Drug does not appear to reduce risk of heart attack or death following CABG surgery

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Use of MC-1 (a naturally occurring metabolite of vitamin B6) before and for 30 days after coronary artery bypass graft surgery did not reduce the risk of heart attack or cardiovascular death, according to a JAMA study being released early online April 1 to coincide with its presentation at the annual conference of the American College of Cardiology. The study will be published in the April 16 issue of JAMA.

“Coronary artery bypass graft (CABG) surgery is one of the most important therapeutic options for relieving angina and improving survival and quality of life in patients with multivessel coronary artery disease. It is the most commonly performed cardiac surgical procedure in the world, and in 2005, more than 250,000 CABG procedures were performed in the United States,” the authors write. Serious complications can include heart attack, recurrent angina, kidney insufficiency, stroke, and death. Phase 2 trial data suggest that MC-1 may reduce death or heart attack in high-risk patients undergoing CABG surgery.

John H. Alexander, M.D., M.H.S., of Duke University Medical Center, Duke Clinical Research Institute, Durham, N.C., and colleagues with MEND-CABG II, a phase 3, multicenter, randomized trial, assessed the cardioprotective effect of MC-1 administered before and continued for 30 days after CABG surgery, compared with placebo, in 3,023 intermediate- to high-risk patients undergoing CABG surgery with cardiopulmonary bypass.

The researchers found that the primary efficacy outcome, cardiovascular death or nonfatal heart attack at 30 days, occurred in 140 of 1,510 patients (9.3 percent) in the MC-1 group and 133 of 1,486 patients (9.0 percent) in the placebo group. All-cause death was higher among patients assigned to MC-1 than placebo at 4 days (1.0 percent vs. 0.3 percent) but was similar at 30 days (1.9 percent vs. 1.5 percent). There was no beneficial effect of MC-1 seen in any prespecified subgroup or on other outcomes.

There was no difference in the incidence of postoperative stroke, atrial fibrillation, or kidney function between the two groups. Patients assigned to receive MC-1 and placebo had similar intensive care unit and hospital lengths of stay.

“MEND-CABG II demonstrates that among intermediate- to high-risk patients undergoing CABG surgery, MC-1, 250 mg/d, given immediately before and for 30 days following surgery did not reduce cardiovascular death or nonfatal [heart attack]. Myocardial injury remains a significant problem following CABG surgery. Effective therapies to reduce perioperative morbidity and mortality are needed but remain elusive,” the authors conclude.

Source: JAMA and Archives Journals