CHAPTER 16

Appropriate Use Criteria for Revascularization

Lloyd W. Klein, MD, FACC,[1] Enrique Padilla Campos, MD[2]

[1]Professor of Medicine, Rush Medical College, Chicago, IL

[2]Cardiovascular Disease Fellow, Advocate Illinois Masonic Medical Center, Chicago, IL

Introduction

The Appropriate Use Criteria for Revascularization (AUC) is a vital instrument that guides the best application of the evidence base and existing guidelines. It assists the clinician to optimize patient selection for percutaneous coronary intervention (PCI), coronary artery bypass graft surgery (CABG) and medical therapy in patients with both stable ischemic heart disease (SIHD) and acute coronary syndromes (ACS). The AUC has broad implications for the future of cardiovascular health care: in the years to come, the AUC will become the foundation for tethering payment decisions and quality assessment to patient-centered therapeutic decision-making.

Why Do Appropriate Use Criteria Exist?

In contrast to practice guidelines that summarize published data to classify levels of utility, the AUC integrate the guidelines, clinical trial evidence and clinical experience to specify what clinical decision is best supported[1] without regard to financial considerations or socioeconomic status. The initial structure of the AUC was developed through a process combining evidence-based medicine, guidelines, and practice experience by engaging a technical panel in a modified Delphi exercise as previously described by RAND. The technical panel was composed of 4 interventional cardiologists, 4 cardiovascular surgeons, 8 general cardiologists, other physicians who treat patients with cardiovascular

disease or health outcome researchers, and 1 health plan medical officer (also a physician). 180 scenarios illustrative of commonly observed clinical situations were developed by a writing committee and scored by the separate technical panel on a scale of 1 to 9. Scores of 7 to 9 indicated that revascularization was considered "appropriate" and likely to improve health outcomes or survival. Scores of 1 to 3 indicated revascularization was considered "inappropriate" and unlikely to improve health outcomes or survival. The mid range (4 to 6) indicated a clinical scenario for which the likelihood that coronary revascularization would improve health outcomes or survival was considered "uncertain". Subsequent revisions of the AUC have replaced "inappropriate" with "rarely appropriate" and "uncertain" with "may be appropriate". The most recent version included 5 surgeons and 5 interventionists.

Rationale

   PCI significantly reduces mortality and recurrent myocardial infarction in ACS. No revascularization strategy in SIHD is considered to be the dominant approach because the optimal balance of efficacy, safety and cost concerns are different for each patient. Furthermore, the benefits of any given treatment option is usually not homogeneous. Even when studies show that a procedure is beneficial for an overall study population, the benefit may be large for some subgroups and negligible (or even harmful) for others. This granularity, both those captured in registries and trial data, may reasonably impact treatment choice in many situations. In addition, the risk of peri-procedural complications including death, stroke, bleeding and myocardial infarction require judicious case selection. The OAT trial demonstrated that not all recent occlusions opened percutaneously had improved outcomes. The COURAGE trial suggested that optimal medical therapy in multivessel SIHD might produce similar hard endpoint outcomes (death, myocardial infarction & stroke) as complete

revascularization with stenting. More recently, ORBITA has shown that PCI in low risk patients does not improve symptoms or exercise time relative to a sham procedure.[2]

Defining appropriate versus inappropriate use of PCI helps to identify procedural overuse, areas for quality improvement and opportunities for cost savings. Concern regarding overutilization is a crucial issue the profession must address if it is to continue to enjoy the privileges of self-referral and self-regulation. Good outcomes and high operator volumes alone are not sufficient to define high quality. In isolation, these surrogate measures encourage the performance of large volumes of low risk procedures of uncertain appropriateness and the avoidance of high-risk, carefully selected cases.

The most recent AUC divide ACS from SIHD indications.[3] In the acute patient, wide latitude is given to selection of lesions for treatment, as confirmed by the evidence base. However, the lack of strong data in SIHD confirming PCI as superior to CABG in multivessel disease leads to many situations where caution is appropriately advised before proceeding with PCI. In such cases, these particular scenarios should be carefully reviewed with respect to the AUC. **Table 1** summarizes the factors that influence appropriateness of revascularization.

Use of the AUC as a Report Card

A multicenter, prospective study of all PCI patients within NCDR undergoing PCI between July 1, 2009 and September 30, 2010 at 1091 US hospitals was undertaken.[4] Of 500,154 total PCIs, 355,417 (71.1%) were for ACS (ST-segment elevation myocardial infarction, 103,245 [20.6%]; non–ST-segment elevation myocardial infarction, 105,708 [21.1%]; high-risk unstable angina, 146,464 [29.3%]), and 144 737 (28.9%) for SIHD. In ACS, 350,469 PCIs (98.6%) were classified as appropriate, 1055 (0.3%) as uncertain, and 3893 (1.1%) as inappropriate. For SIHD, 72,911 PCIs (50.4%) were classified as appropriate, 54,988 (38.0%) as uncertain, and 16,838 (11.6%) as inappropriate. The majority of inappropriate PCIs for SIHD were performed in patients with no angina (53.8%), low-risk ischemia on

noninvasive stress testing (71.6%), or suboptimal (≤1 medication) anti-anginal therapy (95.8%). Overall, the rate of inappropriate PCI was 4.1%; hospitals in the lowest quartile had inappropriate PCI rates of <1.73% versus >4.62% for the highest quartile hospitals.

Bradley and colleagues[5] evaluated the association between patient selection for PCI and post procedural outcomes. In 203,531 patients undergoing elective PCI, the association between a hospital's proportion of nonacute PCIs categorized as inappropriate and in-hospital mortality, bleeding complications, and use of optimal guideline-directed medical therapy at discharge was evaluated. When categorized as hospital tertiles, the range of inappropriate PCI was 0.0% to 8.1% in the lowest tertile, 8.1% to 15.2% in the middle tertile, and 15.2% to 58.6% in the highest tertile. However, a hospital's proportion of inappropriate PCIs was not associated with in-hospital mortality, bleeding, or medical therapy at discharge.

More recent studies seem to suggest that fewer inappropriate procedures are being performed. Washington State published AUC findings in procedures performed between 2010 and 2013.[6] The proportion of elective PCIs classified as appropriate increased from 26% in 2010 to 38% in 2013, whereas the proportion of inappropriate PCIs decreased from 16% to 13%. Desai and colleagues[7] reported the 5-year findings after Chan et al and found that during the 5 years from 2010 – 2014, the percent of inappropriate PCIs decreased from 26% to 13%, but interestingly, the uncertain category also decreased, from 44% to 13%.

Limitations of the AUC

A large number of cases cannot be classified by the AUC either because a stress test is unavailable (50% of unclassifiable cases, 8.5% of all PCIs in the NCDR) or the magnitude of ischemic risk is not documented (42% of unclassifiable cases, 7.2% overall). This high percentage of unclassifiable cases threatens the accuracy of the process and represents a loophole in the methodology.

Previously, the utilization of the terminology "inappropriate" implied not just the lack of supportive evidence but also rather the presence of negative studies, which was not true in many of the scenarios graded by the technical panel. Moreover, the technical panel conceived "inappropriate" as being related to specific lack of clinical trial evidence of improved mortality, excluding measures of improved quality of life or symptom relief. To clarify this meaning, "inappropriate" was changed to "rarely appropriate" in the 2012 revision of the AUC. The "uncertain" classification also created ambiguity that the appropriateness could not be definitively classified within existing medical knowledge. The high rate of uncertain indications for elective PCIs (38%) suggests that more research is needed to clarify the benefits of PCIs for those patients and as such "uncertain" is now described as "may be appropriate." There are several clinical scenarios in SIHD that the AUC matrices categorize as "may be appropriate" but which are frequently considered highly appropriate for revascularization in clinical practice. Such scenarios include cases with intermediate sized defects on stress testing, discrepancies between symptom and stress test abnormality severity and when there is moderate severity angina in the presence of sub-maximal medical therapy. This divergence between what the AUC currently deems "may be appropriate" and what is often viewed as appropriate in current practice emphasizes the fact that each patient scenario is unique. Every individual poses a distinct set of variables to consider and balancing these often-conflicting factors may reasonably result in disparate decision-making depending on one's emphasis.

Reliance on stress test imaging modalities to evaluate the amount of myocardium at jeopardy has raised numerous concerns. Nuclear and echocardiographic stress tests may be inaccurate in multivessel disease, prior infarction and when target level of physiologic stress is not achieved. The use of iFR or FFR in ambiguous scenarios is now regarded as best practice. Recent guidelines[8] suggest that these modalities should be used more often to assess intermediate stenoses to create functional

SYNTAX scores to better define which patients are likely to benefit from more aggressive

revascularization strategies.

There is also concern that the AUC as formulated have never been linked to outcomes. A recent

study[9] could not link PCI appropriateness, as determined by the AUC, with 30-day or 1-year outcomes. In

a cohort of 3,817 non-ACS patients, 47% (n=1,494) of the cases were considered appropriate; 1.8%

(n=54) was inappropriate; and 51% (n=1,604) were uncertain. Despite similar procedural complications

in the three groups, a significantly higher rate of in-hospital complications was observed in the

inappropriate PCI group (inappropriate, 11%; appropriate, 1.9%; uncertain, 2.4%; $P<. 001$). However,

this did not translate to a higher rate of MACE at either 30 days (inappropriate, 7%; appropriate, 3.2%;

uncertain, 4.1%; $P=. 32$) or 1 year (inappropriate, 11.8%; appropriate, 13.1%; uncertain, 15.3%; $P=. 32$).

In multivariable analysis, no associations were observed between procedural appropriateness and either

in-hospital or 1-year outcomes.

Implications for Reimbursement

Reimbursement for revascularization will likely soon be dependent on its appropriateness. Since

the AUC and its structure were never intended as a means to determine payment for procedures, there

is substantial trepidation within the interventional community over its application for this purpose. As

pay-for-performance and other connections between quality and reimbursement are developed, the

flaws in the AUC could result in incorrect assessments of operator quality. When the AUC were initially

developed, the intention was for application to broad quality assessment. If the AUC did not adequately

capture the reasoning for a particular procedure, it had no important consequence. That would no

longer be apposite if third-party payors disallow payment because of an inconsistent stress test result or

a low class of angina.

The widespread apprehension is whether there is sufficient room in the interpretation of the AUC to manipulate these criteria and diminish their discrimination (e.g., size of stress test defect or number of anti-anginal medications). The fear is whether physicians, who understand very well the vagueness of such indicators, will continue to be objective in reporting them, recognizing that reimbursement depends on the answers. On the other hand, if the appropriateness decision is made by a person whose job is to save expenses for a third party payer, this vagueness could be exploited by insurers and used as an excuse to deny payment even when PCI was appropriate

Although the AUC may be useful in helping to guide insurance coverage, the AUC classification should not be the solitary reason used to deny coverage. Application of AUC in this way might be harmful to patients and could be contrary to shared decision-making. Conversely, individual third party payors should not develop their own "appropriateness criteria" for insurance coverage that are not based on guidelines and that are not subject to peer review. Coverage determinations should take into account reasonable decisions by health care providers who are following accepted clinical guidelines.

Updates to the AUC

The recently published 2017 AUC for coronary revascularization differ in several respects from prior versions. These changes include: 1) changing the classification of optimal medical therapy from a certain number of drugs and eliminating the previous defining matrix, 2) changing the terminology from "inappropriate" to "rarely" appropriate and from "uncertain" to " may be appropriate", 3) combining intermediate and high-risk non-invasive findings, 4) including CT derived calcium scores and LV function as non-invasive findings, 5) combining the various CCS classes into a single "symptomatic" group, and 6) insisting on a shared decision making approach in which patient preferences and goals are strongly considered.

A large percentage of PCI patients with SIHD have relatively mild ischemia, 1-2 vessel disease and are either asymptomatic or have symptoms without anti-anginal medications. Between 2012 and 2017, the AUC ratings have changed considerably for these patients and most are currently rated as "may be appropriate" rather than "inappropriate" in the 2012 iteration. This is a group of patients for whom the treatment choice should be based on survival or subsequent MI, not angina relief. Although some studies show a survival benefit with PCI for the entire group of SIHD patients, no studies have been sufficiently powered to examine differences between optimal medical therapy and PCI with optimal medical therapy for low-risk subgroups of patients at the AUC scenario level.

Two studies specifically impact the terminology change from "rarely appropriate" to "may be appropriate" because of changing relative survival and MI outcomes in SIHDs. The network metanalysis by Windecker[10] showed improved survival for PCI versus medical therapy. FAME-II showed that FFR measurements significantly improve case selection for PCI resulting in better outcomes than medical therapy when abnormal, and no improvement when the value is normal.

Future Directions

Figure 1 provides an algorithm that can be used as a first estimate of the best treatment decision. Although it is impossible to construct a decision tree for every conceivable situation and individual patient variation, future iterations of the AUC must do a better job simulating the decision making process and placing the patient's best interests at the forefront. In this regard, the concepts of "value" and "cost-effectiveness" may add significantly to the resolution of the controversy. There will be times when what is best for the individual patient is at variance with AUC and other guidance documents, and future versions of the AUC should incorporate this understanding in its structure.

Conclusions

The importance of the AUC to the future of public health policy and the role of PCI in treating CAD cannot be overstated. The long-time reliance on operator volume and complication rates as the sole criteria for PCI quality promoted unprecedented growth and expansion, but also resulted in unanticipated negative consequences including high cost with little population-level outcome benefit, especially in SIHD. Additionally, overutilization of PCI enabled by the ambiguity of appropriate case selection has raised serious questions by those who pay for the procedures. Future versions of the AUC will hopefully successfully address these complex and critical issues.

The vast majority of PCI is performed in patients who meet criteria that suggest potential benefit based on the existing evidence-base. However, the data also show that there are opportunities to improve patient selection for PCI, as well as to design future studies that evaluate outcome benefits of PCI other than mortality. Reversing our failure thus far to develop and faithfully implement a system that accurately evaluates interventional decision-making and which is truly focused on improving outcomes for our patients is the single most pressing challenge we face. How our profession responds will characterize our field for years to come.

**Chapter 16: Appropriate Use Criteria for Revascularization**

Tables

Table 1. Factors Influencing Revascularization Appropriateness.

Factors Influencing Revascularization Appropriateness
1. Documentation of the presence and anatomic severity of coronary stenosis (angiography, intravascular ultrasound)
• Correlation with physiologic metrics of stenosis severity (stress testing, fractional flow reserve, instantaneous flow ratio)
• Presence, recent changes, and severity of anginal symptoms
• Triggers of angina
• Utilization of anti-anginal medications
• Prior CABG or PCI
• Patient age and activity/stress levels
• Patient preference
• Individual risk for surgery e.g, frailty, co-morbid conditions
• Exercise duration
• Complete vs. incomplete revascularization
• Does the patient want/able to try medications first? (i.e., expected patient compliance)
• What are the patient's short- and long-term goals of therapy? (e.g., elderly)
• Which outcomes/benefits can be anticipated? (e.g., survival, improved quality of life, diminished angina, less CHF, presence of viable myocardium or substantial myocardium at jeopardy)

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Samady H, Fearon WF, Yeung AC, King SB, eds. Interventional Cardiology, Second Edition. McGraw Hill;

2018.

Figures

Figure 1. Revascularization Decision Tree.
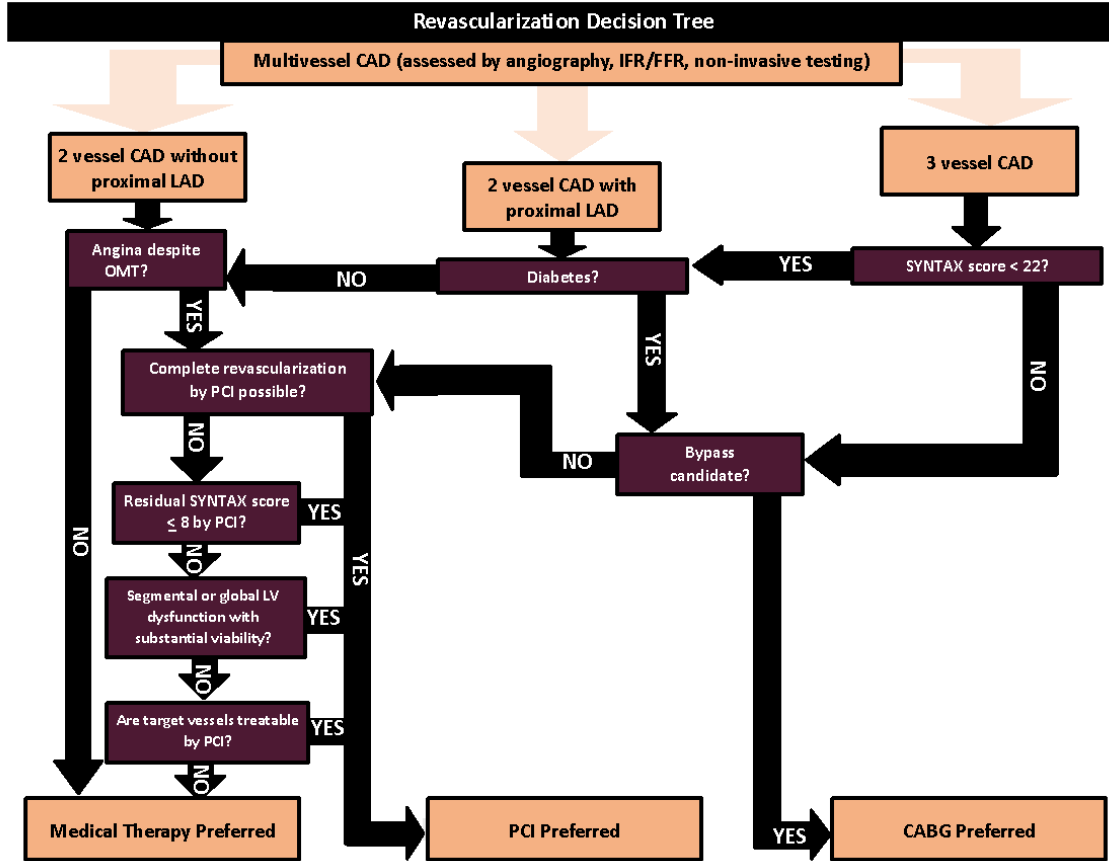
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