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Review article

Guidelines for revascularization: The evidence base matures

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INTRODUCTION

Myocardial revascularization procedures continue to represent important treatment options for patients with acute and chronic coronary artery disease (CAD) and also represent a major source of health care expenditures [1,2]. For the past decade, the indications for revascularization in patients with chronic CAD, and the indications for surgical versus percutaneous revascularization, have been the subject of considerable discussion, debate, and controversy. The guidelines from the American College of Cardiology Foundation/American Heart Association (ACCF/AHA) and the European Society of Cardiology / European Association for Cardiothoracic S (ESC/EACTS) have made major inroads in resolving these issues and have provided the standards for care for interventional cardiologists, surgeons, and the physicians who refer patients for these procedures. The transatlantic guidelines have also been remarkably concordant in their overall recommendations.

The 1993 ACCF/AHA guidelines on the indications for percutaneous coronary intervention (PCI) were revised in 2001 and then updated in 2005, 2007, and 2009 [3–6]. The ACCF/AHA guidelines on coronary bypass graft surgery (CABG), initially published in 1991, were revised in 1999, updated in 2004, and revised completely in 2011 [7–9]. The ESC/EACTS guidelines on myocardial revascularization, published in 2010, represent a comprehensive document covering both surgical and percutaneous approaches [10]. Both guidelines task forces used a common methodology for reporting treatment recommendations (Fig. 1) based on the strength of the recommendation, which is an estimate of the magnitude of the treatment effect, and the level of the evidence (LOE), which is an estimate of the level of certainty of the treatment effect.

Important new issues covered in the recent guidelines documents from both the USA and Europe include the need for risk stratification prior to revascularization and the implementation of risk scores, with emphasis on the need to develop a multidisciplinary team-based approach to provide optimal patient outcomes. The guidelines also address the sensitive and controversial issues of self-referral and ad hoc PCI, while providing detailed recommendations on the indications for revascularization versus optimal medical therapy for stable CAD, PCI versus CABG for multivessel disease, and PCI versus CABG for left main disease.

REVASCULARIZATION FOR LEFT MAIN AND MULTIVESSEL DISEASE

In 2009, the ACCF/AHA PCI guidelines update made a relatively simple and straightforward statement regarding the state of the art percutaneous approaches to left main disease: PCI with stenting may be considered an alternative to CABG in patients with the combination of anatomic conditions associated with a low risk of PCI complications and clinical conditions that predict increased risk of adverse surgical outcomes (class IIb, LOE B). The landscape changed considerably with the results of the Synergy Between PCI With TAXUS and Cardiac Surgery (SYNTAX) trial, a multicenter randomized trial comparing the results of PCI versus CABG in patients undergoing revascularization with left main or multivessel disease. The initial one year follow-up report of SYNTAX in 2009 [11] was followed by the longer-term 3 year follow-up data in 2011 [12]. The SYNTAX investigations demonstrated that the assessment of coronary anatomy was critically important in identifying relatively low-risk and high-risk patients with left main or multivessel disease. A key contribution of this trial was the development of the SYNTAX score [11], with higher scores indicated more severe and complex coronary pathoanatomy.

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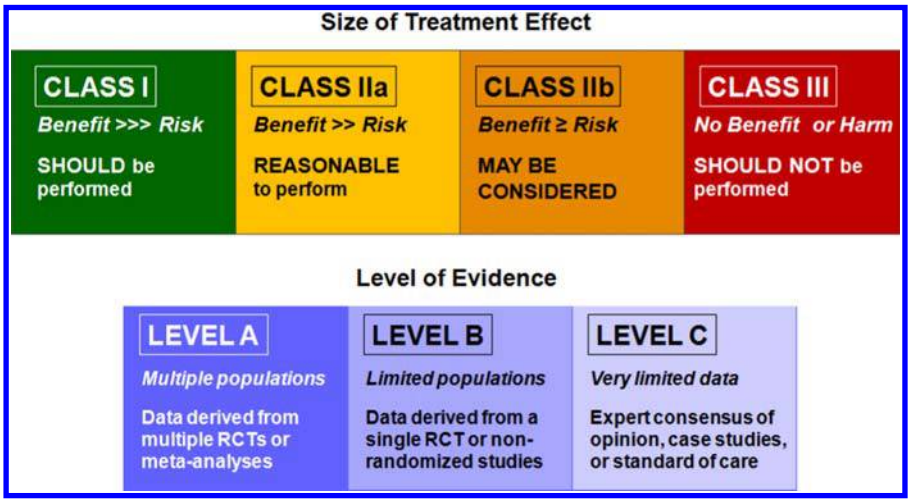

Figure 1. Guidelines recommendation methodology used by the ACCF/AHA and ESC/EACTS guidelines task forces, based on strength of recommendation and level of evidence.

In SYNTAX, patients with lower scores faired equally well (and in some cases better) when treated with PCI compared to CABG, whereas those with higher scores had significantly better outcomes with CABG. Thus, not all patients with left main disease are created equally, and those with left main disease but low SYNTAX scores had more favorable outcomes with PCI. In contrast, survival was enhanced with CABG in patients without left main disease but with three-vessel disease and high SYNTAX scores. These findings have had a major impact in the referral of patients to PCI versus CABG internationally.

The other major contribution of the SYNTAX trial was the development of the multidisciplinary heart team, composed of cardiologists, surgeons, and nurses, to assist in making individualized management decisions based on each patient's clinical and angiographic findings. In addition to decisions regarding suitability of patients for PCI versus CABG, the heart team organizes mortality and morbidity conferences, reviews the institutional results in a transparent manner for bench-marking and guidance in decision-making, and ensures proper patient information and consent, including providing patients with adequate discussion of alternatives, risks and benefits, and both short-term and long-term results. In addition, the heart team designs specific institutional protocols and clinical care pathways for patients with ST-segment elevation myocardial infarction (STEMI), non-STEMI, and other acute coronary syndromes as well as those with stable CAD, accounting for angiographic subsets (as might be determined by the SYNTAX score).

SYNTAX had a major impact on the 2011 update of the ACCF/AHA CABG guidelines [8], which strongly recommended the heart team approach for best management decisions (class I, LOE C) and calculation of SYNTAX scores (class IIa, LOE B). Importantly, these guidelines also emphasized that the anatomic scores need to be balanced against clinical risk scores, such as the EuroSCORE [12] or the Society of Thoracic Surgeons (STS) Score [13], in determining the optimal approach. The recent guidelines also emphasized the necessity of including patients in the decision-making process. The ESC/EACTS guidelines [10] stated explicitly that patients should be adequately informed about potential benefits and both the short-term and long-term risks of revascularization procedures, with sufficient time for informed decision-making. (class I, LOE C). The European guidelines also recommend that the appropriate management strategy in patients with multivessel disease should be discussed with the heart team (class I, LOE C).

Assessment of CAD severity should include not only angiographic scores but also consideration of the functional significance of a coronary stenosis that might be assessed using noninvasive imaging [15–17] or invasive fractional flow reserve (FFR). The landmark Fractional Flow Reserve Versus Angiography for Multivessel Evaluation (FAME) trial demonstrated the incremental prognostic value of adding FFR to coronary angiography in guiding PCI decisions [18,19]. These results were incorporated directly into the 2009 ACCF/AHA PCI guidelines update (Fig. 2).

On the basis of coronary anatomy and functional importance of stenosis, the European guidelines [10] provided recommendations for revascularization versus optimal medical therapy for symptom improvement in patients with stable angina (Fig. 3). These relatively straightforward recommendations included revascularization for a stenosis greater than 50% in patients with limiting angina

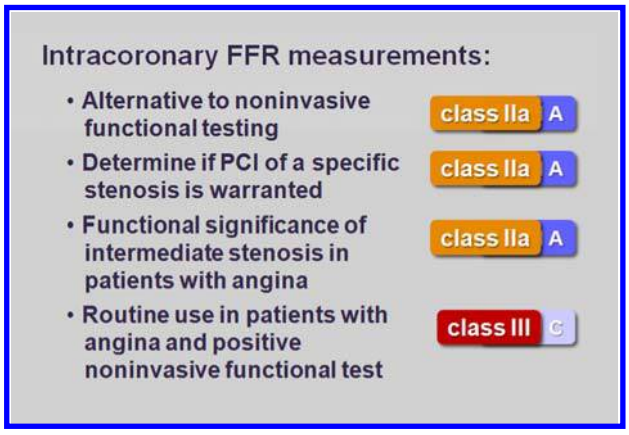

Figure 2. Indications for fractional flow reserve (FFR) measurements in guiding decisions for percutaneous coronary intervention (PCI). From 2009 ACCF/AHA guidelines update for ST-segment elevation myocardial infarction and PCI [6]. Blue tags indicate level of evidence.

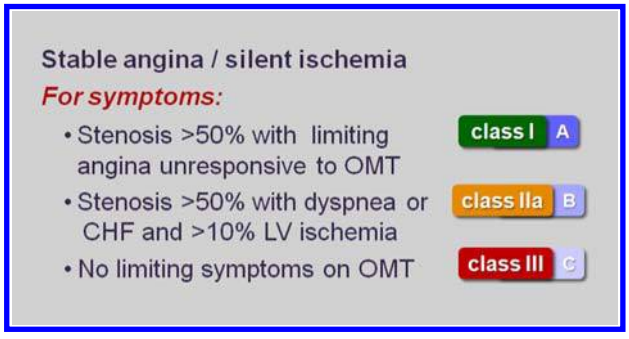

Figure 3. Indications for revascularization versus optimal medical therapy (OMT) in patients with chronic coronary artery disease for improvement in symptoms. From 2010 ESC/EACTS guidelines for myocardial revascularization [10]. CHF = heart failure; LV = left ventricular.

unresponsive to optimal medical therapy (class I, LOE A), and stenosis greater than 50% in patients with dyspnea or heart failure and myocardial ischemia involving greater than 10% of the left ventricular myocardium (class IIa, LOE B). In contrast, there was no enthusiasm for recommending revascularization in patients with no limiting symptoms on optimal medical therapy (class III, LOE C). The European guidelines also made numerous recommendations for myocardial revascularization to improve prognosis (Fig. 4) and, importantly, recommendations regarding the decision for CABG versus PCI, based on anatomy and SYNTAX score (Fig. 5). Similar recommendations followed in the 2011

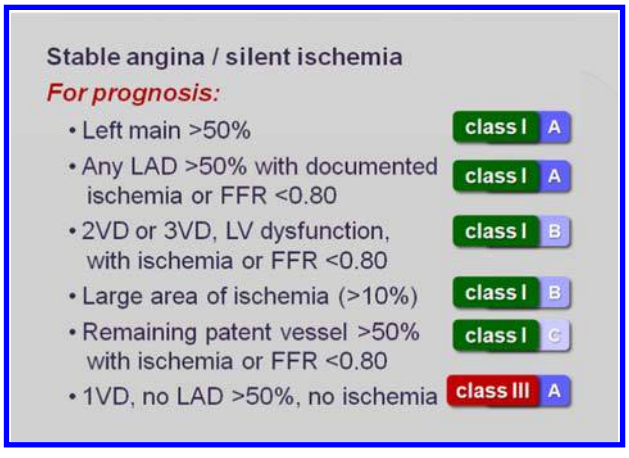

Figure 4. Indications for revascularization to improve prognosis in patients with chronic coronary artery disease for improvement in symptoms. From 2010 ESC/EACTS guidelines for myocardial revascularization [10]. FFR = fractional flow reserve; LAD = left anterior descending coronary artery; LV = left ventricular.

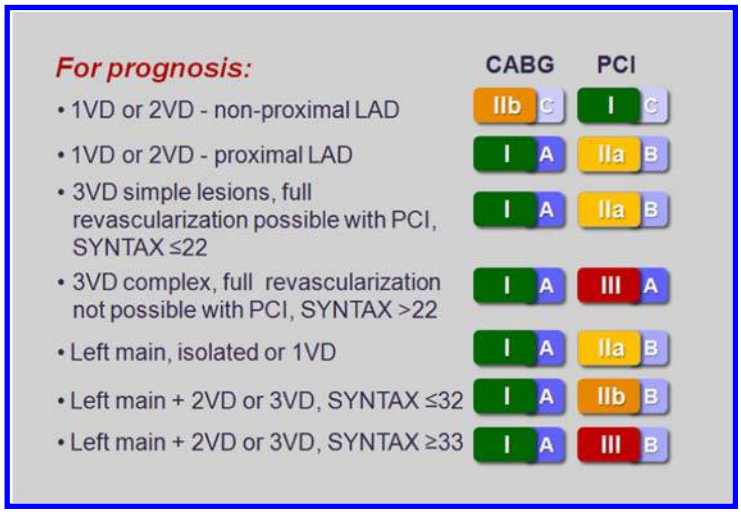

Figure 5. Indications for revascularization with coronary artery bypass surgery (CABG) versus percutaneous coronary intervention (PCI) based on angiographic severity, including number of vessels diseased (VD) and SYNTAX score. From 2010 ESC/EACTS guidelines for myocardial revascularization [10]. CABG is recommended for more severe anatomic findings. LAD = left anterior descending coronary artery.

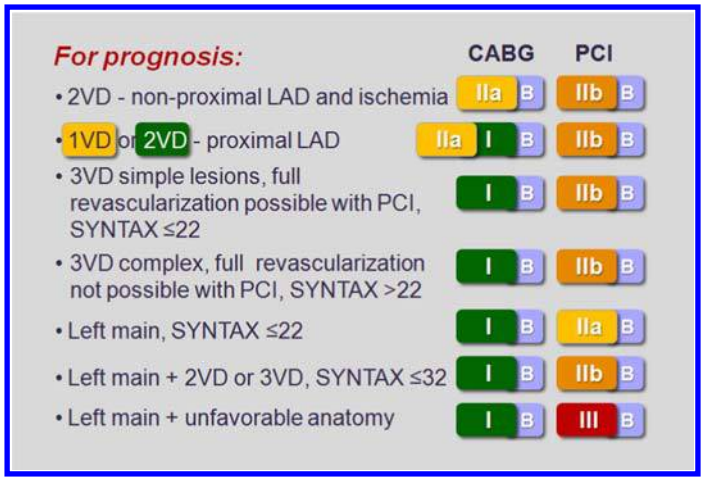

Figure 6. Indications for revascularization with coronary artery bypass surgery (CABG) versus percutaneous coronary intervention (PCI) based on angiographic severity including number of vessels diseased (VD) and SYNTAX score. From 2011 ACCF/AHA guidelines update for indications for CABG [9]. CABG is recommended for more severe anatomic findings. LAD = left anterior descending coronary artery.

revised ACCF/AHA CABG guidelines (Fig. 6). Both the European and U.S. guidelines stressed the relative benefit of CABG for patients with more complex coronary anatomy.

These recommendations for CABG rather than PCI in patients with complex multivessel disease have been confirmed in the recent report of the ACCF-STS Database Collaboration on the Comparative Effectiveness of Revascularization Strategies (ASCERT), in which the National Cardiovascular Data Registry (NCDR) of the ACCF and the STS Database were combined to assess outcomes in a large number of patients 65 years of age or older with two-vessel or three-vessel CAD undergoing non-emergent revascularization [20]. ASCERT studied outcomes in 86,244 such patients undergoing CABG and 103,549 undergoing PCI from 2004 through 2008, using propensity scores and inverse-probability-weighting adjustment to reduce treatment selection bias. Survival was significantly higher in patients receiving CABG than in those treated with PCI.

APPROPRIATENESS OF REVASCULARIZATION DECISIONS

In the United States, there is a growing interest in assessing the appropriateness of cardiovascular procedures, because of concerns of overuse, under-use, and misuse. These concerns apply not only to

the application of diagnostic imaging procedures but also to the appropriate indications for revascularization procedures. Because CABG and PCI are both common and costly [1,2], attention to appropriateness of revascularization is warranted. The ACCF and partner organizations have responded and published appropriate use criteria (AUC) for coronary revascularization, initially in 2009 and updated in 2012 [21,22]. The updated AUC parallel the thinking of the guidelines committees, with more favorable recommendations for CABG in patients with more complicated or unfavorable anatomy (Fig. 7).

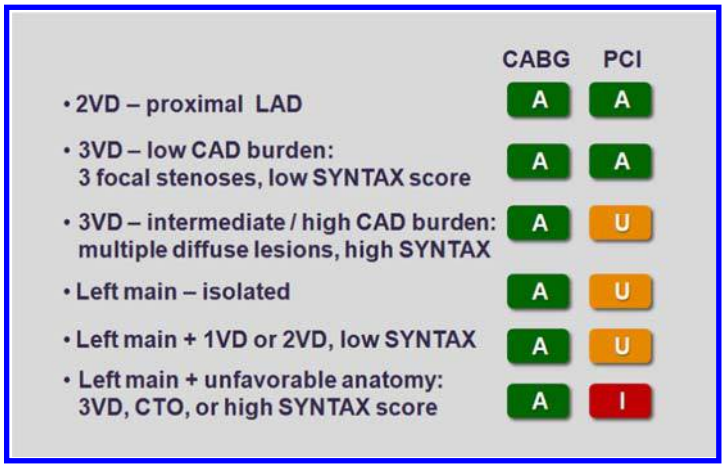

Figure 7. Appropriate use criteria for myocardial revascularization using coronary artery bypass surgery (CABG) versus percutaneous coronary intervention (PCI)) based on angiographic severity including number of vessels diseased (VD) and SYNTAX score. From 2012 ACCF update on appropriate use criteria for coronary revascularization [22]. A = appropriate; I = inappropriate; U = appropriateness uncertain; CTO = chronic total occlusion; LAD = left anterior descending coronary artery.

Whether the actual decisions for proceeding with CABG or PCI in clinical practice follow the international guidelines recommendations and AUC is uncertain. There is evidence that clinical practice may deviate from consensus recommendations. A report from the NCDR comparing the indications for nearly 500,000 PCI procedures relative to the published AUC concluded that PCI performed for acute indications were nearly always appropriate, but this was not the case for management decisions in patients with chronic CAD. For the nearly 144,000 non-acute procedures in this study, 50.4% were graded appropriate, 38% were of uncertain appropriateness, and 11.6% were considered inappropriate procedures, with the majority of these latter procedures performed in patients with little to no angina or with low-risk ischemia on stress testing. There was also substantial variability in the rate of inappropriate PCI for non-acute indications among medical centers. Better understanding of the clinical settings in which inappropriate PCIs occur and reduction in their variation across hospitals are worthy targets for quality improvement efforts. This report from the NCDR has received considerable attention in the national media and has also generated cogent reaction from the interventional cardiology community [23]. It is also noteworthy that the agreement among expert clinicians and the AUC writing group is often inconsistent regarding the certainty or uncertainty of PCI in specific clinical situations, with marked variation in ratings between individual physicians and the AUC technical panel [24].

The rate of CABG surgery in the United States and Europe has declined in recent years, but the rate of PCI has remained relatively constant [1,2]. Multivessel PCI, in particular, continues to be performed commonly in patients with complex anatomy. Both CABG and PCI are costly to our health care sustemsTrials such as SYNTAX and FAME have drawn much needed attention to the relative risks and benefits of CABG versus PCI in angiographic subsets as well as the need to assess the functional significance of coronary stenoses in making revascularization decisions. These concepts are now well imbedded in international guidelines. Equally important is the renewed emphasis on a team-based approach in clinical decision making to ensure optimal patient outcomes.

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