



A Comparison of Clinical Outcomes Following On- Versus Off-CABG Shows Mixed Results

Written by Phill Vinall

Although coronary artery bypass grafting (CABG) is usually performed with the use of cardiopulmonary bypass (on-pump CABG), CABG without bypass (off-pump CABG) might reduce the number of major adverse events related to the heart-lung machine (MACCRE) and improve outcomes. Investigators discussed the results of 3 studies that tested this hypothesis.

GERMAN OFF-PUMP CORONARY ARTERY BYPASS IN THE ELDERLY [GOPCABE] STUDY

Anno Diegeler, MD, PhD, University of Leipzig/Herz-und Gefäßklinik GmbH, Abteilung Herzchirurgie, Bad Neustadt, Germany, presented the results of the GOPCABE study [Diegeler A et al. *N Engl J Med* 2013], which showed no significant difference in clinical outcome between the 2 approaches at 30 days and at 12 months.

In GOPCABE, patients aged ≥ 75 years who were scheduled for elective first-time CABG were randomly assigned to off-pump (n=1271) or on-pump surgery (n=1268). The primary endpoint was a composite of death, myocardial infarction (MI), additional revascularization, stroke, and new onset renal replacement therapy 30 days after surgery.

At 30 days, the primary composite endpoint was not significantly different between the 2 treatments (7.8% for off-pump vs 8.2% for on-pump; OR, 0.95; 95% CI, 0.71 to 1.28; p=0.74). Of the components of the primary endpoint, only the repeat revascularization rate was significantly different and favored the traditional on-pump technique (1.3% vs 0.4%, respectively; p=0.04).

The investigators noted no significant differences between the 2 groups for the primary composite endpoint or repeat revascularization at 12 months. The results were similar in a per-protocol analysis that excluded the 177 patients who had crossed over from their assigned treatment to the other treatment. A potential limitation of this study was that it was a modified intent-to-treat analysis and only local data confirmation was performed.

CORONARY ARTERY BYPASS SURGERY OFF- OR ON-PUMP REVASCLARIZATION [CORONARY] STUDY

André Lamy, MD, MHSc, McMaster University, Hamilton, Ontario, Canada, reported the 1-year results of the CORONARY study [Lamy A et al. *N Engl J Med* 2013]. The 30-day results have been previously published [Lamy A et al. *N Engl J Med* 2012]. As with GOPCABE, the investigators found no significant differences in the primary composite outcome or in the occurrence of major clinical events between the 2 groups.

The study was conducted in 4752 patients (aged ≥ 70 years or younger patients with risk factors) from 79 sites in 19 countries. It utilized a surgical expertise-based design, whereby only surgeons considered to have expertise in the specific type of surgery were assigned to perform that procedure. Patients were randomly assigned to off-pump (n=2375) or on-pump CABG (n=2377). Clinical outcomes were assessed at 1 year. Quality of life and cognitive function were assessed at discharge, 30 days, and 1 year.

The primary composite endpoint (death, nonfatal stroke, nonfatal MI, or nonfatal new renal failure requiring dialysis) was not significantly different between off-pump (12.1%) and on-pump procedures (13.3%; HR, 0.91; 95% CI, 0.77 to 1.07; p=0.24). There were no individual differences between the 2 groups in the primary endpoint components, rate of revascularization procedures, quality of life, neurocognitive functions, or in any of the subgroup analyses.

The authors noted that, based on mid-term results, both procedures are reasonable options when in experienced hands.

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ON-PUMP VERSUS OFF-PUMP CABG IN HIGH-RISK PATIENTS EUROSCORE 6+ [PRAGUE6] STUDY

The PRAGUE 6 trial [NCT00606372] results indicated that off-pump surgery in high-risk patients is associated with a lower incidence of serious complications and is a safer way of direct revascularization in these patients. Jan Hlavicka, MD, Kralovske Vinohrady University Hospital, Prague, Czech Republic, presented the findings of this prospective, randomized, single center, intention-to-treat assessment study.

The primary endpoint was the composite of death, MI, stroke, and new renal failure requiring hemodialysis at 30 days post operation. Patients were mean age 74 years with a mean additive EuroSCORE (Table 1) of 7.7; approximately 64% of the 206 enrolled patients had a recent MI. A total of 206 patients were randomly assigned to off-pump (n=98) or on-pump CABG (n=108).

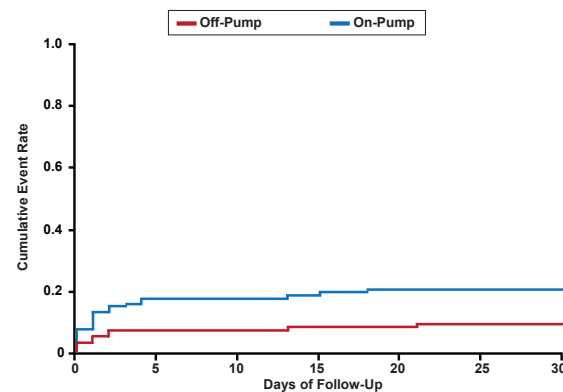
Table 1. EuroSCORE Risk Assessment Criteria

Factors	Score
Patient-related factors	
Age	1
Sex	1
Chronic pulmonary disease	1
Extracardiac arteriopathy	2
Neurological dysfunction	2
Previous cardiac surgery	3
Serum creatinine	2
Active endocarditis	3
Critical preoperative state	3
Cardiac-related factors	
Unstable angina	2
Left ventricular dysfunction	
Preop EF 30%-50%	1
Preop EF <30%	3
Recent myocardial infarct	2
Pulmonary hypertension	2
Surgical-related factors	
Emergency	2
Other than isolated CABG	2
Surgery on thoracic aorta	3
Postinfarct septal rupture	4

CABG=coronary artery bypass grafting; EF=ejection fraction.

At 30 days, the primary composite endpoint was significantly lower in the off-pump (9.2%) versus on-pump group (20.6%; HR, 0.41; 95% CI, 0.19 to 0.91; p=0.028; Figure 1), driven exclusively by a nearly 3-fold increase in the rate of MI between the off-pump and on-pump groups (4.1% vs 12.1%; HR, 0.32; 95% CI, 0.11 to 0.99; p=0.048). Off-pump patients tended to have a lower incidence of secondary endpoints (eg, need for red blood cell transfusion and re-exploration for bleeding or tamponade). Study limitations included the small number of patients, single-center design, use of only 5 surgeons, and short-term (30-day follow-up) results.

Figure 1. Incidence of Combined Primary Endpoint During First 30 Days



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Taken together, the conflicting results of these 3 studies (2 showed no difference, 1 favored off-pump CABG) indicate a need for larger, well-controlled studies with longer follow-up. Of particular interest is whether there are patients for whom one approach may be safer than the other.

HPS2-THRIVE: Niacin Fails to Show Benefit in Patients at High Risk of Vascular Events

Written by Phil Vinall

The results of this large randomized controlled trial in patients with well-controlled lipid levels but who are at a high risk of cardiovascular events once again call into question the the clinical benefits of niacin despite an increase in high-density lipoprotein cholesterol (HDL-C), and reductions in triglyceride levels and low density lipoprotein cholesterol (LDL-C) levels. Jane M. Armitage, MD, Oxford University, Oxford, United Kingdom, presented the results of the Treatment of HDL to Reduce the Incidence of Vascular Events trial [HPS2-THRIVE Collaborative Group. *Eur Heart J* 2013]. Prof. Armitage reported that adding extended-release niacin plus laropiprant (ERN/LRPT), an antiflushing agent, to background therapy with simvastatin (with or without ezetimibe) did not reduce the risk of heart attack, stroke, and revascularizations, and was associated with significantly increased serious adverse events (SAEs).

HPS2-THRIVE randomized 25,673 patients from China, United Kingdom, and Scandinavia with a prior history of myocardial infarction (MI), ischemic stroke or transient ischemic attack, peripheral arterial disease, or diabetes with other cardiovascular disease, on a background