

Results of the FREEDOM sub study reported

31 October 2013

According to a recent study of diabetic patients who underwent revascularization for multi-vessel coronary artery disease (CAD), patients treated with insulin experienced more major adverse cardiovascular events after revascularization than those not treated with insulin.

The findings of a sub group analysis of the FREEDOM trial were presented today at the 25th 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 global prevalence of adult diabetes mellitus currently exceeds 6.4 percent (285 million) and is projected to increase to 7.7 percent (439 million) by 2030. In the United States, 26 percent of diabetics are treated with [insulin](#); these [patients](#) comprise both patients with Type I diabetes as well as more advanced Type II diabetes. Insulin-treated patients are at increased risk for [cardiovascular events](#) after PCI and also have a higher risk of wound infection and mortality after [coronary artery bypass surgery](#) (CABG).

Results of the overall FREEDOM trial, which were first reported last year in the *New England Journal of Medicine*, found that [coronary artery bypass grafting](#) (CABG) reduces mortality and myocardial infarction rates compared to percutaneous coronary intervention (PCI), though it increases the chance of stroke. This FREEDOM sub group analysis examined the association of clinical outcomes after revascularization by insulin-treated diabetes mellitus (ITDM) status and the respective effect of CABG vs. PCI using first generation drug-eluting stents (PCI/DES). The primary endpoint was a composite of major adverse cardiac events including death, stroke and myocardial infarction analyzed using the logrank test and Cox regression to assess the interaction of treatment received and ITDM status.

A total of 1,850 diabetic patients with multi-vessel disease were randomized 1:1 to either CABG (894 patients) or PCI/DES (956 patients). Baseline and procedure characteristics were largely similar among the groups. A total of 602 patients (32.5 percent) had ITDM (PCI n=325, 34 percent; CABG n=277, 31 percent).

The estimated percentage of patients with a major adverse coronary event after five years was higher in the ITDM group compared to the non ITDM group (29 percent vs. 19 percent, respectively). Regardless of insulin treatment status, the estimated percentage of patients with major adverse coronary events after five years was higher among those that underwent PCI/DES (32 percent in the ITDM group and 25 percent in the non-ITDM group) compared to CABG (24 percent in the ITDM group and 16 percent in the non-ITDM group), although stroke rates were higher among CABG patients. In the ITDM group, the stroke rate was 7.5 for those who underwent CABG compared to 3.7 in those who had PCI/DES. In the non ITDM group, the stroke rate was 4.3 vs. 1.7 respectively.

"In patients with diabetes and multi-vessel [coronary artery](#) disease there are more major adverse cardiovascular events in patients treated with insulin than in those not treated with insulin," said study investigator George Dangas, MD, PhD. Dr. Dangas is Professor of Medicine at the Mount Sinai School of Medicine and Director of Cardiovascular Innovation at the Zena and Michael A. Wiener Cardiovascular Institute of the Mount Sinai Medical Center.

"However, the differences in clinical outcomes between CABG and PCI/DES were maintained regardless of the presence or absence of insulin treatment," Dr. Dangas said.

Provided by Cardiovascular Research Foundation

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