

# Updated guidelines for percutaneous coronary intervention: what are the most important changes?

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An important challenge of practice guidelines is keeping up with the constant supply of new data on which recommendations are based. The American College of Cardiology (ACC) and the American Heart Association (AHA) develop guidelines in numerous areas of cardiovascular care including percutaneous coronary intervention (PCI). Trials presented at AHA, ACC, and the European Society of Cardiology, as well as other selected data, have been reviewed and utilized to update the 2005 guideline with a new publication titled "2007 focused update of the ACC/AHA/Society for Cardiovascular Angiography and Interventions (SCAI) 2005 guideline update for PCI" [1]. Because the guideline process is one that requires full vetting and approval of the recommendation by the sponsoring organizations, more recent trials have not been included and will be addressed in future updates. It is important to remember that the recommendations are classed in four general categories. Class I represents those things that "should be done", or "are recommended", or "are indicated", and/or "are effective or useful". These are recommendations that in general are considered to be broadly agreed upon. Class II represent situations that are also felt to be indicated but with varying levels of opinion. Class IIA represent those recommendations that are felt to be "reasonable", "can be useful/effective/beneficial", or "is probably recommended or indicated". Class IIB are recommendations in which the usefulness/efficacy is less well established and terms used for those recommendations are "may/might be considered or be reasonable", or whose usefulness or effectiveness is unknown or unclear or uncertain or not well established. Class III recommendations are situations that are actually not recommended. This class is listed as one of the recommendations but it is a negative recommendation and uses terms such as "is not recommended", "is not indicated",

"should not be used", "is not useful/effective/beneficial", or "may be harmful".

For "2007 focused update for PCI guidelines", new studies were considered and several issues were addressed. They were: dual antiplatelet therapy and its use in drug-eluting stenting, facilitated angioplasty in the setting of ST elevation myocardial infarction and its differentiation from rescue angioplasty, the use of invasive or conservative strategy in unstable angina/non-ST elevation myocardial infarction (UA/NSTEMI), the dosing of aspirin and clopidogrel and the use of anti-coagulation in the setting of PCI.

The new recommendations regarding dual antiplatelet therapy for drug-eluting stents (DES) were focused on the duration of therapy. A Class I recommendation was: "before implanting a DES, the interventional cardiologist should discuss with the patient the need for and duration of double antiplatelet therapy and confirm the patient's ability to comply with the recommended dual antiplatelet therapy for DES". In addition, a new recommendation: "in patients who are undergoing preparation for PCI and are likely to require invasive or surgical procedures for which double anti-platelet therapy must be interrupted during the next 12 months, consideration should be given to implantation of a bare metal stent (BMS) or performance of balloon angioplasty with a provisional stent implantation instead of the routine use a DES". The overall recommendation for DES as opposed to BMS was little changed and was left to the judgment of the operator balancing the risk and benefit but the language was modified slightly to read: "a DES should be considered as an alternative to a BMS in those patients for whom clinical trials indicate a favorable effectiveness/safety profile." The text explains that the risk/benefit ratio to be considered is not the same as the on-label or off-label use.

Facilitated angioplasty strategies in the setting of STEMI were considered. Based largely on the results of the ASSENT4 Trial [2] and other meta-analyses [3], the planned reperfusion strategy using full dose fibrinolytic therapy followed by immediate PCI was not recommended and was given Class III ("may be harmful"). Recognition that other strategies may be worthwhile in certain circumstances, a Class IIB recommendation

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was issued: “facilitated PCI using regimens other than full dose fibrinolytic therapy might be considered”. The strategy of planned facilitated PCI, which was not recommended, was differentiated from rescue PCI for failed fibrinolysis, and there were modified recommendations to clarify situations following fibrinolytic therapy that should be considered for rescue PCI.

For patients who have suffered acute myocardial infarction and have not undergone primary PCI and yet are not in the acute phase, a new recommendation was issued. Based on the OAT Trial [4], it was recommended that PCI not be performed on “a totally occluded infarct artery >24 hours after STEMI in asymptomatic patients with 1–2 vessel disease if they are hemodynamically and electrically stable and do not have evidence of severe ischemia”. The previous recommendations for intervening in patients who have had prior myocardial infarction remained little changed.

Addressing the issue of UA/NSTEMI, a consideration of the previous trials and meta-analyses [5] was balanced with the results of the ICTUS Trial [6]. The primary recommendation remained the same, “an early invasive PCI strategy is indicated for patients with UA/NSTEMI who have no serious co-morbidity and who have coronary lesions amenable to PCI and who have characteristics for invasive therapy”. This recommendation for early invasive therapy remained unchanged as a Class I indication. However, since the ICTUS Trial was neutral, a Class IIB recommendation was added as follows: “In initially stabilized patients, an initially conservative (i.e. a selected invasive) strategy may be considered as a treatment strategy for UA/NSTEMI patients who have an elevated risk for clinical events including those who are troponin-positive. The decision to implement an initial conservative (versus initial invasive) strategy in these patients may be made by considering physician and patient preference”. These recommendations may seem slightly contradictory but they basically state that the weight of evidence is still in favor of early invasive therapy but, with intensive medical management, a conservative strategy for such patients might also be considered.

The dosing and duration of antiplatelet therapy was also considered. Recommendations were modified slightly to read, “After PCI in patients without allergy or increased risk of bleeding, aspirin 162–325 mg daily should be given for at least one month after BMS implantation, three months after Sirolimus-eluting stent implantation, and six months after Paclitaxel-eluting stent implantation, after which daily long-term aspirin should be continued indefinitely at a dose of 75 mg to 162 mg”. These obviously are North American doses of aspirin. The clopidogrel loading dose of 600 mg was recommended unless patients had received fibrinolytic therapy within the past 24 hours. Based on recommendations from multiple organizations, the clopidogrel duration was extended to 12 months for all patients receiving DES who were not at high risk of bleeding. Longer term duration of antiplatelet therapy was given a IIB recommendation since there is little evidence to guide that therapy. Finally the results of the ACUITY Trial [7] were considered and the addition of bivalirudin as a reasonable an-

ticoagulant therapy in the setting of PCI was added to the previous recommendations for unfractionated heparin and low molecular weight heparins.

In addition, the update emphasized the importance of recommendations for secondary prevention. These carry stronger language about tobacco cessation and more comprehensive medical strategies which are effective for controlling cholesterol, high blood pressure and diabetes complications.

More recent trials which further inform the guidelines include the FINESSE Trial of facilitated angioplasty and the COURAGE Trial of patients with stable ischemic heart disease will be addressed in conjunction with other guidelines undergoing current revision since they were not published in time to meet the deadline for this focused update.

Although not as up-to-date as some would like, the focused update process of the guidelines offers a balance between rapid implementation of new and evolving evidence, and the complete analysis of the implications of those results for clinical practice by the professional societies.

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