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A Randomized Trial of Percutaneous Coronary Intervention added to Optimal Medical Therapy in Patients with Stable Coronary Heart Disease: Results of the Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE) Trial

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Background: It is uncertain whether an initial management strategy of percutaneous coronary intervention (PCI) coupled with aggressive, optimal medical therapy (OMT) is superior to a strategy of OMT alone in reducing long-term clinical events in symptomatic patients with significant coronary artery disease (CAD).

Methods: Between 1999 and 2006, 2,287 patients were randomized at 50 participating hospitals in the U.S. and Canada to PCI and OMT (n=1149) or OMT alone (n=1138). Eligible patients included those with chronic angina pectoris (CCS Class I-III) and angiographically confirmed CAD ($\geq 80\%$ proximal stenosis in at least one epicardial coronary artery). The primary endpoint was a composite of all-cause mortality or non-fatal myocardial infarction (MI), using a time to first event analysis, during a 2.5 to 7.0 year (median 5.0 year) follow-up. Principal secondary endpoints included hospitalization for biomarker-negative acute coronary syndrome and the composite of death, MI or stroke.

Results: Baseline characteristics revealed a mean age of 62 ± 5 years; 85% of patients were men and 86% Caucasian. The mean duration of angina prior to randomization was 26 months with an average of 10 episodes per week. 29% of patients were smokers, 67% had hypertension, 38% prior MI, 71% dyslipidemia, 34% diabetes, 27% previous revascularization, and 69% multi-vessel CAD. Approximately 55% of patients met criteria for metabolic syndrome. Results for primary and secondary clinical outcome measures will be presented.

Conclusions: The COURAGE trial results will elucidate whether there is incremental long-term clinical benefit to an initial treatment strategy of PCI plus OMT versus an initial management strategy of OMT alone.