# On-Pump and Off-Pump Bypass Surgery
## Tools for Revascularization

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Cardiopulmonary bypass (CPB) has been fundamental to the development of coronary bypass surgery. Although some early coronary operations were performed without CPB, widespread coronary surgery only occurred with the aid of perfusion, a support system that has allowed complex coronary reconstruction to be carried out with effective myocardial protection, end organ protection, and consistent and relative safety.

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But CPB is not normal. Despite advances in perfusion technology, negative effects of CPB include blood trauma, activation of a series of inflammatory responses, nonpulsatile flow, and possible embolization of air or debris—most particularly embolization of atherosclerotic debris from the aorta. Within the last decade, increasing attention has been directed to the concept of decreasing perioperative risk by avoiding CPB: "off-pump" or "beating heart" bypass surgery. As a result of increased surgical experience and the development of enabling technology, such as stabilization and exposure devices, off-pump surgery has become increasingly feasible, and today, 20% to 25% of coronary operations in the United States are carried out without CPB.

We now know that off-pump bypass surgery can be accomplished, but does it decrease risk, what risks are decreased, and for whom? As the off-pump concept moved into the surgical arena, the hope was that it would decrease perioperative morbidity and possibly mortality, and the fear was that revascularization would be more difficult, less complete, and less effective over the long term. Multiple studies have addressed these issues, including observational studies of large patient populations using statistical risk adjustment, observational trials of smaller patient subsets thought to specifically benefit from off-pump surgery, and randomized trials. All of these study designs suffer from some disadvantages. Nonrandomized studies have the disadvantages of bias in treatment selection and the possibility that differences in patient-related characteristics will mask the effect of surgical strategy, and randomized trials have the disadvantages of bias at the point of inclusion into the study and the danger that small trials of selected patients will not be representative of the broader group of patients presenting for revascularization.

The study by Légaré et al[1] published in this month's *Circulation* is a trial of 300 patients (out of 933 eligible for randomization) who were randomized in the operating room to on- or off-pump surgery once it was determined that revascularization could be accomplished with either strategy.[1] Thus, it is a small trial of selected patients. Emergency operations in patients with an ejection fraction of <30% were excluded, and review of overall patient characteristics show a relatively good-risk patient population. Both the on- and off-pump groups received an average of 3 grafts per patient, and substantial numbers of arterial grafts were used. Twenty beating-heart patients (14%) were converted to the CPB group because of hemodynamic instability, and a patient in the CPB group was converted to the off-pump group because of the presence of ascending aortic atherosclerosis. The outcomes were excellent for both groups (1% mortality), and no significant differences in morbid events were noted, including such end points as transfusion requirement, intubation time, ICU time, and hospital stay.

To date, 3 other randomized trials of on- versus off-pump surgery have been completed and have shown either no outcome differences or small differences. Van Dijk et al[2] randomized 281 low-risk patients and found that blood utilization was slightly increased in the CPB group, as was enzyme release. Follow-up at 1 year after operation showed no neurocognitive differences.[3] In a single surgeon study, Puskas et al[4] noted similar and low mortality and stroke rates for on- and off-pump patients, but found the off-pump groups had lower transfusion rates and less enzyme release. A randomized trial from the United Kingdom documented lower hospital stay and a decreased risk of atrial fibrillation and blood transfusion for the off-pump group, but equivalent mortality and stroke rates.[5] The randomized trials that exist, therefore, have involved good-risk or standard-risk patients and have documented low procedure-related risk for both treatments. They also have documented equivalent revascularization for both treatment groups in terms of mean numbers of grafts performed per patient.

Other studies of on- versus off-pump surgery have been designed differently, have included different types of patients, and have produced different conclusions. Some large-database observational studies have attempted to use risk-adjustment strategies to account for bias in treatment selection. Al-Ruzzeh et al[6] reviewed the United Kingdom database for 1997 to 2001 and found significant differences in mortality, and neurological, pulmonary, and renal complications, all in favor of off-pump surgery. A report from the

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Society of Thoracic Surgeons National Database by Cleveland et al[7] noted a decreased risk of mortality and neurological, renal, respiratory, and bleeding complications in their off-pump group.

Single-institution observational trials have also noted differences, sometimes differences in major risk such as mortality and stroke, usually in favor of the off-pump approach.[8,9] Another consistent theme throughout the nonrandomized trials is a relatively high risk for the on-pump patients relative to the risks for either the on- or off-pump group in the randomized trials.

Therefore, in the "real-life" studies when multiple institutions are surveyed, there are high-risk patients included in on-pump groups that have not been included in the randomized trials. Exclusion of patients from the randomized trials has been at least in part based on deliberate exclusions of patients thought to be at high risk for CPB, for example, patients with severe ascending aortic atherosclerosis. These are sound exclusions based on ethical, patient-focused grounds. This policy, however, does make it more difficult for off-pump surgery to demonstrate an advantage, particularly in a small trial. It is also important to remember that randomized trials include not only selected patients but also selected surgeons, who are capable of performing surgery with either strategy. Surveys of nationwide practice patterns are likely to include surgeons who will not have the experience with off-pump surgery to be able to shift patients at high risk out of the on-pump group. The availability of off-pump surgery makes on-pump surgery safer. The fact that the randomized trials have not demonstrated a general superiority of the off-pump approach does not mean that off-pump surgery is not a superior strategy for some patient subsets.

The risks of CPB are not the same for every patient. Some observational studies have focused on smaller subsets of patients thought to be at high risk for perfusion and have shown dramatic benefit for the off-pump approach. A case-control study by Sharony et al[10] of patients with echocardiographically documented aortic atherosclerosis showed that the off-pump approach appeared to decrease the risk of mortality (3.8% versus 11.4%, $P<0.003$), stroke (2.4% versus 4.7%, $P=0.08$) and overall complication rate (8.1% versus 21.3%, $P<0.001$). Cleveland et al[7] also found a decreased rate of stroke for the off-pump group of patients in the STS Database labeled as having cerebrovascular disease. Ascione et al[11] noted a decreased risk of renal dysfunction with off-pump surgery.

It is also important to remember that off-pump surgery does not eliminate the danger of atherosclerotic embolization as long as partial occluding clamps are still used on the ascending aorta.[12] Increased experience with aortic connectors for proximal anastomoses and complex internal mammary artery (ITA) grafting offer the possibility of further decreasing the aortic trauma and embolization risk associated with off-pump surgery.

Elderly patients have been thought to be at increased risk for CPB, and multiple observational studies have focused on this subset. Virtually all of these studies have shown some benefit of off-pump surgery, usually a decreased risk of death and stroke, and some have shown a decreased length of stay.[13,14]

If there is some possibility of achieving a lower procedure risk with off-pump surgery, even though the difference may not be in major outcomes, why not utilize this strategy routinely and exclusively? The main issue is the effectiveness of revascularization. Great strides have been made in off-pump techniques such that the numbers of grafts per patient and graft patency data for off-pump patients have been documented to be very favorable.[8] However, despite improvement, the same revascularization cannot be achieved in every patient as is possible with on-pump surgery. Although revascularization in the randomized trials was equivalent, that has not been true in some observational trials of on- versus off-pump surgery, in which the number of grafts per patient was less for the off-pump group and complete revascularization was less common. In addition, complete revascularization is not the only criterion for effective revascularization. Increasing evidence has shown that multiple ITA graft strategies produce improved long-term outcomes when compared with the policy of using an ITA to left anterior descending artery (LAD) graft and vein grafts to other vessels.[15,16] The three prior randomized trials were basically ITA-LAD plus vein graft trials. The study by Légaré et al[1] did involve a high degree of ITA and arterial revascularization, although this was associated with a relatively high rate of crossover from off-pump to on-pump surgery.

Complex arterial grafting is not incompatible with off-pump surgery, but those strategies add another dimension of difficulty, particularly when patients need multiple anastomoses or sequential or composite arterial grafts, and have small, diffusely diseased or intramyocardial vessels. One clear conclusion that one can make from the minimal differences in perioperative morbidity documented in the randomized trials comparing off-pump and on-pump surgery is that for good-risk patients, it is not wise to compromise optimal revascularization for the purpose of performing the operation without CPB.

Off-pump surgery and CPB are both tools to achieve surgical myocardial revascularization. Both strategies are here to stay, and both have specific advantages and disadvantages in specific patient subsets. Today, it is our opinion that that following principles hold.

1. For low-risk patients, CPB is safe; measurable morbidity is not common; and randomized trials show small, if any, differences in procedure-related outcomes. CPB provides optimal exposure and an optimal surgical field, and, when complex revascularization is desirable—particularly using multiple ITA grafts—these operations are carried out efficiently using CPB.

2. Patients with severe ascending aortic and/or arch atherosclerosis or previous stroke are a group at increased risk during the use of CPB and may often benefit from off-pump surgery and, in particular, an off-pump surgery approach that minimizes aortic manipulation.

3. Elderly patients appear to experience a more rapid recovery and may have a lower stroke rate when off-pump surgery is used.

Both on-pump and off-pump surgical strategies are in evolution. Combinations of perfusion (either partial or total CPB) and beating-heart surgery are being explored. The "one size fits all" era is over, and multiple strategies for performing surgical revascularization are available and effective. The mission of coronary surgeons in the future will be to apply the approaches available to different subsets of patients in a way that maximizes long-term benefit and minimizes short-term risk.

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