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Effect of Loading Dose of Atorvastatin Prior to Planned Percutaneous Coronary Intervention on Major Adverse Cardiovascular Events in Acute Coronary Syndrome: The SECURE-PCI Randomized Clinical Trial.

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Abstract

IMPORTANCE: The effects of **loading** doses of statins on clinical outcomes in patients with **acute coronary syndrome** (ACS) and **planned** invasive management remain uncertain.

OBJECTIVE: To determine if periprocedural **loading** doses of **atorvastatin** decrease 30-day **major adverse cardiovascular events** (MACE) in patients with ACS and **planned** invasive management.

DESIGN, SETTING, AND PARTICIPANTS: Multicenter, double-blind, placebo-controlled, randomized clinical trial conducted at 53 sites in Brazil among 4191 patients with ACS evaluated with **coronary** angiography to proceed with a **percutaneous coronary intervention** (PCI) if anatomically feasible. Enrollment occurred between April 18, 2012, and October 6, 2017. Final follow-up for 30-day outcomes was on November 6, 2017.

INTERVENTIONS: Patients were randomized to receive 2 **loading** doses of 80 mg of **atorvastatin** (n = 2087) or matching placebo (n = 2104) before and 24 hours after a **planned** PCI. All patients received 40 mg of **atorvastatin** for 30 days starting 24 hours after the second **dose** of study medication.

MAIN OUTCOMES AND MEASURES: The primary outcome was MACE, defined as a composite of all-cause mortality, myocardial infarction, stroke, and unplanned **coronary** revascularization through 30 days.

RESULTS: Among the 4191 patients (mean age, 61.8 [SD, 11.5] years; 1085 women [25.9%]) enrolled, 4163 (99.3%) completed 30-day follow-up. A total of 2710 (64.7%) underwent PCI, 333 (8%) underwent **coronary** artery bypass graft surgery, and 1144 (27.3%) had exclusively medical management. At 30 days, 130 patients in the **atorvastatin** group (6.2%) and 149 in the placebo group (7.1%) had a MACE (absolute difference, 0.85% [95% CI, -0.70% to 2.41%]; hazard ratio,

0.88; 95% CI, 0.69-1.11; P = .27). No cases of hepatic failure were reported; 3 cases of rhabdomyolysis were reported in the placebo group (0.1%) and 0 in the **atorvastatin** group.

CONCLUSIONS AND RELEVANCE: Among patients with ACS and **planned** invasive management with PCI, periprocedural **loading** doses of **atorvastatin** did not reduce the rate of MACE at 30 days. These findings do not support the routine use of **loading** doses of **atorvastatin** among unselected patients with ACS and intended invasive management.

TRIAL REGISTRATION: clinicaltrials.gov Identifier: NCT01448642.

Comment in

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