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OPTIMAL MEDICAL THERAPY WITH OR WITHOUT PCI FOR STABLE CORONARY DISEASE

In patients with stable coronary artery disease, it remains unclear whether an initial management strategy of 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. This study used a randomized trial involving 2287 patients who had objective evidence of myocardial ischemia and significant coronary artery disease at 50 U.S. and Canadian centers. Between 1999 and 2004, 1149 patients were assigned to undergo PCI with optimal medical therapy (PCI group) and 1138 to receive optimal medical therapy alone (medical-therapy group). The primary outcome was death from any cause and nonfatal myocardial infarction during a follow-up period of 2.5 to 7.0 years (median, 4.6). There were 211 primary events in the PCI group and 202 events in the medical-therapy group. The 4.6-year cumulative primary-event rates were 19.0% in the PCI group and 18.5% in the medical-therapy group (hazard ratio for the PCI group, 1.05; 95% confidence interval [CI], 0.87 to 1.27; P=0.62). There were no significant differences between the PCI group and the medical-therapy group in the composite of death, myocardial infarction, and stroke (20.0% vs. 19.5%); hospitalization for acute coronary syndrome (12.4% vs. 11.8%); or myocardial infarction (13.2% vs. 12.3%). As an initial management strategy in patients with stable coronary artery disease, PCI did not reduce the risk of death, myocardial infarction, or other major cardiovascular events when added to optimal medical therapy.

Boden WE, O'Rourke RA, Teo KK, Hartigan PM, Maron DJ, Kostuk WJ, et al. Optimal medical therapy with or without PCI for stable coronary disease. N Engl J Med. *2007 Apr 12;356(15):1503-16. Epub 2007 Mar 26.*

Comment:

Coronary intervention is clearly a beneficial treatment with reduction of death and MI in patients with both ST elevation MI and non-ST elevation MI/acute coronary syndromes. The COURAGE trial looked at the benefit of optimal medical therapy with PCI vs. optimal medical therapy alone in patients with stable coronary artery disease (CAD). Understanding this study is aided by remembering a few caveats that help frame the unsurprising results.

- Patients with high risk markers such as an early positive stress test, low ejection fraction, refractory angina, etc. were excluded from this study.
- While the COURAGE trial started with a large number of screened patients (35,539), only a small group of patients (3,071—less than 10 percent) were found eligible for the study. Of these eligible patients, only 2,287 (74 percent of eligible patients) actually enrolled in the study. Considering there were 50 centers involved, this represented an average of only one CAD patient enrolled per month per center. This suggests that the results of this study apply to a very narrow segment of patients since such a small percentage of screened patients were eligible. Additionally, 26% of eligible patients were not enrolled. In this study, enrollment occurred after angiography which raises the concern that there may have been a selection bias based on the patient's angiogram. These observations cast doubt on the generalizability of the study results.

- There was a 32 percent crossover of "medical therapy only" patients to PCI at 10 months. Unfortunately, because of the “intention to treat analysis,” these crossover patients remained in the “medical therapy only” group for statistical analysis of outcomes. This attributes the benefits of PCI in these patients to medical therapy.
- Symptoms of angina were significantly reduced at one and three years (though not at five years) in the PCI group despite the large number of crossovers. The need for antianginal medications was reduced through five years. These benefits were achieved without an increased risk of death or MI thus demonstrating the safety of PCI.

We’ve known for a long time that the benefit of PCI in stable patients is in symptom reduction. In view of this, the COURAGE results are not surprising: there was no MI or heart attack reduction benefit from PCI in stable patients, and yet PCI does provide symptom reduction without increasing the risk of death or MI. Therefore, all patients with stable angina should receive optimal medical therapy. The role of PCI in this relatively small proportion of patients who enter the cath lab is relief of symptoms (not reduction of death or MI). The message appearing in the popular press when this trial was published gave the impression that people should not have stents because they are being done unnecessarily. This is unfortunate because the vast majority of patients going through cath labs (generally 70%, but more like 80-85% at the Minneapolis Heart Institute) are those unstable CAD patients who can enjoy clear mortality and MI reduction benefits from PCI.

— **D. Lips MD,** Senior Consulting Cardiologist, Medical Director of Cardiac Catheterization Laboratory, Minneapolis Heart Institute.

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EDITOR-IN-CHIEF	MANAGING EDITOR	CONTRIBUTING EDITOR
M. Nicholas Burke, MD	Michelle Croteau	D. Lips, MD

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Minneapolis Heart Institute
920 East 28th Street, Suite 300 • Minneapolis, Minnesota 55407 • Telephone: 612-863-4899
View electronically at www.mplsheart.com/journalscan

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