

オンポンバイパス術とオフポンバイパス術の短期予後は同等である

CORONARY trial: オンポンバイパス術とオフポン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）および人工心肺不使用（オフポン）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61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、確実にオフポンまたはオンポン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（オフポン患者9.9%およびオンポン患者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（オフポン群で2,375人中16人、あるいは0.7%に対しオンポン群で0.2%）。

Full Text

A large randomized trial comparing bypass surgery done with a heart-lung machine (on-pump) and without it (off-pump) found no differences in results between techniques overall but some clinically relevant differences, according to research presented at the American College of Cardiology's 61st Annual Scientific Session.

Off-pump coronary artery bypass graft (CABG) surgery eliminates the need to insert a cannula into the aorta, to cross-clamp the aorta, connect the patient to the heart-lung machine, and stop and restart the heart, suggesting that patients would do better with this approach. However, small, randomized clinical trials and meta-analyses have not been able to determine conclusively whether one CABG technique has better outcomes than the other. The CORONARY trial, conducted at 79 centers in 19 countries, compared the risks and benefits of off-pump and on-pump bypass in the largest patient population studied to date. While the CORONARY trial was recruiting patients, data from the ROOBY (Randomized On/Off Bypass) trial were published showing poor results for off-pump bypass.

"After ROOBY's results, we looked again at our trial design and decided to continue, with the approbation of the Data Safety Monitoring Board," said André Lamy, MD, Division of Cardiac Surgery at Canada's McMaster University in Hamilton, ON, and one of the study's three lead investigators. "ROOBY was done through the U.S. Veterans Administration at only 18 hospitals. Our trial was international and much larger, it had more women and sicker patients and our surgeons were more experienced in off-pump procedures"

Since October 2007, the CORONARY trial has enrolled 4,752 patients with coronary artery disease who were slated for CABG and randomly assigned to off-pump or on-pump surgery after a complete assessment to make sure they were suitable candidates for both techniques. The mean patient age was 67.6 years, 80.9 percent were men and the average number of grafts was 3.1 per patient.

For the primary composite outcome of death, myocardial infarction, kidney failure and stroke at 30 days post-bypass, the results were statistically neutral: 9.9 percent for off-pump patients and 10.3 percent for the on-pump group. Similarly, no differences were seen for individual events of the composite outcome. These results were a surprise to the researchers. Based on previous meta-analyses, Dr. Lamy and his colleagues expected that off-pump CABG would decrease the rate of stroke and renal failure.

"We found that off-pump did reduce the amount of blood products needed, reoperation for bleeding, pulmonary complications and acute kidney injury, but there was also more revascularization in off-pump patients, meaning that surgery didn't work completely," Dr. Lamy said. This was a rare occurrence (16 of 2,375 patients, or 0.7 percent versus 0.2 percent in the on-pump group), but it is considered a technical failure and requires the patient to return to the operating room for a repeat CABG or for a stent in the cath lab, where imaging systems guide those catheter-based procedures.

"This introduces a new concept in cardiac surgery, allowing patient-specific decisions for bypass surgery," Dr. Lamy said. "Off-pump procedures are trickier and more stressful, and the benefit is for the patient, not the surgeon, so in many places, they're simply not done. My goal is to persuade surgeons to individualize the technique – to do off-pump bypass or on-pump when indicated – so their patients will benefit."

The CORONARY trial will conduct safety and efficacy follow-up at five years and assess total costs and neuro-cognitive results at 30 days and at five years after CABG. The 30-day cost data and neuro-cognitive results are expected within six months.

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