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LEADERSHIP PAGE

The ACC Looks to Balance Emerging Science and Clinical Practice Guideline Development

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A number of new clinical trials released over the last few months have caused both physicians and the media to raise questions about the need to change current clinical practice guideline (CPG) recommendations. Answers to these questions must reflect back on the careful and collaborative methods by which the American College of Cardiology (ACC) authors its CPGs in partnership with the American Heart Association (AHA) and other professional organizations. Although well-conceived and executed trials add to the totality of evidence upon which recommendations can be made, whether any single trial can or should alter a diagnostic or treatment recommendation must be considered deliberately and often at a time removed from the initial trial release. Experts must weigh the quality of the evidence and dispassionately debate the merits of any trial, balancing the desire to speed new or improved therapies into practice against any associated risks, some of which are not often apparent on initial review.

One of the biggest new trials—the PARADIGM-HF (Multicenter, Randomized, Double-blind, Parallel Group, Active-controlled Study to Evaluate the Efficacy and Safety of LCZ696 Compared to Enalapril on Morbidity and Mortality in Patients With Chronic Heart Failure and Reduced Ejection Fraction) trial—generated the most buzz about the future of heart failure treatment during the 2014 European Society of Cardiology (ESC) Congress in Barcelona, Spain. The study, which compared the combination angiotensin receptor-neprilysin inhibitor LCZ696, an investigational new heart failure drug, with enalapril in patients with heart failure and reduced ejection fraction, was stopped early because of overwhelming benefit with LCZ696. At a mean of 27 months follow-up, the primary outcome of cardiovascular death and hospitalization for heart failure had occurred in 21.8% of patients in the LCZ696 group versus 26.5% in the enalapril group (hazard ratio: 0.80, 95% confidence interval: 0.73 to 0.87, $p < 0.001$). In addition, LCZ696 significantly reduced the incidence of the individual endpoints of total death, cardiovascular death, and hospitalization for heart failure, and decreased the symptoms and physical limitations of heart failure (1).

Results from the CvLPRIT (Complete Versus Lesion Only PRimary-PCI Trial), also released at the 2014 ESC Congress, found that patients with ST-segment elevation myocardial infarction (STEMI) undergoing complete revascularization had better outcomes and experienced fewer major adverse cardiac events compared with those who had only "culprit" artery revascularization (2). These results reinforce data from another trial, PRAMI (Preventive Angioplasty in Myocardial Infarction), published in 2013, which showed percutaneous coronary intervention (PCI) of all coronary arteries with major stenoses (i.e., >50% angiographic narrowing) may improve outcomes (3). Although questions remain about the exact timing of nonculprit artery PCI (i.e., at the time of primary PCI or later during the index hospitalization), whether certain patients benefit versus others, whether fractional flow reserve might guide decisions, and the role of patient complexity

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and hemodynamic stability, the results have raised enough concern that the College has recently withdrawn its recommendation that nonculprit artery PCI not be performed at the time of primary PCI from the Foundation's Choosing Wisely campaign until the issue can be settled. The ACC is working with the AHA and its other partners on the guidelines for management of patients with STEMI to address these findings. Changes to the PCI guidelines and appropriate use criteria for revascularization are also under advisement.

The 1-year results of a third trial that may alter clinical practice was also reported at ESC 2014. In the TASTE (Thrombus Aspiration in ST-Elevation Myocardial Infarction in Scandinavia) trial, investigators assessed the benefit of routine thrombus aspiration at the time of primary PCI for STEMI patients (4). In contrast to a previous study, they reported no survival benefit with routine thrombus aspiration or any reduction in a combined endpoint of death, rehospitalization for myocardial infarction, or stent thrombosis.

These and other trials underscore the fact that science is not static, but is rather constantly evolving. The College and others need to be responsive to these dynamic changes and ensure that cardiovascular professionals are providing the most appropriate, evidence-based care. However, there is also a need to maintain the rigorous processes and methodologies associated with CPG development.

This year marks the 30th anniversary of joint ACC/AHA CPG development. This collaborative effort began in response to the U.S. government's request to review the evidence concerning cardiac pacemakers and develop guidelines to limit potential overuse. Since then, there have been 23 guidelines developed across a broad spectrum of cardiovascular diseases and procedures. In a recent report on this 30-year partnership, Jacobs et al. (5) point out that balancing the constant release of new evidence with guideline development and updates is an ongoing challenge. "Although the delivery of timely CPGs is essential," they write, "it is also important to balance speed with deliberation and accuracy and to allow new treatments to adequately dwell in the clinical arena to assess generalizability and long-term outcomes in clinical practice" (5).

Over the last several years, the ACC/AHA Task Force on CPGs has made several changes to guideline development to better navigate through such changing times; for example, by adding formal evidence reviews, expanding the peer-review process, and updating the guideline writing committee selection process to account for the need to include trained methodologists and health economists, as well as to abide by both organizations' relationships with industry policies. The recent guidelines process report notes that creation of ongoing "living" documents is under development on various digital platforms (5).

There are also efforts under way to embed guideline recommendations and prompts within electronic health record systems and mobile devices. The ACC/AHA ASCVD Risk Estimator mobile application released earlier this year in conjunction with the new prevention guidelines is just 1 example of how we are working to make recommendations accessible at the point of care. The College is also excited to pilot its Guideline Clinical Apps intended to quickly disseminate information on 5 specific guidelines: management of atrial fibrillation, treatment of blood cholesterol, assessment of CV risk, management of heart failure, and management of valvular heart disease. The app will also deliver interactive guideline-related tools and provide point-of-care support.

Moving ahead, the ACC will need to pay continued attention to just how, and how quickly, we can and should implement changes to the guidelines, as well as to develop tools to make these guidelines accessible at the point of care. We would be remiss if we didn't factor in cost and value, as well as look closely at what level and quality of evidence triggers the development of new or updating of old recommendations. There are also increasing opportunities to work together to harmonize guideline recommendations with our international colleagues, particularly the ESC (6). Such harmonization could reduce confusion about recommendations across borders, minimize duplication, and perhaps streamline future guideline development efforts across the global community in which we work.

At the end of the day, our fundamental commitment to providing cardiovascular professionals with the best guidance on how to ensure the most appropriate and cost-effective care to cardiovascular patients will remain unchanged. Patients, clinicians, payers, lawmakers, and other stakeholders look for us to lead in this area, and we will continue to do so with our partners.

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