Times They Are A-Changin

For several years we have had periodic updates to the percutaneous coronary intervention (PCI) guidelines but now an entire new document, the first in 7 years, has been published and I recommend it for your reading pleasure (1). But, just in case you have not digested all 47 text pages and referred to the 879 references listed, I thought that I might relay some of the highlights. The evidence on which the guidelines are based continues to accumulate, and the authors are justly proud that there are increasingly Levels of Evidence “A” and “B” (evidence-based) and less “C” (imminence-based) recommendations. All iterations of the guidelines take on a character of their own reflecting the spirit of the times. The earliest PCI (angioplasty) guideline was only 2 pages and concentrated on gaining experience and the requirements for surgical back-up. The American College of Cardiology/American Heart Association (ACC/AHA) guidelines for PCI were published in 1988, 2003, and 2005, and updated in 2007 and 2009. That last one, because of a lot of overlap with the treatment of ST-segment elevation myocardial infarction (STEMI), was a combined PCI and STEMI focused update to capture the results of trials addressing issues pertinent to both.

The current guidelines, the 2011 American College of Cardiology Foundation/American Heart Association/Society for Cardiac Angiography (ACCF/AHA/SCAI) guideline for PCI, is not an update but a stand-alone, new guideline with its own characteristics driven by the times we live in. In this guideline, the major emphasis is on appropriate selection for PCI and coronary artery bypass grafting (CABG). There was extensive collaboration between the PCI Writing Committee and the CABG Writing Committee, who penned their guidelines concurrently along with the STEMI Committee and with consultation with the Stable Ischemic Heart Disease Writing Committee. The most evident collaboration was with the CABG writing group and this was reflected in the first subject addressed in this new guideline. That section is titled, “Heart team approach to revascularization decisions.” Although consultation between cardiologists and surgeons is a common practice in many institutions, this “heart team” approach to decision-making is really borrowed from our European colleagues who made it a centerpiece of their guidelines 2 years ago.

There are a number of other new things in the current guidelines including expanded antiplatelet therapies (the addition of ticagrelor) and the change to firm recommendations for a 600-mg loading dose of clopidogrel and the reduction in chronic aspirin dose to 75 to 100 mg per day. The STEMI section drops the “drip-and-ship” option for patients who cannot have primary PCI and, therefore, receive thrombolysis. This version suggests waiting for signs of failure to reperfuse before transfer. Those who have embraced “drip-and-ship” strategies will be reassured that these are only guidelines. In addition, the paper contains sections on ethics, statin use, hospitals without surgical back-up, radiation safety, and expanded recommendations about anatomic subsets. But the overriding theme in this document is the heart team decision-making process as it relates to selection for revascularization and for PCI versus CABG.

Although there are other studies cited for selection for PCI or CABG, the overriding evidence comes from the SYNTAX (Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery) trial (2) and substudies emanating from it. Careful reading of the guideline is necessary, and by the way, as the text has been abbreviated and tables with specific recommendations have been inserted. The selection of PCI or CABG is divided into “Recommendations to Improve Survival” and “Recommendations to Improve Symptoms” compared to medical therapy. As far as clinical presentation is concerned, there is not much
new for STEMI, which is largely a primary PCI issue when it is available, but for elective catheterization patients, there are extensive recommendations. Many of them reflect the 3-year findings of the SYNTAX trial so that for survival, left main disease gets a Class I recommendation for surgery and a Class IIa recommendation for PCI when the SYNTAX score is <23 and the surgical risk is ≥5%. I guess CABG got the nod here because of its seniority even though PCI beat CABG in this SYNTAX category. If the SYNTAX score was <34 and the survival risk was >2%, PCI got a Class IIb recommendation (uncertain benefit). So, for left main disease with low or intermediate SYNTAX scores and close to usual surgical risk, PCI is a consideration according the guidelines. Of course, surgery has been compared to medical therapy for left main disease even if the evidence is now almost historical. The catch-22 is that PCI will not be compared to medical therapy for these patients.

For improved survival or medical therapy in multivessel disease patients, PCI gets only a Class IIb (of uncertain benefit). CABG for survival benefit in 3-vessel disease and 2-vessel disease with major ischemia gets a Class I (3-vessel) and Class IIa (2-vessel). The best PCI can do with the current evidence is a Class IIb (“the usefulness of PCI to improve survival is uncertain with patients with 2- or 3-vessel CAD”). The ISCHEMIA (International Study of Comparative Health Effectiveness with Medical and Invasive Approaches) trial and others comparing PCI with medical therapy is sorely needed to provide the evidence that PCI can improve survival in patients with extensive ischemia.

The recommendations for symptom relief are more balanced. For unacceptable angina despite guideline-driven medical therapy and significant stenosis in 1 or more arteries, both CABG and PCI get a Class I, Level of Evidence: A recommendation. If medical therapy produces adverse effects or the patient prefers intervention, then for symptom relief a Class IIa is given for CABG and PCI. Even for symptom relief, CABG is recommended over PCI in 3-vessel disease patients with a SYNTAX score ≥22.

We should remember that guidelines are guides, not definitive rules. The consultation of interventionalists, surgeons, and noninvasive cardiologists (the heart team) is a concept that is hard to argue with. It is, however, one that is hard to comply with. The widespread practice of ad-hoc PCI at the time of diagnostic angiography leaves little time for assembling the “heart team.” The guideline, however, mirrors the European guideline in suggesting that for patients with more extensive disease, a practice of taking the patient off the catheterization table to allow for consultation and informed consent is preferable. These recommendations will be embraced by many but will be particularly hard for the ever-expanding number of hospitals that have only PCI available. A section on hospitals without in-house surgery is included in the guideline.

Increasing scrutiny on appropriate decisions about revascularization must encourage innovative ways to assure that all therapeutic options are considered and patients are informed. Future guideline updates should disseminate those solutions that are effective and practical. As Dylan said, “times they are a-changin’,” and guidelines are no exception.

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REFERENCES