# Three-year results from the EXCEL trial presented

October 31 2016

A large-scale randomized trial examining percutaneous coronary intervention (PCI) versus coronary artery bypass graft surgery (CABG) in patients with left main coronary artery disease (LMCAD) and low-intermediate SYNTAX scores found that there was no significant difference in three-year outcomes between the two treatments, with a reduction in 30-day major adverse events with PCI.

Findings were reported today at the 28th annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium. Sponsored by the Cardiovascular Research Foundation (CRF), TCT is the world's premier educational meeting specializing in interventional cardiovascular medicine. The study was also published simultaneously in the *New England Journal of Medicine*.

"The historical gold standard therapy for LMCAD has been open heart surgery with CABG. However, improved outcomes with the newest generation of drug-eluting stents allows a less invasive approach to complex coronary artery disease for many patients," said lead investigator Gregg W. Stone, MD, Professor of Medicine at the Columbia University College of Physicians and Surgeons and Director of Cardiovascular Research and Education at the Center for Interventional Vascular Therapy at NewYork-Presbyterian Hospital/Columbia University Medical Center. He is also Co-Director of Medical Research and Education at CRF. "EXCEL is the first large-scale study to examine whether patients with LMCAD and low or intermediate coronary artery disease complexity can be safely treated

with everolimus-eluting stents, which have been associated with low rates of stent thrombosis, rather than CABG."

Between September 2010 and March 2014, 2,905 patients with LMCAD were recruited at 126 sites in 17 countries, including 1,905 randomized and 1,000 registry patients. Eligible patients (n=1,905) with LMCAD and low or intermediate coronary artery disease complexity (SYNTAX score ?32) were randomized to revascularization with fluoropolymer-based cobalt-chromium everolimus-eluting stents (EES; n=948) or CABG (n=957). The primary endpoint was the three-year composite rate of death, stroke or myocardial infarction (MI), powered for noninferiority testing. Major secondary outcomes included

this endpoint at 30 days, and the composite rate of death, stroke, MI or ischemia-driven revascularization at three years.

At three years, the primary endpoint of death, stroke or MI occurred in 15.4% of EES patients and 14.7% of CABG patients (difference [upper 97.5% confidence limit] = 0.7% [4.0%], Pnoninferiority=0.018; HR [95%CI] = 1.00 [0.79, 1.26], Psuperiority=0.98). The secondary endpoint of death, stroke or MI at 30 days occurred in 4.9% EES patients and 7.9% CABG patients (Psuperiority=0.008). Death, stroke, MI or ischemia-driven revascularization at three years occurred in 23.1% EES patients and 19.1% CABG patients (Pnoninferiority=0.01; Psuperiority=0.10). Patients treated with PCI rather than CABG had fewer MIs, and less bleeding, infections, arrhythmias and renal failure within 30 days, although more repeat revascularization procedures at three years. Fewer patients developed definite stent thrombosis after PCI than symptomatic graft occlusion after PCI at 30 days and three years.

"The three-year follow-up results from EXCEL suggest that PCI with EES is an acceptable or even preferred alternative to CABG in selected patients with LMCAD," said Dr. Stone. "Longer-term follow-up is

needed to examine whether additional differences between the two treatments emerge over time."

The EXCEL trial was funded by Abbott Vascular. Dr. Stone reported no relevant disclosures.

The results of EXCEL will be presented on Monday, October 31 at 9:00 AM ET in the Main Arena (Ballroom, Level 3) of the Walter E. Washington Convention Center.

Provided by Cardiovascular Research Foundation