Letters to the Editor

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Off-pump versus conventional coronary artery bypass grafting: Randomized studies

To the Editor:

We congratulate Puskas and colleagues[1] on their prospective, randomized study assessing the efficacy of off-pump coronary artery bypass grafting (CABG) relative to conventional CABG techniques. We are pleased to see that their early in-hospital findings are similar to the results of the Beating Heart Against Cardioplegic Arrest Study (BHACAS) 1 and 2 trials conducted by our group.[2] Indeed, since our first randomized study[3] several others have been published, some with respectable sample sizes,[4-5] and the Surgical Management of Arterial Revascularization Therapies (SMART) trial is the latest in this series. We appreciate that the available presence of all these trials somehow reduces the "visibility" of each of them, particularly if they are not the first or the largest.

Puskas and colleagues[1] (a total of 17 authors of the SMART trial) in the introduction of their article state, "Moreover, most previous studies have failed to adequately address legitimate concerns about the completeness of revascularization provided or to document the quality of anastomoses." Furthermore, they state, "There have been no published reports comparing OPCAB versus CABG with CPB among randomly assigned patients unselected for coronary anatomy, ventricular function, or comorbidities." This is simply not the case.

The BHACAS 1 trial was the first ever randomized study, carried out between March 1997 and August 1998. The randomization rate was 32%, and all patients underwent complete coronary revascularization. The limited number of grafts per patient was the result of stringent selection criteria that excluded those who needed grafting of the distal branches of the circumflex artery, because this was regarded as too difficult at the beginning of our experience with off-pump CABG surgery.

After establishing the safety of the technique, we then moved to BHACAS 2 (September 1998 through November 1999), in which coronary anatomy was not an exclusion criterion. We excluded from the study emergency and salvage operations and patients with such potentially confounding variables as previous stroke, renal failure, and reoperative CABG, which might have affected the interpretation of clinical outcome. Nevertheless, the off-pump and conventional CABG groups of BHACAS 2 included 48% and 43% of urgent in-hospital unstable angina referrals, 17% and 13% of those with previous myocardial infarction less than 14 days before surgery, 24% and 23% of patients with ejection fraction less than 50%, and 32% and 30% of patients with diabetes, respectively. The overall randomization rate was 63%, a much higher percentage than the 43% reported by Puskas and colleagues.[1] More importantly, we achieved a homogenous distribution of risk factors between groups. This unfortunately did not happen in Puskas and colleagues' SMART trial,[1] where for example the values for previous stroke history were 9% and 1% ($P = .018$) in the on-and off-pump groups, respectively.

The BHACAS trials also provided midterm clinical outcomes, with particular attention to mortality and cardiac-related events, both as single trial or pooled analysis of the 401 randomized patients, and concluded that off-pump CABG significantly reduces early in-hospital morbidity without compromising outcome in the first 1 to 3 years after surgery relative to conventional on-pump technique. We believe that when bringing to light new evidence it is important to present in a complete and objective fashion what is already available in the literature: "Give to Caesar what is Caesar's."

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Reply to the Editor:

Drs Ascione and Angelini have written to emphasize the contributions they have previously made in conducting and reporting randomized clinical trials of off-pump coronary artery bypass grafting (CABG) versus CABG with cardiopulmonary bypass (CPB). Indeed, these authors and their coworkers have made numerous contributions to our understanding of patient outcomes with these two surgical techniques. Among their contributions is a series of publications reporting various outcome variables from two groups of selected patients randomized to undergo OPCAB or conventional CABG/CPB. As they have noted in their own letter to the Editor, the first of these groups of patients was selected to exclude those requiring grafts to the distal branches of the left circumflex artery, whereas the second group was selected to exclude patients with previous stroke and renal failure, as these were considered potentially confounding variables. Both studies reported important advantages of OPCAB over conventional CABG/CPB and were landmark publications. Neither rigorously documented the completeness of revascularization. Indeed, BHACAS 2 reported that 70% of CPB patients versus 56% of OPCAB patients had 3 grafts or more; this difference (the manuscript does not state whether this was a statistically significant difference) was especially noted in grafts to the lateral wall of the left ventricle. The mean number of grafts per patient in each group was not reported.[1]

In the SMART trial,[2] my coauthors (to each of whom I am grateful) and I sought to demonstrate that OPCAB could be safely applied to the general population of patients referred for elective surgical coronary revascularization and that an equivalently optimal revascularization could be achieved in both groups. Patients were not excluded on the basis of any coronary anatomy, ventricular dysfunction, or comorbidities, including prior stroke or renal failure. Indeed we believed it important to randomize "all comers," and we did so. Thus, this trial compared outcomes among truly unselected patients referred for nonemergency CABG. (Among the numerous demographic variables tracked, incidence of prior stroke was regrettably different between the randomized groups. This is a simple function of sample size.) We believed it important to document the optimal revascularization that should be performed for each patient before randomization. The grafts actually performed were then compared with those intended, creating a formal index of completeness of revascularization (ICOR), which was found to be virtually identical between groups. The ICOR was also similar between groups for the lateral wall of the left ventricle, documenting that OPCAB with modern stabilizing devices could provide complete revascularization of all areas of the heart in unselected patients. Other end points, including serum levels of myocardial enzymes, transfusion requirement, and length of stay, strongly favored the OPCAB group, consistent with the findings of previous randomized trials in selected patients.

We look forward to reporting angiographic graft patency and longer term outcomes from these randomized cohorts as those data become available, building on the important foundation that Drs Ascione, Angelini,[1] Van Dijk,[3] Diegeler,[4] Czerny,[5] Zamvar,[6] and others have laid.

> *"I prefer nothing more than that I should be true to myself and they to themselves."*
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> *—Julius Caesar, letter to Cicero, quoted in Cicero, Letters to Atticus, 9.16.2.*

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Abdominal tumors with cavoatrial extension

To the Editor:

We congratulate Chiappini and associates[1] on their outstanding results in the treatment