

Evidence-based cardiac surgery

Lawrence H. Cohn, MD

Earlier this year I attended the Cardiovascular Conference at Snowmass, Colorado, one of the longest running cardiology postgraduate courses (approximately 37 years), which brings together thought leaders in the various areas of acquired heart disease. I came away from this meeting very impressed that cardiologists worldwide are deriving an increasing amount of what they apply to their practice and care of their patients from evidence-based cardiology studies. Approximately 100 prospective randomized studies, mostly related to coronary artery disease, were discussed during that week, with enough study acronyms to test the most agile thinker. I reflected on this and wondered, (1) what are we doing in cardiac surgery to validate many of the applications we believe are the best techniques and therapies for patients, and (2) do we fully understand that our medical counterparts are basing their therapy for patients, including surgical therapy, on these evidenced-based studies?

Clearly, coronary artery bypass surgery has been reviewed in many of these trials. Recent studies from database outcomes strongly suggest that coronary artery bypass grafting (CABG) should be more frequently used than stent placement inasmuch as CABG is associated with fewer long-term morbid events than coronary stenting.^{1,2} But when it comes to comparison of different forms of commonly used surgical techniques and technologies for valve surgery, arrhythmic surgery, and heart failure, there is a paucity of evidence-based trials. At that same meeting in January, I presented data from the Brigham and Women's Hospital related to "hybrid" therapy for combined aortic valve and coronary disease in high-risk, elderly individuals: an elective, minimally invasive aortic valve replacement performed after a percutaneous coronary intervention in the morning for moderate coronary disease with the intent to decrease operation time and trauma. Clearly, this is a pilot study for feasibility, safety, and effectiveness, but the *first* question I received from the audience was, "Have you done a prospective randomized study validating this therapy against the standard form of therapy with a full sternotomy and combined aortic valve replacement and coronary artery bypass surgery?"

Not only should cardiovascular surgeons focus more on evidence-based studies, particularly for areas clearly controversial, but we also should be leading the way in organization and performance of these studies. One of the few prospective randomized valve surgery studies that has shaped my practice is the one by Cohen and associates,³ who, in a prospective randomized study, demonstrated that stentless versus stented bioprosthetic valves offered no advantage in mortality, left ventricular remodeling, or reduction of left ventricular masses. Similarly, the REMATCH (Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure) trial,⁴ a very important evidence-based study, one of a very few in the area of heart failure, demonstrated that therapy with a left ventricular assist device is better than medical therapy for end-stage heart failure.

I believe we need to be proactive in many areas of investigation. Lately, some in our specialty have been lamenting about the reduction of caseload and referral of patients to medical and interventional therapy, without really understanding the mindset of our cardiology colleagues. We have to be more aggressive in promoting studies to prove which surgical therapies are the best therapies so that we not only compete with our cardiologic colleagues, but demonstrate to an increasingly informed patient population that there is evidence demonstrating one surgical technology is better than another.

From the Division of Cardiac Surgery, Brigham and Women's Hospital and Harvard Medical School, Boston, Mass.

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Address for reprints: Lawrence H. Cohn, MD, The Department of Surgery, Brigham and Women's Hospital, 75 Francis St, Boston, MA 02115-6110 (E-mail: lhcohn@bics.bwh.harvard.edu).

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Many examples of knowledge gaps exist. One glaring example that clearly needs clarification is the surgical treatment of atrial fibrillation. There is need for multiple studies on a prospective randomized basis to review catheter techniques versus the new surgical techniques, technology versus technology, to determine success rate and reproducibility of minimally invasive techniques versus standard surgical therapy. Even ablation of the left atrial appendage has yet to be studied in a prospective manner. We (and that includes cardiologists) cannot even agree on what "success" is after atrial fibrillation procedures. If we do not perform these studies, I am concerned that payors may doubt the validity of certain procedures and may request these studies or perhaps label them experimental.

As noted, many surgeons are also talking about "hybrid" therapy and building operating suites to perform combined CABG/valve procedures with minimally invasive methods. We need to validate these approaches. We need more critical studies on heart failure devices, especially with cardiac defibrillators and ventricular resection,² and we need more studies related to off-pump versus on-pump CABG.

The increasing use of clinical outcomes databases (such as The Society of Thoracic Surgeons database) by cardiac surgeons can be leveraged to suggest the most fruitful areas for prospective analysis. The National Institutes of Health and other funding nonprofit organizations are the preferred pathways for these studies. At the recent meeting of The

American Association for Thoracic Surgery, the National Institutes of Health, recognizing the need for more evidence-based surgical studies, convened a request for proposal for the establishment of a cardiac surgical research and outcomes network. More than 30 hospital-based units appeared at the orientation and information session eager to participate. Finally, we must understand the American Heart Association/American College of Cardiology cardiac disease guidelines, such as the soon-to-be released valvular heart disease guidelines compiled after an exhaustive meta-analysis of worldwide valve disease literature.

I think we as an aggressive, intelligent community of cardiovascular specialists can and should find ways to determine our future and the future care of our patients in a much more critical and evidence-based manner.

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