Improved Early Outcomes After OPCAB: When Will the Final Answer Come?

To the Editor:

Off-pump coronary surgery is an alternative technique currently under clinical evaluation to define its role and indication in the therapy for ischemic heart disease. Magee et al.1 retrospectively analyzed standard on-pump (CABG) and off-pump (OPCAB) coronary bypass cases from the years 1999 and 2000 in the Society of Thoracic Surgeons database. Using risk adjustment and propensity analysis to correct for nonrandom treatment assignment, they suggest that OPCAB is associated with some degree of early survival benefit and reduced perioperative morbidity. This is in accordance with the conclusion previously drawn by other authors using similar statistical methods to correct for selection bias.2,3

In our opinion, these data are not conclusive. In fact, risk adjusting and balancing score methods are not substitutes for randomized clinical trials, as they cannot correct for known variables that might affect the outcome but are not reported in databases (ie, coronary anatomy and surgeon skill, as correctly reported by the authors).4 In addition, and even more importantly, this statistical approach cannot correct for unknown variables, which might affect outcomes, not correlated strongly with measured variables.4 Also, differences in outcomes as reported by Magee et al.4 are quite small, and large prospective studies enrolling thousands of patients are needed to confirm these data. Indeed, a prospective randomized study detecting statistically significant differences in 30-day mortality (2.91\% CABG versus 2.40\% OPCAB) requires the randomization of 15,598 patients in each treatment group (\(\alpha=0.05\), power=0.8). Up to now, only a few small randomized studies have been published, and a recent meta-analysis failed to show any statistically significant early clinical benefit between CABG and OPCAB.5

For these reasons, possible clinical benefits of OPCAB versus CABG remain a perception of some, but not all, surgical teams that dedicate their efforts to the improvement of this technique, but the final answer to this question is not expected to come soon.

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Response

We appreciate the cogent observations and comments of Parolari et al regarding our recent analysis1 from the STS National Cardiac Database of over 200,000 patients undergoing coronary artery bypass surgery (CABG) during a 2-year period. As the authors imply, in the hierarchy of clinical investigation, the large, prospective, randomized trial holds the highest order of evidence. Yet 8 years after the introduction of beating-heart surgery into routine clinical practice, only 5 randomized, single-center trials comparing on-pump and off-pump CABG have been completed, enrolling fewer than 1400 patients cumulatively. Furthermore, only one multicenter, randomized study of 2200 patients is currently underway in the United States (Veteran’s Administration). With enrollment only 35\% complete, it will be many years before outcomes evidence is available.

The next tool of clinical investigation in the hierarchy of outcomes study is the retrospective analysis of large outcomes databases using propensity score computer matching to correct for selection bias, as was done in our study.1 This has been referred to as “randomization after the fact.” We concur with Parolari et al and acknowledge that there are limitations inherent to this analysis as a result of unreported or indeterminate variables in the database and lack of prospective randomization. Despite these limitations, it provides the advantage of more rapid evaluation of outcomes in a larger number of patients who are more representative of “real-world” CABG surgery than those selected to meet the inclusion criteria of a randomized trial.

A large, prospective, randomized clinical trial comparing off-pump and on-pump coronary artery bypass has not been forthcoming and, if completed, will also have significant inherent limitations. Indeed, such a clinical trial could not be justified without conclusive supporting data from large, retrospective comparisons such as this one. We disagree that the data in this study are not conclusive. To the contrary, the differences in outcomes are indeed not small but highly significant according to sophisticated statistical analyses.

The hypothetical trial referred to by the authors is neither underway nor planned in the foreseeable future. Until this can be completed, large (>16,000 patients per treatment group compared in this study), retrospective, “randomized” comparisons based on propensity matching and risk stratification to account for selection bias offer the next best available data for evidence-based practice and add valuable information to the complex process of evaluating surgical procedures.

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