Practice guidelines are designed to provide evidence-based and expert judgment assessment of optimal practices. The American College of Cardiology (ACC) and the American Heart Association (AHA) developed guidelines related to cardiovascular care. These guidelines must be periodically updated to reflect the accumulating evidence. In 2009, the decision was taken to issue a single focused update reflecting changes and recommendations regarding ST-elevation myocardial infarction (STEMI) and percutaneous coronary intervention (PCI).

This decision was driven primarily by the accumulating data, which had a significant overlap between these 2 guideline processes. The 2009 focused update does not address all the issues covered in the complete guideline for STEMI or the previous guideline for PCI but rather reflects updated recommendations based on evidence that had accumulated since the last update of 2007.

It is important to remember how the recommendations are classified and the language used to convey the recommendations. Class I represents how and what should be done, or “are recommended”, or “are indicated”, and/or “are effective and useful”. Class II is divided into 2 categories. Class IIa represents what “is reasonable”, “can be useful/effective/beneficial”, or “is probably recommended/indicated”. Class IIb represents what “may/might be considered”, “may/might be reasonable”, or “usefulness/effectiveness is unknown/unclear/uncertain or not well established”. Class III, on the other hand, represents what “is not recommended”, “is not indicated”, “should not or is not useful/effective/beneficial and may be harmful”. It is important for clinicians to understand that Class II recommendations are not negative recommendations. Only Class III represents recommendations of things to be avoided. This system differs from the European guidelines, in which Class III listing is omitted. In addition to the classes, the level of evidence is reflected as Level A, “based on evidence from multiple randomized trials or meta-analyses with general consistency of direction and magnitude of effect”. Level B recommendations are based on a single randomized trial or nonrandomized studies. Level C recommendations are based on expert opinion, case studies or standard of care.

For the 2007 focused update, several issues were considered. Some of those of interest are recommendations for the use of glycoprotein (GP) IIb/IIIa receptor antagonists in STEMI, recommendations for the use of thienopyridines, duration of thienopyridine therapy, recommendations for the use of anticoagulants in patients with STEMI, recommendations for triage and transfer of patients with STEMI, thrombus aspiration during PCI or stenting, the indications for use of contrast agents in patients with chronic kidney disease who are undergoing PCI, the use of hemodynamic measures (fractional flow reserve) in patients undergoing PCI, the use of PCI in patients with unprotected left main disease, and the recommendation for timing of angiography and antiplatelet therapy in acute coronary syndromes.
Recommendations for the use of glycoprotein IIb/IIIa receptor antagonists was influenced by the fact that much of the evidence regarding the use of these agents was established in an era before dual antiplatelet therapy was widely used. Three trials bring into question whether GP IIb/IIIa provides significant additional benefit for patients with STEMI who receive adequate dual antiplatelet therapy. Those trials were BRAVE III, On-TIME 2, and HORIZONS-AMI (Harmonizing Outcomes with Revascularization and Stents in Acute Myocardial Infarction). In addition, 2 meta-analyses examined the use of small molecule agents compared to abciximab in STEMI. Based on this evidence, the committee recommended that the use of various GP IIb/IIIa antagonists demonstrates similar effectiveness in the setting of primary PCI, and therefore, they were all given a Class IIa recommendation. The committee also agreed that, in the setting of dual antiplatelet therapy plus unfractionated heparin or bivalirudin as the anticoagulant, the routine use of GP IIb/IIIa antagonists can be useful but cannot be recommended as routine therapy.

The major changes in recommendations regarding thienopyridines were reflected by the emergence of prasugrel and the results of the TRITON TIMI-38 study (Trial to Assess Improvement in Therapeutic Outcomes by Optimizing Platelet Inhibition with Prasugrel-Thrombolysis in Myocardial Infarction). Based on that trial, both clopidogrel and prasugrel were given Class I recommendations in the setting of primary PCI for STEMI.

The evidence regarding the optimal duration of thienopyridine therapy following STEMI or PCI remains weak. Previous recommendations for 1-year use of clopidogrel were expanded to include prasugrel. The disclaimers that this should be based on bleeding risk were kept similar to previous guidelines, as were the recommendations regarding continued therapy beyond 1 year.

The use of anticoagulation in patients with STEMI was expanded to include bivalirudin based on the results of the HORIZONS-AMI trial. Bivalirudin was included as a Class I indication for primary PCI.

Triage and transfer for PCI (for STEMI) included a new recommendation regarding the advice that each community should develop a system of care for patients presenting with STEMI to be at least as comprehensive as those recommended by Mission Lifeline, a recommendation of the AHA. Two trials, CARESS-in-AMI (Combined Abciximab Reteplase Stent Study in Acute Myocardial Infarction) and TRANSFER-AMI (Trial of Routine Angioplasty and Stenting after Fibrelysis to Enhance Reperfusion in Acute Myocardial Infarction), led to the recommendation that patients who present at remote hospitals and receive thrombolytic therapy should be considered for immediate transfer to PCI-capable facilities, instead of waiting for evidence of reperfusion or lack of reperfusion. STEMI patients judged to be high-risk after fibrinolytic therapy were given a Class IIa recommendation for immediate transfer, and patients not at high risk were given a Class IIb recommendation. In other words, early transfer following fibrinolytic therapy was found to be reasonable for high-risk patients and may be considered for low-risk patients.

A number of trials have reported on the benefit of thrombus aspiration during PCI and that is reflected in the new guideline stating that it is reasonable for patients undergoing primary PCI to have thrombus aspiration performed. The use of drug-eluting stents in STEMI patients was strengthened with evidence largely from the HORIZONS-AMI trial.

A previous recommendation that patients with chronic kidney disease should receive iso-osmolar contrast agents was expanded to include iso-osmolar and low-molecular weight agents based on randomized trials and meta-analyses.

The FAME trial created strong evidence for consideration of fractional flow reserve in the performance of PCI. The use of hemodynamic measures during PCI received a Class IIa recommendation, “it is reasonable to use intracoronary physiologic measurements”.

Of great interest, especially in the United States, was the upgrading of the recommendations for unprotected left main coronary artery disease patients. Previous guidelines had recommended PCI only for patients with protected left main disease or for patients who are not surgical candidates. The updated guideline gives a Class IIb recommendation which reads, “PCI of the left main coronary artery using stents as an alternative to CABG may be considered in patients with anatomic conditions that are associated with low-risk of PCI procedural complications and clinical conditions that predict an increased risk of adverse surgical outcomes”. This important change enables appropriate use of stenting for left main coronary disease that was recommended against in the previous versions. The SYNTAX (Synergy between PCI with Taxus and Cardiac Surgery) trial left main cohort influenced this recommendation.

Finally, the recommendation for timing for arteriography and antiplatelet therapy in patients with acute coronary syndromes was upgraded to include prasugrel in addition to the previous recommendations for clopidogrel as adjunctive therapy during all ACS interventions. Both agents received a Class I recommendation. It was also recommended, based on the TIMACS study (Timing of Intervention in Patients with Acute Coronary Syndromes) that early invasive strategies (between 12-24 h) remain preferable for ACS patients; however, based on the ABORD trial, the immediate intervention in non-STEMI and unstable patients was not necessary.

A full reading of the guidelines will reveal other valuable information including the fact that the committee has moved away from using the term “facilitated PCI” for patients with
STEMI, preferring to describe the potential for pharmacoinvasive approaches to be individualized depending on the availability of primary PCI in specific communities. New data continues to emerge and must be considered for inclusion in future updates. Although those trial results are available to the entire cardiac community, the reflective judgment of organizations such as the ACC, the AHA, and the European Society of Cardiology are important to balance the latest evidence with previous experience and judgment. The guideline process will continue to evolve but the shorter timeline to update such guidelines has been of significant benefit in this era of extremely rapid change.

REFERENCES


