

Title:

Off-pump versus on-pump coronary artery bypass graft procedures: individual patient data meta-analysis' preliminary bivariate findings

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Background: For nearly three decades, off-pump (“beating heart”) versus on-pump (utilizing cardiopulmonary bypass) coronary artery bypass grafting (CABG) benefits have been debated. An individual participant data meta-analysis compared short, intermediate, and longer-term bivariate outcomes after combining records from three recent off-pump vs. on-pump multi-center randomized, controlled trials (RCT).

Methods: Contemporary systematic literature review identified three RCTs comparing five-year outcomes (ROOBY, CORONARY, and GOPCABE); merged de-identified records bivariately evaluating whether off-pump CABG benefits existed for all patients, non-converted patients, or “high risk-only” patients. Records from ROOBY (1,104 off-pump; 1,099 on-pump), GOPCABE (1,179 off-pump; 1,191 on-pump), and CORONARY (2,375 off-pump; 2,377 on-pump) were combined totaling 9,325 (4,658 off-pump; 4,667 on-pump) records. There were 8,636 non converted (4,224 off-pump; 4,412 on-pump) patients, 3,022 high risk-only (1,523 off-pump; 1,499 on-pump) with 2,748 non-converted high-risk-only (1,368 off-pump; 1,380 on-pump). Primary endpoints included death and composite [death, repeat revascularization (RR), myocardial infarction (MI)] at one-year and five-years. Secondary endpoints included 30-days/in-hospital death, revised composite including perioperative stroke, perioperative stroke, RR, and MI. Statistical significance was pre-established for primary ($p < 0.050$) and secondary ($p < 0.0025$) endpoints.

Results: The average age was no different between off-pump (mean = 69.28 years; STD = 8.68 years) vs. on-pump (mean = 69.13 years; STD = 8.77 years) ($p = 0.3828$). For elderly patients (> 70 years, > 75 years, or > 80 years) and gender, no treatment-arm imbalance existed; 81.90% off-pump versus 82.34% on-pump were male. There was no difference between other risk factors including urgency status, NYHA and CCS levels, LV function, or history of MI, PCI, stroke, diabetes, BMI, or atrial fibrillation; however, triple vessel disease rates were not treatment-arm balanced (51.72% off-pump vs. 54.77% on-pump; $p = 0.0032$). At five-years, one-year, and thirty days, there were no statistically significant differences for all patients for primary endpoints; for secondary outcomes, these patients had worse 30-day off-pump RR rates ($p = 0.0006$).

Conclusions: Bivariately, this CABG-IPD-MA study compared on-pump versus off-pump CABG outcomes. At 30-days, 1 year and 5 years, no significant bi-variate differences in the primary study outcomes were found. Given these trials enrolled diverse patients with time-dependent secondary outcomes favoring on-pump treatment, risk-adjusted multivariable analyses have been initiated.