Adjudicating coronary revascularization: Appropriate Use Criteria are flawed and have been misapplied

The 2009 Appropriate Use Criteria (AUC) for coronary revascularization were designed to optimize care given deficient practice guidelines. However, due to the constituency of its technical panel and limitations in methodology, the noble intent of the AUC has shifted to use as a punitive tool to eradicate perceived overuse of percutaneous coronary intervention (PCI). In analyzing the current literature, there does not appear to be significant PCI overuse. Moreover, several studies have identified PCI underuse and its resultant hazards. In the 2012 focused update, there has been no substantive change to its flawed conception and application. We describe problems related to the development of the AUC and its use in clinical practice, suggesting several modifications to guide relevant future iterations.

**Keywords:** Appropriate Use Criteria • appropriateness criteria • percutaneous coronary intervention • revascularization

# The origins of Appropriate Use Criteria

In the 2009 publication of the 'Appropriateness Criteria for Coronary Revascularization,' (hereafter referred to as Appropriate Use Criteria or AUC), Patel et al. noted that the "appropriateness criteria are designed to examine the use of diagnostic and therapeutic procedures to support efficient use of medical resources during the pursuit of quality medical care" [1]. Thus, the intent of such criteria is to establish best practice standards, thereby improving quality of care, reducing its variability and possibly reducing its costs. These criteria were specifically designed to extend beyond the guidelines to delineate management of the more common scenarios encountered in clinical practice.

This effort was driven by limitations of practice guidelines that were potently underscored by Tricoci *et al.* in a study evaluating the evolution of recommendations in the American College of Cardiology (ACC)/ American Heart Association (AHA) practice guidelines based on level of evidence [2]. The preponderance of guidelines was found to be supported by level of evidence C, formulated by expert opinion and not trial-based evidence.

This role for AUC, as a valuable supplement to guideline-derived heuristics, was derived from studies of the application of RAND-University of California at Los Angeles necessity criteria for revascularization [3,4]. A retrospective study of 671 patients performed by Kravitz et al. studied these clinical criteria adjudicating necessity of revascularization (coronary artery bypass grafting [CABG] or percutaneous transluminal coronary angioplasty [PTCA]) based on the opinions of nine panelists representing internal medicine, cardiology, and cardiothoracic surgery [5]. A variety of clinical scenarios were assessed that scored appropriateness of revascularization from 1 (designated as inappropriate) to 9 (designated as most appropriate) after a two-round modified Delphi process These panelists were "chosen from a list of nationally recognized leaders nominated by medical specialty societies." Validation for these published criteria was derived from the fact that patients who

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received necessary revascularization within 1 year of angiography had lower mortality than those who did not (8.7 vs 15.8%, p = 0.01). Thus, performing appropriate intervention based on these criteria manifested in positive results, and supported the validity of the RAND-University of California at Los Angeles criteria for detecting underuse of appropriate intervention.

In a prospective study of clinical outcomes, enrolling over 2500 patients followed for a median of 30 months after angiography, Hemingway et al. furthered the notion that implementation of AUC would lead to less underuse of coronary revascularization, and improved clinical outcomes [6]. In 908 patients with indications for PTCA graded as appropriate (score 7-9), over a third were treated medically. These medically treated patients were more likely to have angina at follow-up than those who underwent PTCA (OR 1.97; 95% CI: 1.29-3.00). In 1353 patients within indications for CABG graded as appropriate, over a quarter were treated medically. These medically treated patients were more likely to die or have a nonfatal myocardial infarction (composite outcome; HR 4.08; 95% CI: 2.82-5.93). There was also a graded relation between the appropriateness score and clinical outcome of revascularization over the entire scale of appropriateness (p for linear trend < 0.01). Thus, underuse of revascularization was found to be significantly and powerfully associated with adverse clinical outcomes.

Based on these types of analyses, the predominant and most valuable role of AUC was clear cut: diminish underuse of revascularization and thus improved clinical outcomes. To this effect, the AUC noted that "these criteria provide a framework for discussion and are intended to assist patients and clinicians, but are not to diminish the difficulty or uncertainty of clinical decision making" and "it is not anticipated that all physicians or facilities will have 100% of their revascularization procedures deemed appropriate" [1]. Given the limited nature of this evaluation, only 180 revascularization scenarios were evaluated by the AUC technical panel; anatomic scenarios such as ostial lesions, bifurcation lesions and diffuse disease, and the amount of myocardium supplied were excluded. And if the true purpose of AUC were to guide proper use of revascularization, given that underuse is associated with poor clinical outcomes, some focus would be given to that end of the spectrum.

#### The limitations of 2009 AUC methodology

The AUC committee limited the involvement of interventional cardiologists from the technical panel "so as to not include a majority of individuals whose livelihood is tied to the technology under study" [1]. The 17-member technical panel was composed of only

four interventional cardiologists, in addition to four cardiovascular surgeons, one medical officer from a health plan and eight members representing cardiologists, other physicians who treat patients with cardiovascular disease and health outcome researchers. The implication was that intellectual bias is related to a field of specialty and not selected individuals in that field. Moreover, in diminishing the involvement of interventionalists, as well as cardiovascular surgeons, it was basically minimizing input from the field most knowledgeable about clinical outcomes related to revascularization. Likely due to the constitution of the committee, physician agreement with the conclusions reached by the AUC technical panel is modest at best. Chan et al. studied the consistency in AUC ratings among 85 cardiologists from ten US institutions and the AUC technical panel [7]. For indications identified by the AUC technical panel as appropriate, concordance between the two groups was 94%. Those indications identified as uncertain or inappropriate by the AUC technical panel had much lower concordance at 73 and 70%, respectively. Furthermore, there was marked nonagreement by the physician group, defined by  $\geq 25\%$  of an individual physician's rating outside the physician group's appropriateness category assessment. This ranged from 44% for indications identified as appropriate to 70% for indications identified as inappropriate. Moreover, no individual physician achieved more than 80% agreement.

These disparities may largely be due to the fact that many AUC indications encompass clinical symptoms and stress test results. Clinical symptom assessment in the AUC is based on Canadian Cardiovascular Society (CCS) grading of angina pectoris. This grading was developed in 1972 by Dr Lucien Campeau, who chaired an ad hoc committee, basing its descriptions and differentiations of each class based on personal correspondence and published literature at the time. The descriptions of each CCS grade are rather vague and include measurements based on 'blocks' walked and ambulating at a 'normal pace.' The author himself has noted that "although this grading system of the severity of effort angina has been accepted throughout the world...a revision is desirable considering its potential imperfections and inconsistencies with present-day management of ischemic heart disease" [8].

The AUC assesses many indications based on stress testing, but does so in a seemingly subjective way. We discuss a study by Chan *et al.* [9] below in regards to the application of the AUC (in this instance, specifically in describing the appropriateness of percutaneous coronary intervention (PCI) at participating National Cardiovascular Disease Registry (NCDR) centers), but a follow-up viewpoint by Marso *et al.* merits mention in this section [10]. As Marso *et al.* state, "Although it is clear that stress electrocardiogram criteria can inform risk (using the Duke treadmill score), the instructions for the data abstractors do not explicitly guide them as to when the high-risk electrocardiogram component of a stress test should supplant normal or mildly abnormal imaging portion" [10]. This type of limitation in the AUC criteria would also extend to the uncertainty in a physician determining appropriateness of a PCI indication, given the lack of clarity in classification of stress test results.

Also mentioned in the viewpoint by Marso et al. is the inclusion of chronic total occlusion (CTO) PCI in the AUC, which has been shown to provide symptom relief, improved left ventricular function, avoidance of other procedures and improved survival with successful procedures [10]. There is no assessment of the appropriateness of PCI in other anatomical complex lesion characteristics (e.g., ostial lesions, bifurcations, etc.). However, in comparing single-vessel CTO PCI AUC to one- or two-vessel disease not involving the proximal left anterior descending (LAD) artery, CTO PCI is deemed less appropriate. The AUC technical panel did not comment on outcomes related to multivessel disease and CTO PCI given that 'other variations of multivessel disease are present,' ostensibly leading to permutations that could not be efficiently addressed by the AUC [1]. For example, in the setting of multivessel disease, CTO PCI could be deemed as appropriate as PCI of multivessel disease not involving a CTO. Conversely, if a staged procedure is performed and renders single-vessel CTO PCI as the second intervention, AUC judgment inexplicably changes.

### The misapplication of the 2009 AUC

Application of AUC in the setting of coronary revascularization comes in a time of a more than 40-year trend of improved outcomes in coronary heart disease, undoubtedly based on both prevention and treatment measures [11]. Moreover, there has been a marked decrease in use of PCI, especially after the publication of the Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE) trial [12]. This study, published in 2007, intended to compare a strategy of medical therapy plus PCI versus medical therapy alone in patients with stable ischemic heart disease (SIHD), showed that PCI did not improve survival or prevent myocardial infarction compared with medical therapy alone. However, in COURAGE, patients with significant ischemia on myocardial perfusion study (MPS) had a trend toward mortality benefit from revascularization [13]. Despite this, there has been widespread application of COURAGE as support against the use of PCI, and subsequent decline in the use of and geographic variation in PCI for SIHD [14]. Because of this perceived lack of benefit for PCI, and the perception of financial incentives driving the decision to revascularize, there has been emphasis placed on identifying perceived overuse of revascularization as opposed to underuse, despite the strong evidence arguing for emphasis on the latter.

In this tenor, Chan et al. studied the appropriateness of PCI in a multicenter, prospective study of over 500,000 patients in the NCDR undergoing PCI for acute and nonacute indications [9]. For acute indications, 98.6% of PCIs were classified as appropriate. For nonacute indications, 50.4% of PCIs were classified as appropriate; moreover, 11.6% of these PCIs were classified as inappropriate. With just a superficial understanding of what constitutes these figures, many would presume that there is a significant overuse of PCI. However, in examining the numbers treated within the acute and nonacute indications, 82.7% of the patients in this study had PCI for acute indications. Thus, only 4.1% of the study population had PCI that was defined as 'inappropriate.' Nearly 40% of defined inappropriate PCI was based on AUC scenario 12B, which was defined by one- or two-vessel CAD with no proximal LAD involvement, CCS Class I or II symptoms, a low risk stress test and none/minimal anti-ischemic therapy. The evidence base that would justify this particular scenario as inappropriate for PCI is absent. To the contrary, PCI has been shown to provide significantly superior symptom benefit versus medical therapy alone, in several studies enrolling a substantial number of patients with sub-CCS Class III symptoms [15]. Regardless, the intent of this study was to identify PCI overuse.

Chan *et al.* studied over 200,000 nonacute PCIs in the NCDR with 12.2% classified as inappropriate [16]. With societal and cultural implications, Chan *et al.* argued that higher rates of PCIs in men, whites and those who had private insurance, may, in part, be due to procedural overuse. Ironically, these are the very groups that are generally considered more likely to make informed choices.

A more recent study assessed over 8000 patients undergoing CABG and approximately 34,000 patients undergoing PCI for nonacute indications in New York and classified appropriateness based on AUC [17]. Out of the PCIs able to be rated by AUC (28% lacked sufficient information), 36.1% were appropriate, 14.3% were inappropriate and 49.6% were uncertain by AUC. Of note, 91% of PCIs that were classified as inappropriate had one- or two-vessel CAD with no proximal LAD involvement, and sub-CCS III symptoms. Comparatively, only 1.1% of CABGs were deemed inappropriate by AUC.

Indeed, a more impactful and meaningful study in terms of outcomes would assess and underscore the number of patients that do not receive appropriate PCI per AUC criteria – a percentage likely significantly larger than 4.1%, or even 14.3%. A study by Hemingway et al. in 2008 followed over 9000 patients with suspected stable angina and found that up to 57% of patients deemed appropriate for angiography did not undergo the procedure, which translated into a difference in a combined endpoint of death or acute coronary syndrome on 3-year follow-up (HR 2.67; 95% CI: 1.77-4.01) [18]. Ko et al. retrospectively studied 1625 patients with stable coronary artery disease, of which only 69% with appropriate indication for coronary revascularization underwent treatment. Though possibly confounded by underlying comorbidities, this comparison retains validity in that all patients in the study were well enough to undergo coronary angiography. Compared those that did not get revascularized, patients receiving revascularization with an appropriate indication had a lower adjusted hazard of death or acute coronary syndrome (HR 0.61; 95% CI: 0.42–0.88) [19]. The depiction in the public and lay media has been slanted in the direction of perceived overuse of PCI, largely due to a rather myopic interpretation of the data. The true health hazard is in lack of access to PCI and underuse.

The translation of AUC to clinical practice has been unfortunate. A study by Khawaja et al. studied the clinical implications of abnormal MPS based on AUC. Out of the patients receiving appropriate MPS, 21.0% had studies noting high-risk summed stress scores. Out of these, only 32.4% underwent subsequent angiography, with 50% of these patients proceeding to revascularization [20]. The actual clinical outcomes related to implementation of AUC were questionable in a retrospective study by Barbash et al., which followed 3817 patients undergoing elective PCI [21]. There was no significant difference in major adverse cardiac event rates after PCI at 30 days or 1 year in patients with appropriate, uncertain or inappropriate AUC indications. Similarly, in a study performed assessing over 200,000 patients having undergone nonacute PCI in the NCDR, a hospital's proportion of inappropriate PCIs was not associated with in-hospital mortality, bleeding or medical therapy at discharge [22]. Yet, there has been growing importance placed on AUC that has even translated to a palpable economic impact. For example, New York state Medicaid payments are linked to AUC-based adjudication of PCI appropriateness.

# The 2012 AUC: the answer we have been waiting for?

The 2012 focused update of the AUC for coronary revascularization included a number of specific revi-

sions to the criteria. Proving it is a dynamic document, there were several scenarios in which the technical panel added the use of SYNTAX scores in order to differentiate appropriateness of PCI versus CABG in the setting of left main stenosis and/or multivessel CAD. PCI was considered inappropriate for left main stenosis and additional CAD with intermediate-to-high CAD burden [23]. The technical panel specified that the ranking of uncertain "should not be viewed as excluding the use of revascularization for such patients." Also, the panel noted that "the AUC are intended to evaluate overall patterns of care regarding revascularization rather than adjudicating specific cases." Interestingly, the technical panel included one- or two-vessel CAD without involvement of proximal LAD in an asymptomatic patient without noninvasive testing, deeming the scenario inappropriate for PCI. Given these one- or two-vessel CAD, nonproximal LAD scenarios seem to be quite frequent in discussions regarding inappropriate PCI, as they are deemed largely uncertain or inappropriate, the results of the Fractional Flow Reserve-Guided PCI versus Medical Management in Stable Coronary Disease (FAME 2) Trial should significantly transform further iterations of AUC [24]. In FAME 2, patients with fractional flow reserve (FFR) guided PCI plus the medical therapy were compared with patients receiving medical therapy, in the setting of stable coronary artery disease [24]. Only patients with FFR  $\leq 0.80$ received revascularization in the trial. Recruitment was prematurely halted after enrollment of 1220 patients because of a significant between-group difference in the percentage of patients progressing to the primary endpoint, a composite of death, myocardial infarction or urgent revascularization (HR 0.32; 95% CI: 0.19-0.53), favoring the FFR-guided PCI group. Many of those urgently revascularized underwent revascularization due to an acute coronary syndrome. As stated in the FAME 2 manuscript, four patients in the PCI group (0.9%) and 23 patients in the medical therapy group (5.2%) underwent an urgent revascularization that was triggered by a myocardial infarction or by unstable angina with evidence of ischemia on ECG (hazard ratio with PCI, 0.13; 95% CI: 0.04-0.43; p < 0.001 [24]. Of note, over 75% of patients in the FFR-guided PCI and medical therapy arms had sub-CCS class III angina, with over 10% in each arm classified as asymptomatic. These data should lead to rethinking of the currently available data examining inappropriate PCI. For example, given that the study by Chan et al. [9] demonstrated a 4.1% rate of inappropriate PCI and a substantial number of these were in patients that may have had functionally significant stenosis meriting PCI, regardless of symptom status - how many clinically inappropriate PCIs really occurred?

#### **Future perspective**

Because of the largely unfounded negative stigma applied to AUC scenarios that are deemed less than appropriate, there will be a change in nomenclature reflected in the upcoming 2014 AUC criteria. 'Appropriate,' 'Uncertain' and 'Inappropriate' will be transitioned to 'Appropriate,' 'May Be Appropriate,' and 'Rarely Appropriate' [25]. The AUC process has been redefined in representation, given that the writing committee now comprises three interventional cardiologists, two cardiac surgeons and two health outcomes researchers. After development of a list of indications, assumptions and definitions through literature review and guideline mapping, a review panel of greater than 30 members will provide feedback, leading to revision.

Health outcomes measures need to be included in future iterations of AUC, given the most marked impact of PCI in SIHD is symptom improvement [26]. Clearly, these benefits are greatest in patients that are markedly impaired by severe angina before the procedure. This type of quality of life data can impact the cost–effectiveness (i.e., cost/quality adjusted life year) related to PCI. Much attention has been placed on limiting overuse of PCI by exploiting perceived inappropriate interventions, seemingly in an effort to cut costs. It may be more economically advantageous, and rational, to focus on providing therapies to subsets of patients achieving the greatest improvement in quality adjusted life years at an acceptable cost, using widely accepted cost–effectiveness metrics as justification.

The critiques of Marso *et al.* prior to the release of the 2012 AUC criteria largely hold true for the 2012 criteria [10]. There is a lack of adequate representation of interventional cardiology on the technical panel, a lack of specific criteria for stress testing, an inability to link stress test results to coronary anatomy, an overdependence on preprocedure stress testing, inadequate use of angiographic variables and questionable validity of NCDR self-reported data. To remedy these issues, the ACC Interventional Council and Society for Clinical Angiography and Intervention (SCAI) have put forward a number of recommendations [27]. We echo them here with some modification:

- Increase the number of interventionalists on the technical panel;
- Nuclear perfusion scans should not be the single 'gold standard' for determining the significance of stenosis;
- Increased use of FFR, intravascular ultrasound and optical coherence tomography, especially in scenarios currently designated as 'uncertain' appropriateness of revascularization [28];
- Incorporate more patient-centric robust quality of life metrics (e.g., Seattle Angina Questionnaire) in determining severity of angina;
- Form recommendations based on the current literature, not just the most recent guidelines;
- End points should not be limited to mortality and cost; quality of life outcomes should also be considered;
- Include a 'Heart Team' approach, involving cardiologists, interventional cardiologist, and cardiothoracic surgeons, when the appropriateness of revascularization, or its modality, is uncertain;
- Eliminate criteria regarding CTO PCI given lack of other anatomical disease subsets described or base criteria on actual data;
- Neither the guidelines nor the AUC should be used as a rubber stamp to sanction procedures or as a gavel to outlaw them.

#### Conclusion

The AUC should be applied as a broad programmatic quality measure and not parsed out on a case-by-case basis. The few scenarios that drive most of the 'inappropriate' use need basic evidence-based revision. The AUC should be uniformly applied, addressing PCI underuse and lack of access given the strong evidence

### **Executive summary**

- The 2009 Appropriate Use Criteria (AUC) was designed to extend beyond the guidelines to delineate management of the more common scenarios encountered in clinical practice.
- Critical limitations in the makeup of the AUC technical panel and its resultant methodology have led to a flawed document misapplied in current clinical practice.
- Studies using AUC to examine appropriateness of percutaneous coronary intervention (PCI) have been directed at identifying perceived PCI overuse via suspected methods, while largely ignoring clear PCI underuse and the palpable resultant hazards.
- Future iterations of AUC should embody a more evidence-based approach in determining appropriateness of PCI, including emphasis on quality of life metrics and fractional flow reserve.

supporting resultant hazards. The application of AUC should move away from its use as a punitive tool.

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