

## No Added Benefits of PCI over Optimal Medical Therapy Alone in Patients with Coronary Artery Disease

Boden WE, O'Rourke RA, Teo KK, et al. Optimal medical therapy with or without PCI for stable coronary disease. *N Engl J Med* 2007;356:1503–16.

### Study Overview

**Objective.** To evaluate if percutaneous coronary intervention (PCI) with intensive pharmacologic therapy and lifestyle intervention (optimal medical therapy) is superior to optimal medical therapy alone in reducing the risk of cardiovascular events in patients with stable coronary artery disease (CAD).

**Design.** Randomized controlled trial.

**Setting and participants.** Between 1999 and 2004, 2287 patients with objective evidence of myocardial ischemia and stable CAD from 50 care centers in the United States and Canada were randomized to either PCI plus optimal medical therapy (PCI group;  $n = 1149$ ) or optimal medical therapy alone (medical therapy group;  $n = 1138$ ). All patients received aspirin 81 mg to 325 mg daily or clopidogrel 75 mg daily if intolerant to aspirin. Optimal medical therapy consisted of long-acting metoprolol, amlodipine, and isosorbide mononitrate alone or in combination as well as either lisinopril or losartan as secondary prevention.

**Main outcome measures.** The primary outcome measure was a composite of death from any cause and nonfatal myocardial infarction (MI). Secondary outcomes included a composite of death, MI, and stroke and hospitalization for unstable angina.

**Main results.** After a median follow-up of 4.6 years (interquartile range, 3.3–5.7 years), 211 patients in the PCI group and 202 patients in the medical therapy group had primary events, resulting in cumulative primary event rates of 19% and 18.5%, respectively (hazard ratio [HR] for the PCI group, 1.05 [95% confidence interval {CI}, 0.87–1.27];  $P = 0.62$ ). There were no significant differences between the PCI group and the medical therapy group in the composite outcome of death, MI, and stroke (20% vs. 19.5%; HR, 1.05 [95% CI, 0.87–1.27];  $P = 0.62$ ); in rates of hospitalization for acute coronary syndrome (12.4% vs. 11.8%; HR, 1.07 [95% CI, 0.84–1.37];  $P = 0.56$ ); or in rates of MI (13.2% vs. 12.3%; HR, 1.13 [95% CI, 0.89–1.43];  $P = 0.33$ ).

**Conclusion.** As an initial management strategy in patients

with stable CAD, the addition of PCI to optimal medical therapy did not reduce the risk of death, MI, or other major cardiovascular events.

### Commentary

Although CAD remains the number one killer of Americans [1], substantial progress has been made in developing drug therapy and procedures to reduce morbidity and mortality from CAD [2]. One important intervention is angioplasty, often referred to as PCI, which allows direct intervention on an occluded coronary artery and has been clearly shown to reduce mortality in patients with acute MI. More than 85% of PCIs are performed on patients with “stable” CAD—on blockages not associated with an acute coronary event but rather those that may cause angina with activity. The logic for the use of PCIs in this clinical scenario is simple: intervene on blockages before they occlude and the rate of coronary events and death may be reduced. Unfortunately, this logic has not been tested rigorously until now.

The study by Boden and colleagues provides stunning results. Nearly 2300 patients were randomized and those who received PCI plus optimal medical therapy had no better rates of acute MI, stroke, death, or hospitalizations from CAD than patients who received optimal medical therapy alone. In fact, the rates of acute MI, stroke, death, and hospitalizations were slightly higher in the PCI group but this difference was not statistically significant. Patients were followed for nearly 7 years, suggesting a lack of both short-term and long-term benefit. In addition, subgroup analysis showed no additional benefit with PCI compared with medical therapy alone.

### Applications for Clinical Practice

For patients with stable CAD, PCI does not offer clinical benefits over medical therapy alone. Because nearly 850,000 PCI procedures are performed every year at a cost of approximately \$20,000 to \$50,000 each [3], eliminating these elective procedures will not only save patients substantial hassle and risk but will also have beneficial effects on the costs of health care in the United States. Given the mediocre rates of use of optimal medical therapy, our attention should focus on ensuring that all patients with CAD receive appropriate drug

therapy and not wasteful or unnecessary procedures.

—*Review by Ashish K. Jha, MD, MPH*

### References

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3. Hlatky MA, Boothroyd DB, Brooks MM, et al. Clinical correlates of the initial and long-term cost of coronary bypass surgery and coronary angioplasty. *Am Heart J* 1999;138(2 Pt 1): 376–83.

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