

EDITORIAL

Patency in Off-Pump Coronary Artery Bypass Graft Surgery

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Khan et al [Khan 2004] recently reported a study in which 104 patients with triple-vessel disease were randomized to either off-pump or on-pump coronary artery bypass graft (CABG) surgery. Khan et al observed a significant reduction in the angiographic patency at 3 months in the off-pump group. I wish to highlight some weaknesses of the study, and the report.

In an accompanying editorial [MacGillivray 2004], MacGillivray and Vlahakes refer to the technical skill of the surgeons and its impact on anastomotic patency. There is no doubt that off-pump surgery is technically more demanding, and this is one of the reasons why it has not been more widely adopted. The authors [Khan 2004] state that in the 2 years before the study began, 98 (13%) of 753 isolated CABG operations performed by the 2 participating surgeons were done using the off-pump technique. Therefore if both surgeons had done a similar number of cases, each would have done fewer than 50 off-pump cases in the preceding 2 years. Because these cases would have been treated early on in the physicians' experience and constituted only 13% of their practice, a significant proportion of these cases would have been patients with 1- or 2-vessel disease. On the basis of this experience, the surgeons cannot be considered experienced in the off-pump technique, especially for 3-vessel disease patients, who were the subjects of their study. In the Beating Heart Cardioplegic Arrest Studies (BHACAS) trial [Angelini 2002], the surgeons initially excluded patients who needed grafts in the posterior territory, because surgery in these patients is technically more complex. Only when the surgeons had obtained sufficient experience (200 patients) with the off-pump technique was the trial extended to all patients with 3-vessel disease. The surgeon in the Surgical Management of Arterial Revascularization Therapies (SMART) trial [Puskas 2003] had performed at least 200 operations [Puskas 2001] before embarking on the randomized controlled trial (RCT). Along with my colleagues, I have previously reported an RCT [Zamvar 2002] comparing the off-pump and on-pump techniques. I had performed 150 off-pump CABG operations (80% of my CABG practice) in the 14 months

before the commencement of the trial. To be absolutely comfortable with both techniques must be a prerequisite for the surgeons performing a surgical RCT.

In surgical trials, experience of the surgeons performing the trial is critically important. Khan et al [2004] contend that surgical skill was not a factor in their trial, because they had high patency in the on-pump group. This argument is flawed. Even though the generic skills required to perform off-pump and on-pump CABG are the same, there are many other differences, and the off-pump procedure is technically considerably more demanding.

One detail missing from the report is the patency rates in the off-pump group for the individual surgeons. Randomization was stratified according to the surgeon, so that both surgeons performed similar numbers of on- and off-pump procedures. Was there any difference between the two surgeons in the patency rates in the off-pump group? An initial analysis of the study was presented at the International Society of Minimally Invasive Cardiothoracic Surgery (ISMICS) meeting in New York in June 2002, and the presenting author mentioned that most of the nonpatent grafts in the off-pump group occurred in procedures performed by one particular surgeon. This observation is obviously very important, and should have been included in the report. A significant difference between the two surgeons in the proportion of nonpatent grafts would of course make substantial difference to the conclusion of the paper.

Inappropriate citation of references is presented in the introductory paragraphs. The authors quote two studies [Roach 1996, Newman 2001] to support their statement that cardiopulmonary bypass (CPB) is believed by many to be a major cause of postoperative morbidity, including neuropsychological impairment. The first paper [Roach 1996] reported a study of the predictors of type I and type II cerebral outcomes but did not mention CPB as an independent predictor of neuropsychological impairment. The second paper [Newman 2001] reported longitudinal assessment of neurocognitive function after CABG surgery and identified predictors of cognitive decline. Again, CPB was not one of them. RCTs have been reported that show that off-pump CABG surgery is associated with marked [Zamvar 2002] or modest [van Dijk 2002] decrease in cognitive dysfunction.

The authors quote two studies [Subramanian 1997, Sabik 2002] to say that there is some evidence that off-pump surgery increases the risk of recurrent angina and the need for reoperation. The report by Subramanian [1997] was a study of 199 patients who had minimally invasive CABG surgery through

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minithoracotomy, subxiphoid, or lateral thoracotomy incision. Technically, these operations are very different from the off-pump CABG operations done via a median sternotomy. Sabik [2002] studied hospital outcomes in patients undergoing off-pump or on-pump CABG surgery. Neither of these two papers states that the risk of recurrent angina or need for reintervention was increased in patients undergoing off-pump surgery.

RCTs occupy a very high position in the hierarchy of evidence, and it is essential that reporting of RCTs be to a very high standard. The CONSORT (Consolidated Standards of Reporting Trials) statement [Altman 1996] was adopted for this reason. It is surprising that these issues escaped the attention of the peer-reviewing process of the *New England Journal of Medicine*.

“What we hope to do ever with ease, we must first learn to do with diligence.”

Samuel Johnson

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