Outcomes of off-pump versus on-pump coronary artery bypass grafting: Impact of preoperative risk

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Background: It is unknown whether purported benefits of off-pump coronary artery bypass grafting are patient-specific within the Society of Thoracic Surgeons National Cardiac Database or dependent on center volume or operating surgeon.

Methods: The Society of Thoracic Surgeons National Cardiac Database was queried for all patients undergoing nonemergency, isolated coronary artery bypass between January 1, 2005, and December 31, 2010, who had Predicted Risk of Mortality scores and participant/surgeon identifiers. Of these 876,081 patients ("all sites"), 210,469 underwent surgery at participant sites that had performed more than 300 off-pump and 300 on-pump coronary artery bypass operations during the 6-year study period ("high-volume sites"). Operative mortality, stroke, acute renal failure, mortality or morbidity, and prolonged postoperative length of stay were analyzed with conditional logistic models for all sites and for high-volume sites, stratified by participant center and surgeon, and adjusted for 30 variables that comprise the Society of Thoracic Surgeons coronary artery bypass grafting risk models.

Results: Off-pump coronary artery bypass was associated with a significant reduction in risk of death, stroke, acute renal failure, mortality or morbidity, and postoperative length of stay compared with on-pump coronary artery bypass after adjustment for 30 patient risk factors in the overall sample. This held true within high-volume centers. In the overall sample, there was a significant ($P < .05$) interaction between off-pump coronary artery bypass and Predicted Risk of Mortality for death, stroke, acute renal failure, and mortality or morbidity.

Conclusions: Off-pump coronary artery bypass was associated with reduced adverse events compared with on-pump coronary artery bypass after adjustment for 30 patient risk factors and center and surgeon identity. Patients with higher Predicted Risk of Mortality scores had the largest apparent benefit. (J Thorac Cardiovasc Surg 2013;145:1193-8)

The interest in off-pump coronary artery bypass (OPCAB) has largely been driven by the increased awareness of the deleterious effects of cardiopulmonary bypass (CPB) and aortic manipulation. Although an abundance of literature comparing on-pump coronary artery bypass (ONCAB) and OPCAB exists, the optimal surgical approach remains in question. Although many surgeons and centers have adopted the off-pump technique, the majority of coronary artery bypass grafting (CABG) performed worldwide is on-pump. In 2010, 21% of all primary CABG cases in the Society of Thoracic Surgeons (STS) National Adult Cardiac Surgery Database were performed with off-pump techniques.[1]

Several prospective, randomized trials including a meta-analysis of these trials have not shown an in-hospital mortality advantage for OPCAB compared with ONCAB.[2-7] These trials are limited by a relatively low sample size, especially when trying to detect differences in an infrequent event, such as mortality, stroke, or myocardial infarction. Furthermore, these trials have enrolled predominantly low-risk patients. Thus, it remains unclear which particular patient populations may benefit most from OPCAB.

Numerous retrospective reviews of large databases have demonstrated a mortality benefit for OPCAB versus ONCAB.[8-10] Such large real-world databases have the advantage of being adequately powered to detect significant differences in outcomes and are representative of a typical patient population spectrum. Registry studies include a spectrum of patients with mixed risk profiles. Ascertaining which patient subgroups may benefit from OPCAB could inform selective or increased adoption of OPCAB for that particular risk group. Recent studies of the STS Database have shown a mortality benefit of OPCAB for higher-risk patients.[11,12]

One major criticism of both randomized controlled trials and single-center observational analyses is that these studies are conducted at single centers with extensive off-pump experience. It is unclear what role hospital organizational structure in specialized centers, specialized technical skill, or OPCAB volume may play in particular outcomes after CABG. Relatively few studies have been conducted assessing center and surgeon volume with OPCAB, and recent

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ACD

Abbreviations and Acronyms

ARF	= acute renal failure
CABG	= coronary artery bypass grafting
CI	= confidence interval
CPB	= cardiopulmonary bypass
euroSCORE	= European System for Cardiac Operative Risk Evaluation
MM	= mortality or morbidity
ONCAB	= on-pump coronary artery bypass
OPCAB	= off-pump coronary artery bypass
OR	= odds ratio
PLOS	= postoperative length of stay
PROM	= Predictive Risk of Mortality
RR	= relative risk
STS	= Society of Thoracic Surgeons

retrospective registry studies have found a mortality benefit with OPCAB in high-volume centers.[13-15]

The purpose of this study is to review the relative and absolute benefit of OPCAB versus ONCAB after adjusting for patient preoperative risk factors within the national database, while also controlling for surgeon and center.

MATERIALS AND METHODS

Study Population

The STS National Cardiac Database was queried for all patients undergoing nonemergency, isolated primary CABG between January 1, 2005, and December 31, 2010, who had complete data fields to calculate Predictive Risk of Mortality (PROM) scores and participant/surgeon identifiers. Of these 876,081 patients ("all sites"), 210,469 cases underwent surgery at participant sites that had performed more than 300 OPCAB and 300 ONCAB cases during the 6-year study period ("high-volume sites"). The distributions of patients' preoperative characteristics in both ONCAB and OPCAB groups are shown in Table 1. The *P* values for the hypothesis that no difference exists between 2 groups are calculated with chi-square tests for categoric variables and Wilcoxon rank-sum tests for continuous variables.

Society of Thoracic Surgeons Predicted Risk of Mortality

The PROM score was calculated for each patient using the risk factors and regression coefficients from the STS 2008 model. Four PROM groups were defined, such that the number of deaths in groups were similar (first quartile: <1.5%; second quartile: 1.5%-3.0%; third quartile: 3.0%-6.0%; fourth quartile: >6.0%). The mean (interquartile range) PROM was 1.73 (0.52-1.92) overall, 1.69 (0.52-1.89) in the ONCAB group, and 1.84 (0.50-2.04) in the OPCAB group. In high-volume centers, the PROM was 1.75 (0.52-1.94) overall, 1.74 (0.53-1.93) in the ONCAB group, and 1.78 (0.50-1.97) in the OPCAB group.

Data Management and Statistical Analysis

Outcomes after OPCAB versus ONCAB were compared by intent-to-treat within the entire sample and within each PROM group both descriptively and by statistical models. Unplanned conversions from off-pump to on-pump were treated as off-pump cases. The effect of OPCAB versus ONCAB on operative mortality, stroke, acute renal failure (ARF), any mortality or morbidity (MM), and prolonged postoperative length of stay (PLOS >14 days) was analyzed with conditional logistic models for all sites and for high-volume centers, stratified by participant or by surgeon. Unadjusted models with OPCAB as the only variable were fitted, as well as adjusted models including all 30 patient risk factors that comprise the STS isolated CABG 2008 mortality models and surgery date.[16] Risk factors for the calculation of PROM included age, body surface area, creatinine, dialysis, ejection fraction, preoperative atrial fibrillation, congestive heart failure and New York Heart Association classifications, chronic lung disease, cardiovascular disease, cerebrovascular accident, diabetes and type (insulin or noninsulin dependent), number of diseased vessels, preoperative intra-aortic balloon pump/inotropes, shock, sex, immunosuppressive treatment, mitral insufficiency, percutaneous coronary intervention, peripheral vascular disease, timing of myocardial infarction, hypertension, aortic insufficiency, tricuspid insufficiency, aortic stenosis, left main disease, race, and time trend. Finally, a set of conditional logistic models tested the interaction term between the OPCAB and PROM groups to determine whether differences between OPCAB and ONCAB depended on PROM.

To further depict the relationship between the outcomes and PROM, generalized additive models were used with smoothing splines of PROM. The predicted outcome rates and their pointwise 95% confidence intervals (CIs) from these models were presented as figures to visually discriminate between the 2 treatment groups.

RESULTS

Table 2 displays the adjusted (by patient factors) and unadjusted odds ratios (ORs) and their 95% CIs of OPCAB versus ONCAB in the overall study sample and in high-volume sites. Both adjusted and unadjusted models were stratified by center. OPCAB was associated with significant reduction in risk of death, stroke, ARF, any MM, and PLOS greater than 14 days compared with ONCAB after adjustment for 30 patient risk factors in the overall sample. Within high-volume centers alone, OPCAB also was associated with a significant reduction in risk of death, stroke, ARF, any MM, and PLOS.

Table 3 displays the adjusted (by patient factors) and unadjusted ORs and their 95% CIs of OPCAB versus ONCAB in the overall study sample and in high-volume sites. Both adjusted and unadjusted models were stratified by surgeon identity. The significant reduction in risk of death, stroke, ARF, MM, and PLOS of OPCAB compared with ONCAB was somewhat more pronounced after stratifying by surgeon at all sites and high-volume centers.

In the overall sample, there was a significant ($P < .05$) interaction between OPCAB and PROM for death, stroke, ARF, and MM, indicating that OPCAB was associated with a greater reduction in these adverse events in patients with higher PROM scores. Figure 1 displays the MM for all patients with OPCAB versus ONCAB at varying levels of PROM, showing the separation of lines with OPCAB having lower MM.

Table 4 shows the observed mortality and stroke in each PROM quartile. As the PROM quartile increases, the mortality and stroke rates are higher in both OPCAB and ONCAB. This effect is also present with high-volume centers. Yet in all PROM quartiles, the observed rates of death and stroke in OPCAB were lower compared with those in ONCAB. The magnitude of that difference increased with