

Future research appears warranted to focus on further reducing periprocedural TAVR complications, including strokes, vascular events, and short- and long-term risk and prevention of paravalvular AR.

## The CABG Surgery Off-or On-Pump-Revascularization Study

Written by Maria Vinall

Results of a study that was designed to compare the benefits and risks of performing coronary artery bypass grafting surgery (CABG) off-pump (beating heart) versus on-pump showed no difference in major clinical events at 30 days, with off-pump procedures associated with reduced rates of transfusions, reoperations for bleeding, acute kidney injury, and respiratory infection/failure but an increased rate of early repeat revascularizations.

The Coronary Artery Bypass Grafting Surgery Offor On-Pump Revascularization Study [CORONARY; NCT00463294] was designed to test the hypothesis that off-pump CABG would reduce short-term (30 days) major clinical events and that these benefits would be maintained over the long term (5 years). The short-term study results were presented by Andre Lamy, MD, Population Health Research Institute, McMaster University, Hamilton, Ontario, Canada.

CORONARY was a randomized, double-blind international trial (79 centers in 19 countries). Eligibility included patients who were undergoing planned isolated CABG with median sternotomy and at least 1 of the following risk factors: age ≥70 years, peripheral vascular disease, cerebrovascular disease, carotid stenosis >70%, and renal insufficiency. Patients were also eligible if they were aged 60 to 69 and years had at least 1 additional risk factor or were aged 55 to 59 years with at least 2 additional risk factors-diabetes, urgent revascularization, smoker, or left ventricular ejection fraction (LVEF)  $\leq$  35%. Each operation was performed by a surgeon with expertise (>2 years; >100 procedures) in the specific type of surgery that the patient was assigned to receive. The first coprimary outcome was a composite of mortality, nonfatal stroke, nonfatal myocardial infarction (MI), and new renal failure that required dialysis at 30 days. The 5-year results will be available in 2016 and comprise the first coprimary outcome plus repeat coronary revascularization at a mean of 5 years. Secondary efficacy outcomes included rates of blood transfusion, recurrent angina, cardiovascular death, and cost-effectiveness.

A total of 4572 subjects (mean age 68 years) participated in the study. Most (81%) were men, and one-third had a prior MI. Baseline preoperative angiograms indicated that the majority (off-pump 56.1%; on-pump 60.4%) had triplevessel disease. At 30 days, 9.8% and 10.3% of patients who received off-pump versus on-pump procedures reached the primary composite outcome (HR, 0.95; 95% CI, 0.79 to 1.14; p=0.59). Off-pump CABG was associated with significantly fewer blood transfusions and reoperation for bleeding, less acute kidney injury, and fewer respiratory complications but more early repeat coronary revascularizations (Table 1). No difference in primary outcome was noted at hospital discharge, nor were there any differences by subgroup.

Table 1. Outcomes at 30 Days.

	Off- pump	On- pump	RR (95% CI)	p value
Blood transfusions	50.7%	63.3 %	0.80 (0.75–0.85)	<0.001
Reoperation for bleeding	1.4%	2.4%	0.61 (0.40–0.93)	0.02
Acute kidney injury	28.0%	32.1%	0.87 (0.80–0.96)	0.01
Respiratory complications	5.9%	7.9%	0.79 (0.63–0.98)	0.03
Early repeat coronary revascularizations	0.7%	0.2%	HR, 4.01 (1.34–12.0)	0.01

The investigators concluded that in experienced hands, both procedures are reasonable options, based on short-term results. The difference in morbidity that was observed in the 30-day results may or may not lead to clinically significant differences during the long-term follow-up that is being conducted. Whether the unblinded nature of the trial (both patients and investigators were aware of study group assignment, but the endpoint adjudication committee members were unaware) or this interim report will bias the long-term follow-up of trial patients is unclear [Lamy A et al. *N Engl J Med* 2012].

## Moderate PE Treated with Thrombolysis (MOPETT Study)

Written by Maria Vinall

Pulmonary embolism (PE) is one of the most common preventable causes of death (responsible for >100,000 deaths annually) and the third leading cause of cardiovascular mortality. Thrombolysis with standard doses of 100 mg tissue plasminogen activator (t-PA) over 2 hours is recommended in appropriately selected severe PE patients (patients with hemodynamic instability