

Appropriate PCI Use

Making sense of the guidelines and appropriateness criteria.

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During the past year, accusations have been swirling that certain operators in the states of Maryland, Texas, and Pennsylvania have implanted unnecessary coronary stents. This firestorm has extended nationwide and has challenged the cardiology community. With the recent publication of the 2011 Guidelines for Percutaneous Coronary Intervention (PCI), the debate over what is “appropriate use” of PCI continues.¹ The purpose of this article is to review the differences between the published guidelines and appropriateness criteria and how to apply them in the real world to ensure the best possible patient care.

GUIDELINES FOR PCI

Guidelines for the clinical practice of PCI first appeared in 1982 and, thereafter, were revised at periodic intervals. The most recent extensive revision occurred in November 2011.¹ The writing committee consists of representatives of the American College of Cardiology Foundation (ACCF), the American Heart Association, and the Society for Cardiovascular Angiography and Interventions (SCAI). The guidelines are based on an extensive review of the literature and consensus opinion. The assessments of care consist of two paired major categories: (1) Class of Recommendation: an estimate of the degree of the treatment effect considering risks versus benefits in addition to evidence and/or consensus regarding whether a treatment or procedure is useful/effective, or in some situations, may cause harm; and (2) Level of Evidence: an estimate of the certainty or precision of the treatment effect. An outline of the terminology and metrics are presented in the *Guidelines for PCI Terminology and Metrics* sidebar.

APPROPRIATENESS CRITERIA

The first publication of appropriateness criteria for coronary revascularization was in 2009.² It was a report from a task force consisting of representatives from the ACCF, SCAI, the Society of Thoracic Surgeons, and the American Association for Thoracic Surgery, along with key subspecialty societies. Approximately 180 clinical scenarios were developed by a writing committee and were then consensus scored by a separate technical panel.

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Scores of 1 to 9 were used to indicate whether revascularization was considered appropriate and likely to improve health outcomes or survival. Revascularization was considered to be either PCI or coronary artery bypass graft surgery. In a select subgroup of clinical scenarios, the appropriateness of PCI versus coronary artery bypass graft surgery individually was also considered. An outline of the terminology and metrics is presented in the *AUC Terminology and Metrics* sidebar.

In an accompanying editorial, Dr. Doug Weaver suggested that the term *appropriate use criteria* (AUC) would better reflect the important role the criteria play in identifying appropriate use of medical technology and procedures. It was suggested that, thereafter, documents of this nature should use the descriptor *AUC*,³ and therefore, this terminology will be used throughout the remainder of this article. It is anticipated that additional updates and revisions of the AUC will be shortly forthcoming now that the 2011 PCI Guidelines have been published.

DIFFERENTIATION OF GUIDELINES VERSUS AUC

The periodically published clinical guidelines for PCI essentially involve a summary and discussion of evidence from clinical trials and/or publications. This should be considered a strict classification and level of evidence system to guide clinical therapy. On the other hand, the AUC has more specific clinical features.⁴ There is a great emphasis placed on presenting features and clinical status. The AUC reflects a more contemporary clinical practice of which clinical trials may exclude many high-risk patients.

Rather than contradictory, these two formats should be considered complementary. It should be emphasized that the AUC involves more clinical judgment and opin-

ion based on the foundation of the guidelines. However, not every clinical variable can be weighed in either of these two reference points.

ASSESSMENT OF THE GUIDELINES AND AUC IN CLINICAL PRACTICE

The key study by Anderson et al⁵ analyzed data from the National Cardiovascular Data Registry (NCDR) CathPCI Registry to assess whether PCIs were performed in keeping with published guideline indications. They found that most of the procedures were performed for class 1 indications, but there was a significant relationship between evidence-based indications and in-hospital outcomes. Anderson et al concluded that closer adherence to guidelines can reduce variations in care, improve quality, and may ultimately result in better outcomes.

The most important assessment of the AUC was by Chan et al⁶ in a study (also based on NCDR CathPCI Registry data) of more than 500,000 PCIs that were performed between 2009 and 2010 at 1,091 United States hospitals. Of these, > 70% were performed for acute indications such as ST-segment elevation, non-ST-elevation, and high-risk unstable angina. Approximately 30% were for nonacute or elective indications. Of the acute indications, 98.6% were classified as appropriate, 0.3% as uncertain, and 1.1% as inappropriate. However, for the nonacute elective indications, 50% were appropriate, 38% were uncertain, and 11.6% were inappropriate. In the inappropriate group, there was a range of 6% to 16.7%, with substantial variation between hospitals.

PCI SCORECARDS AND BENCHMARKS

Even before appropriate use criteria were developed, there were scorecard systems in place in various states. The results of these were quite variable, and there was concern that public reporting could impede the aggressive use of PCI in appropriate cases with patients who had no other reasonable options.⁷

Recently, the NCDR CathPCI Registry, in its quarterly reports to participants, is now assessing AUC in PCI procedures and benchmarking these to a national reference point.⁸ Various assumptions were made to match PCI procedures to AUC. The CathPCI Registry assessment found that most of the acute cases that were deemed to be inappropriate by AUC criteria were ST-elevation myocardial infarction patients who were listed as stable and asymptomatic and had PCI performed > 12 hours from symptom onset. In the elective/nonacute cases, the majority of inappropriate PCI occurred in patients who had one- to two-vessel coronary disease that did not involve the proximal left anterior descending artery, were on no anti-ischemic therapy, had no or mild angina symp-

GUIDELINES FOR PCI TERMINOLOGY AND METRICS^{a,b}

Class of Recommendation

- Class I
 - Procedure or treatment is useful/effective
 - Procedure/treatment should be performed/administered
- Class IIa
 - In favor of treatment or procedure being useful/effective
 - It is reasonable to perform the procedure/treatment
- Class IIb
 - Usefulness/efficacy is not as well established
 - Procedure/treatment may be considered
- Class III: No Benefit
 - Procedure or treatment is not useful/effective
 - Not helpful
 - No proven benefit
 - Procedure/treatment should not be considered
- Class III: Harm
 - Procedure or treatment is not useful/effective
 - Excess cost—without benefit or harmful
 - Harmful to patients
 - Procedure/treatment should not be considered

Level of Evidence

- Level A
 - Multiple populations evaluated
 - Data derived from multiple randomized clinical trials or meta-analysis
- Level B
 - Limited populations evaluated
 - Data derived from a single randomized trial or nonrandomized studies
- Level C
 - Very limited populations evaluated
 - Only consensus opinion of experts, case studies, or standard of care

^aGuidelines are based on extensive review of the literature and consensus opinion.

^bAdapted from Levine GN et al. J Am Coll Cardiol. 2011;58:e44–e122.¹

AUC TERMINOLOGY AND METRICS^a

Composition of Clinical Features

- Clinical presentation
 - Acute coronary syndrome, stable angina, etc.
- Severity of angina
 - Canadian class I, II, III, IV
- Extent of ischemia on noninvasive testing
- Other prognostic factors: diabetes, reduced heart function, etc.
- Extent of anatomic disease by angiography
- Evidence that patient is receiving optimum medical therapy
 - Two classes of antianginal agents within the previous 2 weeks

AUC Scorecard for Coronary Revascularization By Technical Panel Vote on a Scale From 1 to 9

- Appropriate: score of 7 to 9
 - Generally acceptable
 - Reasonable approach for the indication
 - Likely to improve the patient's health outcomes or survival
- Uncertain: score of 4 to 6
 - May be acceptable
 - May be a reasonable approach for the indication
 - Uncertainty—more research and/or patient information is needed
- Inappropriate: score of 1 to 3
 - Not generally acceptable
 - Not a reasonable approach for the indication
 - Unlikely to improve the patient's health outcomes or survival

^aAdapted from Patel MR et al. J Am Coll Cardiol. 2009;53:530–553.²

toms, and had low-risk noninvasive studies for ischemia. The major message from this initial experience is that all PCI cases, particularly those in nonacute clinical scenarios, need to be carefully scrutinized. Operators need to be attentive to appropriate documentation of patient symptom complex, presentation, ischemic evaluation, anatomy, and whether they are on optimal medical therapy.

The Centers for Medicare & Medicaid Services (CMS) has recently announced a new Recovery Audit Contractor demonstration program to assess whether Medicare pay-

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ments are going toward procedures that are medically appropriate and necessary.⁹ This program is to be implemented in 11 states for a 3-year period starting January 2012. The program is an attempt to revise the current pay and chase model of tracking down improper Medicare payments after the fact. The theory is that the most effective way to limit the amount of taxpayer dollars lost to improper payment is to review the medical record and other supporting documentation for the claim before the billing is paid. To date, CMS has given no details as to what “medically appropriate and necessary” criteria they will use, whether it be current published guidelines and/or AUC or a formula of their own choosing.

BUILDING A QUALITY ASSURANCE INITIATIVE

There is an old analogy that the best defense is a strong offense. Although the current conditions may seem treacherous for the practice of interventional cardiology, this is an opportunity to look further into the process of ensuring the quality and appropriateness of care for patients.

Since its inception 12 years ago, the NCDR CathPCI Registry has been a resource for national benchmarking of in-hospital outcomes,¹⁰ as well as an excellent source for institutions to track their indications, process, and outcomes using a national yardstick. Other institutional, state, or regional databases also serve as resources for data collection and analysis. Regardless, a structure of a strong comprehensive database is imperative for any operator and institution performing PCI. Regardless of the database used, familiarization with the terminology, definitions, and elements for electronic health records is essential.¹¹

In the current climate of PCI scrutiny, the SCAI has responded proactively with published position papers to encourage improved quality and oversight for cardiac catheterization and PCI programs. The SCAI position paper by Klein et al¹² outlines the elements needed for a continuous quality improvement (CQI) process. Only validated objective methods are to be used to measure quality. The process should be a fair and impartial review of operator and institutional performance and should include appropriate evaluation and corrective action plans. It is important that membership in a CQI commit-

ELEMENTS OF AN INTERVENTIONAL CARDIOLOGY CQI PROGRAM^a

1. CQI committee consisting of:
 - Director of the cath lab or designate
 - Representative interventional cardiologists
 - Administrative director of the cath lab
 - Additional representatives:
 - Cath lab nursing staff
 - Cath lab radiology technician staff
 - Noninterventional cardiologist
 - Cardiac surgeon
 - Emergency department physician
 - Noncardiology internist
 - Hospital cardiovascular administration
 - Hospital quality assurance staff
2. Identification of quality indicators
3. Systematic data collection using standard definitions
4. Analysis of data with benchmarking
5. Detection of areas that require improvement
6. Development of a plan to correct deficiencies
7. Repeat data collection to assess the effect of corrective action
8. Random case review
9. Regular, structured meetings
10. Mechanism for external review of the program

^aAdapted from Klein LW et al. Cathet Cardiovasc Interv. 2011;77:927-935.¹⁰

tee consist of not only interventional cardiologists and cardiac catheterization laboratory staff, but also of other health care representatives of parallel or complementary services. The position paper emphasizes that use of self-proclaimed centers of excellence and advertising testimonials are not measures of quality. The elements of the SCAI blueprint for a CQI program are presented in the *Elements of an Interventional Cardiology CQI Program* sidebar. There is also another recently published SCAI position paper on public reporting and risk adjustment.¹³

In 2011, the SCAI launched a Quality Improvement Toolkit webinar-based program that provides elements for the development of a comprehensive quality assurance program for cardiac catheterization labs.¹⁴ In addition, the Accreditation for Cardiovascular Excellence program has been developed as an independent evaluator of quality assurance and benchmarking initiatives for cardiac catheterization labs and institutions.¹⁵ All of these are resources that should be utilized to demonstrate the appropriateness of PCI in various situations to further improve patient care and outcomes.

CONCLUSION

The published guidelines and AUC are complementary resources to guide the performance of PCI. These structures continue to loom large in the landscape of patient care, institution quality, and the economics of cardiology practice. It is essential that every PCI operator and institution be familiar with the metrics and be proactive in a quality assurance process. ■

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