The role of the ASCERT study in the current treatment of multivessel coronary artery disease

“...is to keep our focus not on our turf or our profession, but instead on the care of our patients.”

Fred H Edwards
University of Florida, STS Research Center, 633 N St Clair St, Chicago, IL 60611, USA
Tel.: +1 312 202 5882
Fax: +1 312 202 5867
fred.edwards@jax.ufl.edu

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After two decades of debate, we are still asking the familiar question: “Which patient should have percutaneous catheter intervention and which should have coronary artery bypass grafting?” There does seem to be general agreement on the factors used to make the decision. Short- and long-term survival, stroke rate, the need for reinervention, myocardial infarction, and patient preference all enter the equation.

Fortunately, in recent years, several important studies comparing percutaneous coronary intervention (PCI) with coronary artery bypass grafting (CABG) have shed light on these outcomes so that a clearer picture is beginning to emerge. The SYNTAX [1] and FREEDOM [2] trials have proved particularly valuable in the randomized group, while the large NY State studies [3] and the ASCERT study [4] have used a retrospective observational study design. It is particularly important to note that the results of both the randomized trials and the observational studies are now remarkably consistent.

The largest of these studies is the ASCERT study, which used information from the Society of Thoracic Surgeons National Database linked to data from the National Cardiovascular Data Registry to create a cohort of almost 190,000 patients that were, in turn, linked to Medicare data [4]. It should be emphasized that the ASCERT population consisted of Medicare-aged patients having two- and three-vessel coronary disease requiring nonemergency revascularization. To minimize the impact of selection bias, an exhaustive statistical approach was undertaken to include inverse probability weighting, ‘double robust’ propensity scoring, and propensity matching. Results were virtually the same for each approach. A detailed analysis was carried out to explore the possibility that an unmeasured confounder could account for the differences in PCI and CABG survival. This analysis demonstrated that an unmeasured confounder, if present, would have to be quite prominent, with a risk ratio similar to the presence of diabetes.

One might still ask whether the results of ASCERT are valid? Some have claimed that the results should not be given serious consideration simply because ASCERT is an observational study, and the results of observational studies should not be used to influence clinical decisions. This convenient dismissal ignores the fact that we use the results of observational studies to influence our decisions nearly everyday. Another criticism is that frailty was not taken into account. That is true, but how many other studies have used frailty in their analysis? Some have claimed that the histogram of the propensity model demonstrates selection bias owing to the very high and very low numbers at each extreme of the abscissa. The propensity model was designed to predict the probability of CABG. The curve simply demonstrates the number of patients undergoing CABG with a given propensity score. Of course, if the model predicts a high probability of CABG, then we would want to see a high number of CABG procedures. The fact that the model shows just this tells us that the model is performing as we would expect; it has nothing to do with selection bias.

Other criticisms of ASCERT are easily addressed as well, but no one would claim it is a perfect study. What then should we make of it? As a principal investigator, I will be quick to point out that ASCERT, alone, does not lead to firm conclusions about the relative outcomes of PCI and CABG. However, when taken in context with other contemporary studies, ASCERT occupies a central position echoing the results of other studies, both randomized and observational. ASCERT is the large, national, multi-institutional study of real-world patients that confirms outcomes seen in contemporary studies of select randomized trials and smaller regional observational studies.
It is worthwhile to illustrate these consistent findings. Currently, only the ASCERT survival results have been published, although a manuscript is now being developed to present a comparison of PCI and CABG stroke rates, myocardial infarction rates, and a composite of stroke, myocardial infarction and death. Accordingly, only the ASCERT survival results can be presented here.

At 4 years, the CABG mortality was 16.4% compared with 20.8% for PCI. The CABG:PCI risk ratio was 0.79 (95% CI: 0.76–0.82) at 4 years, indicating a 21% survival advantage for CABG. These results are consistent with several recent observational studies [3,5,6] and at least two contemporary randomized trials [1,7]. Survival results of the ASCERT diabetic population were similar to the results reported in a recent randomized study of diabetics [2]. A pooled analysis of 7812 patients in ten randomized trials demonstrated a CABG survival advantage in patients over 65 years of age (hazard ratio: 0.82; 95% CI: 0.70–0.97) [8].

Certainly, in the stent era, there are small randomized trials showing no survival advantage of CABG compared with PCI, but the majority of larger studies are consistent with the survival results found in ASCERT [10,11].

Therefore, the role of ASCERT is to provide real-world affirmation of the CABG long-term survival advantage reported in both current randomized trials and observational studies. Forthcoming reports from ASCERT will address the nonfatal outcomes in a similar fashion. As pointed out above, survival is one of several considerations in choosing the optimal mode of coronary revascularization. Nonfatal outcomes, such as reintervention and myocardial infarction, generally favor surgery, while neurologic complications usually favor PCI. In the upcoming publications from ASCERT, we envision providing the national real-world perspective on the relative importance of these nonfatal outcomes.

The practical application of ASCERT, as well as the other contemporary studies, lies in the thoughtful unbiased presentation of scientific evidence to our patients. The importance of an authentic ‘heart team’ approach has been emphasized as the ideal conduit for this kind of exchange between the cardiologist, surgeon and patient [12]. The key, as always, is to keep our focus not on our turf or our profession, but instead on the care of our patients.

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