An impossible task done well

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It is both critical and timely for experts of The American Association for Thoracic Surgery to provide our specialty with guidelines for the treatment of atrial fibrillation (AF) because of the frequent association of this arrhythmia with patients undergoing coronary artery bypass grafting surgery, valve surgery, and other less common procedures for acquired cardiac disorders. Numerous observational studies have shown that the concomitant treatment of AF in these patients improves the subsequent quality of life, decreases the incidence of thromboembolism and stroke, and even improves life expectancy relative to patients in whom the AF was either ignored or treated unsuccessfully. However, these AATS guidelines represent the first time that the academic leaders of our specialty have clearly defined their recommendations on how AF associated with more common cardiac surgical problems should be handled. The guidelines confirm that adding arrhythmia surgery concomitantly to CABG and valve surgery actually improves operative mortality and does not increase perioperative morbidity on the basis of level A evidence. For the first time, the guidelines also define the appropriate energy sources to be used and support both hybrid and epicardial ablation. Most importantly, the guidelines support the need for more structured education and training in the field of arrhythmia surgery.

The dilemma for guideline writers is that the only available randomized, controlled trials (RCTs) on this subject are often less definitive in confirming or refuting the salutary effects of treating the AF. We believe that this dichotomy between the findings of observational studies and RCTs says more about the difficulties of controlling randomized trials in cardiac surgery than it says about the benefits, or lack thereof, of concomitant AF surgery.

In their monumental effort at fairness and objectivity, the experts who formulated these new guidelines laboriously included the findings of both observational studies and RCTs. Although this effort is laudable, it often results in confusion and the feeling that AF could be either treated concomitantly or completely ignored and the surgeon would still be in compliance with the practice guidelines. The guideline authors had no choice but to include the available RCTs, no matter how weak and misleading many of them are, because of the slavish dependence of all fields of medicine on the infallibility of RCTs. Indeed, this unquestioned devotion to the validity of RCTs, especially in the nonsurgical medical specialties, demands that all available RCTs be included in these guidelines, even though none of them have a follow-up period of more than 1 year. RCTs are excellent for evaluating certain treatment interventions in medicine, such as the effects of a single drug, but it is problematic in the extreme when they are viewed as being the only valid way to “prove” the safety and efficacy of a specific cardiac surgical intervention. In cardiac surgery, such trials may be “randomized,” but they are usually not adequately “controlled.” Moreover, RCTs tend to marginalize the importance of basic science studies. Do we really need a prospective, randomized trial to “prove” that insulin is an effective therapy for diabetes mellitus, or can we continue to depend on the vast body of basic science and decades of clinical experience for the answer?

Here is but one example of the confusing recommendations that result from the obligation to include RCTs that were not properly controlled or lacked a sufficient follow-up period to answer the question being posed. Recommendation 3 under Research Question 2B regarding late stroke
and transient ischemic attack (TIA) states, “Overall, addition of a concomitant surgical ablation procedure for atrial fibrillation does not change the incidence of late stroke/TIA, but subgroup analysis of non-randomized controlled trials (RCTs) found a significant reduction in late stroke/TIA incidence.” So the question remains, should concomitant AF surgery be performed specifically to reduce late stroke, or should it not? Multiple studies by multiple surgeons have shown that by performing AF surgery correctly, the subsequent stroke and TIA incidence not only is decreased but is virtually eliminated! Yet because this has not been technically “proved” by any RCTs, a surgeon who believes that RCTs are more valid than observational studies in cardiac surgery could choose to ignore the AF and still find justification within these guidelines.

If we could wean ourselves from the dependency on RCTs to guide our clinical practices in cardiac surgery, our patients would be better served. Although RCTs are invaluable in some specialties, we maintain that they are detrimental and dangerous in cardiac surgery, because it is impossible to control all the variables of a cardiac surgical procedure between two surgeons, much less among multiple institutions. The experts who wrote these guidelines are to be congratulated for making a valiant effort to recognize the near universal confidence in RCTs while still using the numerous observational studies to document that our patients are better served by ridding them of AF whenever possible. This exercise in guideline writing deserves a Pulitzer Prize for creativity; however, we fear that, unfortunately, many cardiac surgeons are going to continue to be unconvinced of the benefits of adding concomitant AF surgery to the primary cardiac surgical procedure.

Reference