オフポンプとオンポンプバイパス術技術は同等である（Abstracts # 13-LB-10677 and 13-LB-15974）

CORONARY trial：オンポンプバイパス術とオフポンプバイパス術に関する最大のスタディの結果、両者ともに安全に施行できることが証明された

CORONARY trial: Largest study of on-pump and off-pump bypass proves both can be done safely

人工心肺使用（オンポンプ）および人工心肺不使用（オフポンプ）で施行される冠動脈バイパス術を比較した結果、全体の技術に差はなかったが臨床的には明らかな差があったことが示されたとの研究結果が第62回American College of Cardiology学会で発表された。2007年10月以降、CORONARYトライアルでは、冠動脈疾患を有しCABGを予定された患者4,752人（平均年齢67.6歳、80.0%男性）を徹底的に評価し、確実にオフポンプまたはオンポンプ手術いずれもが適応であることを確認したあとでこれらのいずれかの手術に無作為に割り付けた。患者当たりの平均グラフト数は3.1であった。バイパス術後30日以内の死亡、心筋梗塞、腎不全および脳卒中からなる一次総アウトカムに関しては、統計学的に同等であった（オフポンプ患者9.9%およびオンポンプ患者10.3%）。同様に、この総アウトカムの個々のイベントについても差がなかった。オフポンプ手術の方が必要とする血液製剤の量、出血による再手術、肺合併症および急性腎障害が少なかったが、再血行再建術の施行がより多かった。この発現率はまれであった（オフポンプ群で2,375人中16人、あるいは0.7%に対しオンポンプ群で0.2%）。

Full Text

Two studies presented at the American College of Cardiology's 62nd Annual Scientific Session and simultaneously published online in the *New England Journal of Medicine* show similar efficacy for on- and off-pump heart bypass surgery.

In CORONARY, an international, multicenter trial of on-pump versus off-pump bypass surgery, enrolled 4,752 patients already scheduled to undergo a bypass procedure. The study is the largest to compare the two approaches.

For the primary endpoint of patients' composite outcomes of death, stroke, myocardial infarction or new kidney failure requiring dialysis within one year of surgery, researchers found no significant difference between patients receiving the off-pump and on-pump procedures (12.2 vs. 13.3 percent, $P = 0.24$.) The study previously looked at this primary endpoint for patients at 30 days and also found the two methods to be statistically neutral in the short-term, but conflicting results from other research studies raised uncertainty about patients' intermediate (one year post-surgery) and long-term outcomes.

"We found that both on-pump and off-pump bypass have similar results, even at one year," said Andre Lamy, M.D., lead author of the CORONARY study and professor in the division of cardiac surgery at McMaster University in Ontario. "Both surgical approaches are effective when provided by experienced surgeons."

Coronary artery bypass graft surgery (CABG) is one of the most commonly performed operations in the world and consumes more resources in cardiovascular medicine than any other procedure. In on-pump CABG, the patient's heart is stopped and blood is circulated through a heart-lung machine, where it is oxygenated and returned to the patient. In the off-pump technique, the surgeon uses a retractor to lift the still-beating heart and perform all coronary artery grafts. Off-pump CABG eliminates the need to insert a cannula into the aorta, cross-clamp the aorta, connect the patient to the heart-lung machine and stop and restart the heart.

The CORONARY study included patients from 79 centers in 19 countries who were scheduled to undergo CABG. Participants were randomly assigned to receive on-pump or off-pump CABG after a complete assessment to ensure they were appropriate for both techniques. In addition to the primary endpoint, researchers looked at the need for coronary revascularization between groups. This entails restoring blood flow to the heart through a repeat CABG or placement of a stent and indicates the initial CABG procedure was not successful. Again, results were similar between groups with 1.4 percent of patients in the off-pump group and 0.8 percent of patients in the on-pump group requiring this additional procedure.

The study also assessed the neurocognitive function and quality of life of patients in each group through the use of standardized scales.

"We found a transient improvement in neurocognitive function at hospital discharge among those receiving an off-pump bypass," Dr. Lamy said. "But at one year, our results are similar with both techniques."

According to Dr. Lamy, this transient difference in patients' neurocognitive functions came as a surprise to researchers, as smaller studies have shown evidence of short-term neurocognitive declines among patients receiving both types of bypass. Researchers found patients' quality of life to be similar after both on- and off-pump bypass.

The CORONARY study results differ from those emerging from another large trial that suggested improved outcomes at one year with on-pump surgery. According to Dr. Lamy, this discrepancy is likely related to surgeons' expertise in the two techniques, as well as the surgical risk of each patient.

"Compared to the other trial, our patients were older and sicker, and our surgeons were more experienced, particularly in performing off-pump bypass," he said.

Off-pump bypass requires a higher degree of surgical expertise since the operation occurs while the patient's heart is still beating. Thus, surgical expertise is a key factor affecting patient outcomes, and it is possible that other studies have not controlled for this, Dr. Lamy said.

All surgeons participating in the CORONARY study were required to have performed a minimum of 100 cases in the approach used, though the vast majority of surgeons in their study were highly experienced in both types of procedure, Dr. Lamy said.

"The CORONARY study shows that off-pump bypass is just as good as on-pump. Therefore, surgeons should tailor their surgical approach to their technical expertise and expected technical difficulty," Dr. Lamy said.

The CORONARY study will follow patients for five years. Researchers hope this continued evaluation will provide needed evidence about the success of on- and off-pump bypass beyond the first year.

The CORONARY study was supported by a grant from the Canadian Institutes of Health Research.

The second study is the large, multicenter trial—the German Off-Pump Coronary Artery Bypass Grafting in Elderly Patients, called GOPCABE. It was the first study to evaluate on-pump versus off-pump bypass surgery among patients aged 75 or older. The primary endpoint was individual patients' combined outcomes of death, stroke, heart attack, repeat revascularization or new renal replacement therapy within 30 days of surgery. Researchers found no significant difference in the primary endpoint between patients receiving the on-pump and off-pump procedures (8.2 vs. 7.8 percent, $P = 0.74$).

"Our study shows that coronary bypass surgery can be performed in the elderly population with excellent results, and this is equally true for both techniques," said Anno Diegeler, M.D., Ph.D., head of the department of cardiovascular surgery at the Heart Center Bad Neustadt in Germany and the study's lead investigator. "These findings suggest clinicians can select the lower cost off-pump procedure without risk to the patient."

Previous studies comparing the two techniques also found similar results for on-pump and off-pump CABG, but none of these studies focused exclusively on elderly patients. To address concerns that the elderly may not benefit equally from both techniques because of their higher risks, GOPCABE enrolled 2,539 patients aged 75 or older scheduled for elective, first-time CABG in 12 cardiovascular centers in Germany. Patients were randomized to receive on-pump or off-pump CABG. Results for all components of the primary endpoint were similar between the groups at 30 days. Patients had no significant differences in rates of death (2.8 vs. 2.6 percent), stroke (2.7 vs. 2.2 percent), heart attack (1.7 vs. 1.5 percent), and new renal replacement therapy (3.1 vs. 2.4 percent), and a slim difference in repeat revascularization (0.4 vs. 1.3 percent). At 12 months, researchers again found no significant difference in the composite endpoint between on- and off-pump (14.0 vs. 13.1 percent, $P = 0.483$).

Study results are important for surgeons who favor off-pump surgery, Dr. Diegeler said.

"For surgeons who prefer off-pump surgery, our study confirms that off-pump CABG is safe and the quality is equal to on-pump surgery for elderly patients. At 12 months, we had a survival rate of 93 percent among our off-pump patients and 92 percent for on-pump," he said. He notes that the surgeon's level of experience is critical in assessing the two techniques.

According to Dr. Diegeler, the similar result from both techniques is beneficial to facilities and patients in developing countries, where the on-pump procedure may come at a higher cost since instruments used in off-pump CABG can be re-sterilized, but components of the machine used in on-pump cannot.

While this study provides support for the efficacy and safety of both CABG techniques in the elderly, Dr. Diegeler said further work is needed to look at CABG outcomes in other special populations, including patients deemed high-risk for surgery.

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