstable angina was a component of the primary endpoint. As a secondary endpoint it was independently evaluated by an analysis of time to first event. There were 60 reports of unstable angina in the lovastatin group and 87 in the placebo group. The incidence rate for the lovastatin group was 1.8% and 2.6% for the placebo group with a relative risk of 0.69.

The subgroup results are consistent with what was observed for the primary endpoint; this would be expected given that about 45% of the events observed for the primary endpoint were due to unstable angina. Most of the events were seen in males, in patients under 65, in LDL levels above 130 and in patients with 2 or more risk factors.

Table 15. Results for Unstable Angina

	Lovastatin	Placebo	Relative Risk	95% CI	P-value
All patients	60/3304 (1.8%)	87/3301 (2.6%)	0.68	0.49, 0.95	.02
Gender					
Male	57/2805 (2.0%)	78/2803 (2.8%)	0.72	0.52, 1.02	.06
Female	3/499 (0.6%)	9/498 (1.8%)	0.34	0.09, 1.24	.10
Age					
<65	37/2589 (1.4%)	60/2600 (2.3%)	0.62	0.41, 0.93	.02
≥65	20/612 (3.3%)	25/594 (4.2%)	0.78	0.43, 1.40	.40
Baseline LDL					
<130	5/348 (1.4%)	10/343 (2.9%)	0.48	0.16, 1.41	.18
≥130	55/2956 (1.9%)	77/2958 (2.6%)	0.71	0.50, 1.0	.05
Baseline LDL					
<160	39/2402 (1.6%)	52/2381 (2.2%)	0.74	0.49, 1.12	.15
≥160	21/902 (2.3%)	35/920 (3.8%)	0.60	0.35, 1.04	.07
Risk factors					
1	17/1241 (1.4%)	21/1229 (1.7%)	0.80	0.42, 1.52	.49
≥2	43/2063 (2.1%)	66/2072 (3.2%)	0.65	0.44, 0.95	.03

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### Fatal and Nonfatal Mis

Fatal and nonfatal MIs were components of the primary endpoint and included death from MI, definite acute Q-wave MI, non-Q-wave MI, and silent subclinical MI. As a secondary endpoint it was independently evaluated by an analysis of time to first event. There were 57 MIs reported in the lovastatin group and 95 in the placebo group. The majority of these first events were nonfatal (>90%) in both groups. The incidence rate for the lovastatin group was 1.7% and 2.9% for the placebo group with a relative risk of 0.60.

The subgroup results, again, show the strongest effect for lovastatin over placebo in men, in patients under 65 and in patients with 2 or more risk factors.

Table 16. Results for Fatal and Nonfatal MI's

	Lovastatin	Placebo	Relative Risk	95% CI	P-value
All patients	57/3304 (1.7%)	95/3301 (2.9%)	0.60	0.43, 0.83	.002
Gender					
Male	53/2805 (1.9%)	89/2803 (3.2%)	0.59	0.42, 0.83	.002
Female	4/499 (0.8%)	6/498 (1.2%)	0.67	0.19, 2.38	.54
Age					
<65	34/2589 (1.3%)	66/2600 (2.5%)	0.51	0.34, 0.78	.002
≥65	19/612 (3.1%)	27/594 (4.6%)	0.69	0.38, 1.23	.21
Baseline LDL					
<130	9/348 (2.6%)	11/343 (3.2%)	0.81	0.34, 1.96	.64
≥130	48/2956 (1.6%)	84/2958 (2.8%)	0.57	0.40, 0.81	.002
Baseline LDL					
<160	37/2402 (1.5%)	64/2381 (2.7%)	0.57	0.38, 0.86	.007
≥160	20/902 (2.2%)	31/920 (3.4%)	0.66	0.38, 1.15	.14
Risk factors					
1	14/1241 (1.1%)	16/1229 (1.3%)	0.87	0.43, 1.78	.70
≥2	43/2063 (2.1%)	79/2072 (3.8%)	0.54	0.37, 0.79	.001

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